

EXAMINING HHS'S PUBLIC HEALTH PREPARED- NESS FOR AND RESPONSE TO THE 2017 HURRICANE SEASON

HEARING BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED FIFTEENTH CONGRESS FIRST SESSION

OCTOBER 24, 2017

Serial No. 115-67



Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov

U.S. GOVERNMENT PUBLISHING OFFICE

27-737

WASHINGTON : 2018

COMMITTEE ON ENERGY AND COMMERCE

GREG WALDEN, Oregon
Chairman

JOE BARTON, Texas <i>Vice Chairman</i>	FRANK PALLONE, JR., New Jersey <i>Ranking Member</i>
FRED UPTON, Michigan	BOBBY L. RUSH, Illinois
JOHN SHIMKUS, Illinois	ANNA G. ESHOO, California
MICHAEL C. BURGESS, Texas	ELIOT L. ENGEL, New York
MARSHA BLACKBURN, Tennessee	GENE GREEN, Texas
STEVE SCALISE, Louisiana	DIANA DEGETTE, Colorado
ROBERT E. LATTA, Ohio	MICHAEL F. DOYLE, Pennsylvania
CATHY McMORRIS RODGERS, Washington	JANICE D. SCHAKOWSKY, Illinois
GREGG HARPER, Mississippi	G.K. BUTTERFIELD, North Carolina
LEONARD LANCE, New Jersey	DORIS O. MATSUI, California
BRETT GUTHRIE, Kentucky	KATHY CASTOR, Florida
PETE OLSON, Texas	JOHN P. SARBANES, Maryland
DAVID B. McKINLEY, West Virginia	JERRY McNERNEY, California
ADAM KINZINGER, Illinois	PETER WELCH, Vermont
H. MORGAN GRIFFITH, Virginia	BEN RAY LUJAN, New Mexico
GUS M. BILIRAKIS, Florida	PAUL TONKO, New York
BILL JOHNSON, Ohio	YVETTE D. CLARKE, New York
BILLY LONG, Missouri	DAVID LOEBSACK, Iowa
LARRY BUCSHON, Indiana	KURT SCHRADER, Oregon
BILL FLORES, Texas	JOSEPH P. KENNEDY, III, Massachusetts
SUSAN W. BROOKS, Indiana	TONY CARDENAS, California
MARKWAYNE MULLIN, Oklahoma	RAUL RUIZ, California
RICHARD HUDSON, North Carolina	SCOTT H. PETERS, California
CHRIS COLLINS, New York	DEBBIE DINGELL, Michigan
KEVIN CRAMER, North Dakota	
TIM WALBERG, Michigan	
MIMI WALTERS, California	
RYAN A. COSTELLO, Pennsylvania	
EARL L. "BUDDY" CARTER, Georgia	
JEFF DUNCAN, South Carolina	

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

VACANCY
Chairman

H. MORGAN GRIFFITH, Virginia <i>Vice Chairman</i>	DIANA DEGETTE, Colorado <i>Ranking Member</i>
JOE BARTON, Texas	JANICE D. SCHAKOWSKY, Illinois
MICHAEL C. BURGESS, Texas	KATHY CASTOR, Florida
SUSAN W. BROOKS, Indiana	PAUL TONKO, New York
CHRIS COLLINS, New York	YVETTE D. CLARKE, New York
TIM WALBERG, Michigan	RAUL RUIZ, California
MIMI WALTERS, California	SCOTT H. PETERS, California
RYAN A. COSTELLO, Pennsylvania	FRANK PALLONE, JR., New Jersey (<i>ex officio</i>)
EARL L. "BUDDY" CARTER, Georgia	
GREG WALDEN, Oregon (<i>ex officio</i>)	

CONTENTS

	Page
Hon. H. Morgan Griffith, a Representative in Congress from the Commonwealth of Virginia, opening statement	1
Prepared statement	3
Hon. Diana DeGette, a Representative in Congress from the state of Colorado, opening statement	4
Hon. Greg Walden, a Representative in Congress from the State of Oregon, opening statement	6
Prepared statement	7
Hon. Frank Pallone, Jr., a Representative in Congress from the State of New Jersey, opening statement	8
Prepared statement	9

WITNESSES

Robert P. Kadlec, M.D., Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services	12
Prepared statement	15
Answers to submitted questions	101
Scott Gottlieb, M.D., Commissioner, U.S. Food and Drug Administration	24
Prepared statement	26
Answers to submitted questions	130
Kimberly Brandt, Principal Deputy Administrator for Operations, Centers for Medicare and Medicaid Services	40
Prepared statement	42
Answers to submitted questions	138
Stephen C. Redd, M.D., RADM, Director of the Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention	50
Prepared statement	52
Answers to submitted questions	146

SUBMITTED MATERIAL

Article entitled, “Like Going Back in Time’: Puerto Ricans Put Survival Skills to Use,” New York Times, October 24, 2017, submitted by Ms. DeGette	95
--	----

EXAMINING HHS'S PUBLIC HEALTH PREPAREDNESS FOR AND RESPONSE TO THE 2017 HURRICANE SEASON

TUESDAY, OCTOBER 24, 2017

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:02 a.m., in room 2123, Rayburn House Office Building, Hon. Morgan Griffith (vice chairman of the subcommittee) presiding.

Present: Representatives Griffith, Brooks, Collins, Barton, Walberg, Walters, Costello, Carter, Walden (ex officio), DeGette, Schakowsky, Castor, Tonko, Clarke, Ruiz, Peters, and Pallone (ex officio).

Also Present: Representatives Olson, Bilirakis, Duncan, Green, González-Colón, and Wasserman-Schultz,

Staff Present: Jennifer Barblan, Chief Counsel, O&I; Ray Baum, Staff Director; Karen Christian, General Counsel; Kelly Collins, Staff Assistant; Zachary Dareshori, Staff Assistant; Lamar Echols, Counsel, O&I; Adam Fromm, Director of Outreach and Coalitions; Ali Fulling, Legislative Clerk, O&I, DCCP; Theresa Gambo, Human Resources/Office Administrator; Alex Miller, Video Production Aide and Press Assistant; Christopher Santini, Counsel, O&I; Jennifer Sherman, Press Secretary; Natalie Turner, Counsel, O&I; Hamlin Wade, Special Advisor, External Affairs; Everett Winnick, Director of Information Technology; Christina Calce, Minority Counsel; Jeff Carroll, Minority Staff Director; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Chris Knauer, Minority Oversight Staff Director; Miles Lichtman, Minority Policy Analyst; Jon Monger, Minority Counsel; and C.J. Young, Minority Press Secretary.

OPENING STATEMENT OF HON. H. MORGAN GRIFFITH, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF VIRGINIA

Mr. GRIFFITH. I can go ahead and get started. I thank everybody. I appreciate it.

We are here today to examine the Department of Health and Human Services' public health preparedness for and response to the 2017 hurricane season. In the last 2 months, Texas, Florida, Puerto Rico, and the U.S. Virgin Islands have been devastated by hurricanes.

I first want to express our heartfelt sorrow for the millions of Americans impacted by these devastating storms and say that all members of this committee, on both sides of the aisle, stand with those affected by these hurricanes. I would also like to thank Dr. Burgess and Dr. Ruiz, both members of this subcommittee, who each recently visited Puerto Rico to assess the impact these hurricanes have had and continue to have on our fellow Americans.

This committee has been conducting oversight of the Federal response to the recent hurricanes since shortly after Harvey made landfall in Texas. Unfortunately, I expect that our work here will continue for years to come. The committee's jurisdiction involves not just the public health issues we will be discussing today but also rebuilding the electrical grid, addressing environmental clean-up, and restoring telecommunications, to name only a few.

The people of Puerto Rico and the U.S. Virgin Islands continue to face a long road to recovery and many are living without power and running water.

I believe we are going to be joined today by Representative Jenniffer González-Colón from Puerto Rico, someone who knows all too well about the difficult challenges her home is facing. Thank you for being here at this important hearing.

From coordinating the overall Federal healthcare response to ensuring that individuals have the medical treatment they need to protecting the blood and pharmaceutical supply to granting emergency waivers and everything in between, HHS has been working with tirelessly to provide medical care and services to individuals affected by the storms. The overwhelming majority of healthcare facilities in the impacted areas went above and beyond to protect and treat those in harm's way, yet media reports indicate that some healthcare providers failed in their duty to protect their patients. There was a tragic situation at a nursing home in Florida where 14 residents died after the facility lost its air-conditioning, and this, despite a hospital across the street that never lost power or cooling.

The response in Puerto Rico and the U.S. Virgin Islands has involved numerous Federal agencies working together with each other and state and local officials. For example, before Hurricane Maria made landfall in Puerto Rico and every day since, HHS, the Department of Defense, the Department of Veterans Affairs, and the Federal Emergency Management Agency, or FEMA, have been coordinating with local emergency response officials to provide medical care and help reestablish the island's healthcare infrastructure. HHS has worked with Puerto Rico's Department of Health to prioritize resources needed for dialysis facilities and has coordinated with FEMA to help ensure critical supplies are delivered where they are needed. Similar efforts are ongoing in the U.S. Virgin Islands as well.

But many questions remain. Has the interagency response been effective from the perspective of HHS? Are the Federal policies causing delays in response efforts? Are we utilizing our resources in the most efficient and effective ways to help our fellow Americans in Puerto Rico and the U.S. Virgin Islands in particular?

Finally, it is critical that we understand the public health challenges ahead. Mold formation is likely in nearly all the affected re-

gions. As we have seen after Hurricane Harvey, there is an increased risk for the spread of infectious disease due to contaminated water. Media reports indicate that, 1 month after Hurricane Maria, over 1 million Americans are still without clean, safe drinking water. Rebuilding Puerto Rico and the U.S. Virgin Islands will take years. The healthcare systems are in dire condition, and most of the operational facilities need some degree of assistance. To make matters worse, the electrical grid has been devastated, which has significantly hampered recovery efforts. We still don't even know the full extent of the damage, let alone when our fellow citizens will have electricity and running water restored. We are trying to make sure we are doing everything possible to address the short- and long-term needs of those living in the areas impacted by Hurricanes Harvey, Irma, and Maria, especially in the face of the public health threats that have resulted and will continue to result from these storms.

I would like to thank the witnesses for testifying here today, and I look forward to hearing your testimony.

And with that, I will now yield 5 minutes for an opening statement to Ms. DeGette, the ranking member from Colorado.

[The prepared statement of Mr. Griffith follows:]

PREPARED STATEMENT FOR HON. H. MORGAN GRIFFITH

We are here today to examine the Department of Health and Human Services' public health preparedness for and response to the 2017 hurricane season.

In the last 2 months, Texas, Florida, Puerto Rico, and the U.S. Virgin Islands have been devastated by hurricanes. I first want to express our heartfelt sorrow for the millions of Americans impacted by these devastating storms and say that all Members of this Committee on both sides of the aisle stand with those affected by the hurricanes.

I would also like to thank Dr. Burgess and Dr. Ruiz, both members of this subcommittee, who each recently visited Puerto Rico to assess the impact these hurricanes have had, and continue to have, on our fellow Americans.

This Committee has been conducting oversight of the federal response to the recent hurricanes since shortly after Harvey made landfall in Texas. Unfortunately, I expect that our work here will continue for years to come. The Committee's jurisdiction involves not just the public health issues we will be discussing today, but also rebuilding the electrical grid, addressing environmental cleanup, and restoring telecommunications, to name only a few.

The people of Puerto Rico and the U.S. Virgin Islands continue to face a long road to recovery and many are living without power and running water. We are joined today by Representative Jenniffer González-Colón from Puerto Rico—someone who knows all too well about the difficult challenges her home is facing. Thank you for being here for this important hearing.

From coordinating the overall federal health care response, to ensuring that individuals have the medical treatment they need, to protecting the blood and pharmaceutical supply, to granting emergency waivers, and everything in between, HHS has been working tirelessly to provide medical care and services to individuals affected by the storms.

The overwhelming majority of health care facilities in the impacted areas went above and beyond to protect and treat those in harm's way. Yet, media reports indicate that some health care providers failed in their duty to protect their patients. There was a tragic situation at a nursing home in Florida where fourteen residents died after the facility lost its air conditioning—and this despite a hospital across the street that never lost power or cooling.

The response in Puerto Rico and the U.S. Virgin Islands has involved numerous federal agencies, working together with each other and state and local officials. For example, before Hurricane Maria made landfall in Puerto Rico and every day since, HHS, the Department of Defense, the Department of Veterans Affairs, and the Federal Emergency Management Agency, or FEMA, have been coordinating with local emergency response officials to provide medical care and help re-establish the is-

land's health care infrastructure. HHS has worked with Puerto Rico's Department of Health to prioritize resources needed for dialysis facilities and has coordinated with FEMA to help ensure critical supplies are delivered where they are needed. Similar efforts are ongoing in the U.S. Virgin Islands, too.

But many questions remain. Has the inter-agency response been effective, from the perspective of HHS? Are federal policies causing delays in response efforts? Are we utilizing our resources in the most efficient and effective ways to help our fellow Americans in Puerto Rico and the U.S. Virgin Islands in particular?

Finally, it is critical that we understand the public health challenges ahead. Mold formation is likely in nearly all the affected regions. As we have seen after Hurricane Harvey, there is an increased risk for the spread of infectious disease due to contaminated water. Media reports indicate that one month after Hurricane Maria, over one million Americans are still without clean, safe drinking water.

Rebuilding Puerto Rico and the U.S. Virgin Islands will take years. The health care systems are in dire condition and most of the operational facilities need some degree of assistance. To make matters worse, the electrical grid has been devastated which has significantly hampered recovery efforts. We still don't even know the full extent of the damage, let alone when our fellow citizens will have electricity and running water restored. We are trying to make sure we are doing everything possible to address the short- and long-term needs of those living in the areas impacted by Hurricanes Harvey, Irma, and Maria, especially in the face of the public health threats that have resulted—and will continue to result—from these storms.

I would like to thank the witnesses for testifying here today and I look forward to hearing your testimony.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you, so much, Mr. Chairman.

This 2017 hurricane season has been one of the most damaging on record. Hurricane Harvey broke the record for the greatest amount of rain recorded from a single tropical storm or hurricane in the United States and inundated Houston and south Texas with more than 51 inches of rain. Hurricane Irma became the strongest Atlantic hurricane on record before it hit the Virgin Islands and Florida. And while these storms have been devastating, Hurricane Maria's impact on Puerto Rico and the U.S. Virgin Islands has been nothing less than catastrophic.

Mr. Chairman, as you said, the scope of potential health risks that are caused by this ongoing crisis, it is still coming into focus, but it is clearly considerable. Over a month after Maria hit, the infrastructure in Puerto Rico and the Virgin Islands remains decimated. Nearly 80 percent of Puerto Rico still doesn't have power, and HHS reported that a substantial number of Puerto Rico's hospitals are either nonoperational or require diesel to run generators in order just to keep functioning.

Over a third of Puerto Rican residents lack reliable access to potable water. Contaminated water is also spreading contagious diseases. And while I certainly appreciate the effort by volunteers, including physicians and nurses volunteering their time with the HHS DMAT teams, I am concerned that poor management of the hurricane response at a Federal level may be hindering response efforts. The Federal Government, I believe, probably does not have a complete picture of what healthcare challenges exist because, frankly, most of the island of Puerto Rico lacks adequate communication.

I think that this committee needs to hold further hearings to address the status of all these vital services that you, Mr. Chairman,

talked about. And I even think, as time goes on, we should have field hearings on Puerto Rico, in particular, but also the Virgin Islands, as much of the recovery effort, as you so accurately describe, involves the jurisdiction of this committee. I can't stress enough how important it is for us to send our staff down there to investigate this and how important it is for members to go and investigate this.

I was part of a group of members that went after Hurricane Katrina to New Orleans to observe the recovery efforts. What we found through years of oversight on this subcommittee was this Washington's understanding regarding the situation on the ground was very different than we were able to observe firsthand when we went into the basement of Charity Hospital and we saw what happened to those records. When we had our field hearings—Congresswoman Blackburn was there and a bunch of the rest of us—and we saw what had happened to small business people down there in New Orleans, you just cannot substitute for that. And as we begin to think about our public response as Members of Congress, we need to see what we are doing on the ground.

Mr. Chairman, last week, President Trump said the administration deserves a 10 for its response to the devastation of Hurricane Maria. Given the fact that most residents lack power, nearly a million Americans lack access to safe and reliable drinking water, and endless reports of near subsistence living for many, I find that statement to be breathtaking. I hope that our witnesses today are better prepared than that to talk about what is really happening on the ground and what we can do to address this unfolding crisis.

I hope it will be the beginning of an ongoing and concerted effort to understand what is going on, and I would now like to yield the balance of my time to Representative Castor, who wants to talk, appropriately, about the health challenges facing her State of Florida.

Ms. CASTOR. Well, I thank Ranking Member DeGette for yielding the time. This simply was a catastrophic hurricane season. And we have so many challenges ahead. I want to thank our witnesses who are here today. I want to thank all of my colleagues for holding this hearing. Hopefully this is just the first of many because this is going to be a very long recovery period.

And after 75 lives lost in Texas, 75 lives lost in Florida—including 14 related to a nursing home, that were completely avoidable—we need to discuss that. We know that we have about 50 deaths in Puerto Rico so far, with the threat of bacterial infections growing. I am very concerned about Puerto Rico and the whole interplay between the folks that live there and the U.S. Virgin Islands and their migration and what that means for the health needs of everyone. And on the island, the drinking water issue is simply critical. So I look forward to your expert testimony today and the committee's work in the days ahead. Thank you.

Ms. DEGETTE. I yield back.

Mr. GRIFFITH. The gentlelady yields back.

I now recognize the chairman of the full committee, Mr. Walden of Oregon.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. I thank the vice chairman for holding this hearing. I, too, want to express my deepest sympathy for those who have been impacted by these horrible storms, particularly our fellow citizens in Puerto Rico and the U.S. Virgin Islands. This committee stands ready to assist in whatever way we can. We will continue to be diligent in our oversight of the work that the agencies are doing and the needs of the people there. I am very pleased that Dr. Burgess, who chairs our Health subcommittee, has already been to Puerto Rico, visited some of the hospitals, looked at the healthcare issues. We know we have much more work to do, and we hope to hear from all of you today about what is out there ahead, where we have made progress, where there are still problems that we need to uncover and get better solutions to.

Today, we are examining the Department of Health and Human Services' continuing efforts to protect the public health in Texas, Florida, Puerto Rico, and the U.S. Virgin Islands in the aftermath of Hurricanes Harvey, Irma, and Maria. This is the first in a series of hearings on the preparedness for and responses to Hurricanes Harvey, Irma, and Maria. And, in the coming weeks, we will also hold hearings before the Energy and Environment subcommittees on these matters. And as the vice chairman stated, this committee will be conducting oversight of the rebuilding of Puerto Rico and the U.S. Virgin Islands for years to come.

The public health risk typically associated with natural disasters are varied and include heightened incidences of infectious diseases, diminished access to medical care, and long-term mental health trauma, just to name a few of the concerns we all need to be aware of. These risks can be particularly dangerous, especially for vulnerable populations, such as infants, dialysis patients, individuals who may be immunosuppressed, and, of course, the elderly.

Tragically, we saw this in the aftermath of Hurricane Irma where 14 elderly residents, as we have heard before, of the Rehabilitation Center at Hollywood Hills in Florida lost their lives as a result of heat-induced death issues after the facility's air-conditioning system failed during the storm. Last week, this committee sent a bipartisan letter to the nursing home's owner requesting information on the facility's emergency preparedness plan, inspection history, and the steps it took to protect residents after its air-conditioning system stopped working.

We will hear today that, while the three major hurricanes to impact the United States in 2017 were distinct events that presented and continue to present their own unique challenges, many of the protocols that are necessary to conduct an effective public health response are immutable. For example, Federal agencies responding to disasters must be able to communicate effectively with each other and with local, state, and territorial officials to identify any areas of need, ensuring that individuals have adequate access to basic necessities, such as food, water and medical supplies, critical in any public health protection effort. And as we head into a recovery phase, it is important we also carefully monitor patients as they transition from hospitals or under medical supervision back to their homes or other long-term living arrangements.

News reports indicate more than 60 percent of Puerto Ricans are now homeless as a result of the devastating hurricanes. We need to make sure, when patients are discharged from the hospitals, that they have safe places to go and don't end up on the streets and then back into the hospital.

However, following Hurricane Maria, various media reports have called into question whether the Federal Government is adequately meeting its obligation to protect the health and welfare of American citizens in Puerto Rico and the Virgin Islands. On this matter, I am eager to gain the perspective of our witnesses who have been on the ground in the areas that have been affected by the most recent hurricanes. Making sure that Americans in need get the assistance they require cannot and should not be a partisan matter. If certain agencies aren't pulling their weight, we want to know. If there are Federal laws or policies that are impeding the recovery efforts, we want to know as well.

In addition, we also want to hear about any best practices that can be gleaned from the ongoing recovery efforts and can be utilized in response to any future natural disasters. So, again, thanks to you and your teams for being on the ground trying to do the best you can in these horrible circumstances, but we really need to know the facts, what is working, what is not, where there have been shortfalls, what are the lessons learned, and where do you need additional help to help our citizens.

So, with that, Mr. Vice Chair, I yield back the balance of my time and look forward to the testimony of our witnesses.

Before I do that, I would also like to welcome our newest member to the committee. Mr. Duncan was just approved by the House Conference this morning, Steering Committee last night, replacing Dr. Murphy.

And Jeff, we are delighted to have you on board the committee. Thanks for being here today.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Thank you, Mr. Vice Chairman, for holding this important hearing. I too want to express my deepest sympathy for those impacted by these storms, particularly our fellow citizens in Puerto Rico and the U.S. Virgin Islands. This committee stands ready to assist in whatever way we can.

Today we are examining the Department of Health and Human Services' continuing efforts to protect the public health in Texas, Florida, Puerto Rico, and the U.S. Virgin Islands in the aftermath of Hurricanes Harvey, Irma, and Maria.

This is the first in a series of hearings on the preparedness for and response to Hurricanes Harvey, Irma, and Maria. In the coming weeks, we will also hold hearings before the Energy and Environment subcommittees. And, as the Vice Chairman stated, this committee will be conducting oversight of the rebuilding of Puerto Rico and the U.S. Virgin Islands for years to come.

The public health risks typically associated with natural disasters are varied and include heightened incidences of infectious diseases, diminished access to medical care, and long-term mental health trauma, just to name a few concerns. These risks can be particularly dangerous for vulnerable populations such as infants, dialysis patients, individuals who may be immunosuppressed, and the elderly.

Tragically we saw this in the aftermath of Hurricane Irma where 14 elderly residents of the Rehabilitation Center at Hollywood Hills in Florida lost their lives as a result of heat-induced health issues after the facility's air conditioning system failed during the storm. Last week, the committee sent a bipartisan letter to the nursing home's owner requesting information on the facility's emergency prepared-

ness plan, inspection history, and the steps it took to protect residents after its air conditioning system stopped working.

We will hear today that while the three major Hurricanes to impact the United States in 2017—Harvey, Irma, and Maria—were distinct events that presented, and continue to present, their own unique challenges, many of the protocols that are necessary to conduct an effective public health response are immutable. For example, federal agencies responding to disasters must communicate effectively with each other and with local, state, and territorial officials to identify any areas of need. Ensuring that individuals have adequate access to basic necessities such as food, water, and medical supplies is critical in any public health protection effort.

As we head into a recovery phase, it is important that we also carefully monitor patients as they transition from hospitals or under medical supervision back to their homes or other long-term living arrangements. News reports indicate over 60 percent of Puerto Ricans are now homeless as a result of the devastating hurricanes. We need to make sure when patients are discharged from the hospitals they have safe places to go and don't end up back at the hospital.

However, following Hurricane Maria, various media reports have called into question whether the federal government is adequately meeting its obligation to protect the health and welfare of American citizens in Puerto Rico and the Virgin Islands. On this matter, I am eager to gain the perspective of our witnesses who have been on the ground in the areas that have been affected by the most recent hurricanes.

Making sure that Americans in need get the assistance they require, cannot and should not be a partisan matter. If certain agencies are not pulling their weight, we want to know; if there are federal laws or policies that are impeding the recovery efforts, we want to know that as well. In addition, we also want to hear about any best practices that can be gleaned from the ongoing recovery efforts that can be utilized in the response to any future natural disasters.

Mr. GRIFFITH. Thank you, Mr. Chairman.

Mr. WALDEN. I yield back.

Mr. GRIFFITH. Thank you, Mr. Chairman.

I now recognize the ranking member of the full committee, Mr. Pallone of New Jersey.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman, and thank you for holding this hearing on this critical issue. And I hope that this hearing is the first of many hurricane-related hearings, as Congress needs to hear further from HHS and other agencies regarding the ongoing response and recovery efforts in all of the affected areas.

I would also like to take a moment to recognize the Federal, state, and local responders who are working hard to address the many public health issues which exist as response and recovery continues in all of the areas that were impacted by these three major hurricanes.

I know firsthand of the tragic devastation caused by such immense natural disasters. In 2012, my district was hit hard by Hurricane Sandy. I have never seen worse storm damage in our area in my lifetime. For many, the storm was a worst-case scenario: lost lives, homes flooded, and businesses lost. The fifth anniversary is coming up this weekend, and we still have a lot of people that are not back in their homes or their businesses.

Our Nation is now experiencing historic levels of destruction and loss in Puerto Rico and the Virgin Islands, as well as in Florida, Texas, and along the Gulf Coast, in the wake of Hurricanes Maria, Irma, and Harvey. And while no two natural disasters are alike, the areas affected by these massive hurricanes have unique needs and challenges. While Congress continues to address the response

in Florida and Texas, we must also work to ensure that Puerto Rico and the U.S. Virgin Islands receive the full and immediate support of the Federal Government as they recover. I recognize there are a number of ongoing challenges facing the residents of south Florida and the Gulf Coast, but much of the hearing today will likely need to address the situation in Puerto Rico and the U.S. Virgin Islands. The reports coming from these areas indicate that hundreds of thousands of Americans continue to struggle to meet day-to-day needs, and I am particularly concerned that there are still reports that residents do not have access to food or medicine. As many as a million Americans lack access to reliable sources of clean water. Accounts from the areas affected by these storms paint a dire situation that completely contradict the often rosy stories that come from the President and the White House.

Hurricanes Irma and Maria caused widespread flooding and destruction in Puerto Rico and the U.S. Virgin Islands, including critical damage to electrical grids, telecommunications systems, drinking water systems, and transportation infrastructure. Virtually all residents of Puerto Rico and the U.S. Virgin Islands have been impacted, and these infrastructure failures create acute public health issues. We have seen and heard reports of death, dehydration, and desperation as residents of Puerto Rico and the U.S. Virgin Islands continue to struggle in the post-apocalyptic landscape where fundamental health needs remain unaddressed even a month after Hurricane Maria and almost 2 months after Hurricane Irma.

The lists of serious needs and challenges is long. Many hospitals still do not have reliable power. Many communities in Puerto Rico still lack safe drinking water, and people have resorted to drinking from questionable water sources. Where water service has been restored, residents are still unsure if the water is safe. In a recent EPA briefing to the committee, we learned that crews going into communities to test for water quality were arriving only to find that people still lacked adequate food and drinking water.

So Congress must provide ongoing support in the aftermath of these hurricanes to restore and rebuild, and I hope our witnesses today will help us understand what needs to be improved in the response and recovery efforts so that Congress can more effectively provide assistance and understand the impacts on public health, not just today but in the months and years to come.

I also wanted to say something about the fact that many Puerto Ricans are actually coming from the island to our states, in particular in New Jersey, in my district. And, my mayors and my elected officials locally are saying: You know, is there any kind of help for us? Because a lot of these people come here, and they don't have a lot of money. They need support as well. So that is also something we need to look into.

I would like to yield the remainder of my time to Mr. Green.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Mr. Chairman, thank you for holding this hearing on this critical issue. I hope that this hearing is the first of many hurricane related hearings, as Congress needs to hear further from HHS and other agencies regarding the ongoing response and recovery efforts in all of the affected areas.

I also would like to take a moment to recognize the federal, state, and local responders who are working hard to address the many public health issues which exist as response and recovery continues in all of the areas that were impacted by these three major hurricanes.

I know firsthand of the tragic devastation caused by such immense natural disasters. In 2012, my district was hit hard by Hurricane Sandy. I had never seen worse storm damage in our area in my lifetime. For many, the storm was a worst case scenario: lives lost, homes flooded, and businesses lost.

Our nation is now experiencing historic levels of destruction and loss in Puerto Rico and the U.S. Virgin Islands, as well as in Florida, Texas and all along the Gulf Coast in the wake of Hurricanes Maria, Irma, and Harvey.

No two natural disasters are alike, and the areas affected by these massive hurricanes have unique needs and challenges. While Congress continues to address the response in Florida and Texas, we must also work to ensure that Puerto Rico and the U.S. Virgin Islands receive the full and immediate support of the federal government as they recover.

While I recognize that there are a number of ongoing challenges facing the residents of South Florida and the Gulf Coast, much of the hearing today will likely need to address the situation in Puerto Rico and the U.S. Virgin Islands. The reports coming from these areas indicate that hundreds of thousands of Americans continue to struggle to meet day-to-day needs.

I am particularly concerned that there are still reports that residents do not have access to food or medicine and as many as a million Americans lack access to reliable sources of clean water.

Accounts from the areas affected by these storms paint a dire situation that completely contradict the often rosy stories that come from the White House. Hurricanes Irma and Maria caused widespread flooding and destruction in Puerto Rico and the U.S. Virgin Islands, including critical damage to electrical grids, telecommunications systems, drinking water systems, and transportation infrastructure.

Virtually all residents of Puerto Rico and the U.S. Virgin Islands have been impacted, and these infrastructure failures create acute public health issues. We have seen and heard reports of death, dehydration, and desperation as residents of Puerto Rico and the U.S. Virgin islands continue to struggle in a post-apocalyptic landscape where fundamental health needs remain unaddressed even a month after Hurricane Maria and almost two months after Hurricane Irma.

The list of serious needs and challenges is long. Many hospitals still do not have reliable power. Many communities in Puerto Rico still lack safe drinking water, and people have resorted to drinking from questionable water sources. Where water service has been restored, residents are still unsure if the water is safe. In a recent EPA briefing to the Committee, we learned that crews going into communities to test for water quality were arriving only to find that people still lacked adequate food and drinking water.

Congress must provide ongoing support in the aftermath of these hurricanes to restore and rebuild. I hope that our witnesses today will help us understand what needs to be improved in the response and recovery efforts, so that Congress can more effectively provide assistance and understand the impacts on public health, not just today but in the months and years to come.

Thank you, I yield back.

Mr. GREEN. Thank you, Mr. Chairman.

I thank my colleague for yielding to me today.

Our district in Houston, in Harris County, Texas, was heavily impacted by Hurricane Harvey. We actually had at least eight deaths in our district alone in a very urban area of Houston. But I thank the heroism and the tireless work of our first responders, public health professionals, community members, for helping fellow Texans and Houstonians during their time of need. I would also like to thank my colleagues for supporting our two supplementals so far, and there will be much more for, not just Texas, but Louisiana, Florida, Puerto Rico, the Virgin Islands, and a number of other disasters.

The State of Texas and CMS need to work together to make sure we are taking advantage of every opportunity to help people in need, especially when it comes to Medicaid. I hope CMS will act ex-

peditionously to get the necessary resources to our local hospital in Texas to help uninsured disaster victims. We shifted to recovery in Houston and the Texas Gulf Coast and are responding to public health concerns related to Harvey, including the spread of mold in flooded homes, businesses, and the spread of disease-carrying mosquitoes.

We must also be fully responsive to the environmental impact of Harvey, including community members' possible exposure to toxic chemicals and wastewater. I look forward to hearing from our witnesses and working with our Federal public health agencies to fully address these pressing concerns. And in our office in Houston, we do a lot of casework on typically Social Security, Medicare, veterans, you name it. But now every staff member has casework with FEMA because it goes through the process. But we are working through it, again, with our Federal agencies helping us to make sure we can get people back to where they were before the storm.

And thank my colleague, again, for yielding.

I yield back my time.

Mr. PALLONE. And I yield back, as well, Mr. Chairman.

Mr. GRIFFITH. I thank the gentleman.

I ask unanimous consent that the members' written opening statements be made a part of the record.

Without objection, they will be entered into the record.

Additionally, I ask unanimous consent that Energy and Commerce members not on the Subcommittee on Oversight and Investigations be permitted to participate in today's hearing.

Without objection, so ordered.

Further, just so everybody knows what we are doing, Mr. Duncan has joined the committee and the subcommittee. And we are glad to have him on our subcommittee. However, until a formal motion is made on the floor at approximately 12:30, the Parliamentarians tell us that we have to treat him as a member of the Energy and Commerce Committee but not yet on the Subcommittee on Oversight and Investigations. So he will be treated like all other members in that circumstance, which means he will go last. As the newest member of the committee, he would go last anyway, but we are just rubbing it in. No, but I did want to let everybody else know what the status was so, when they hear a motion later today on the floor, they will understand that that is what the Parliamentarians have told us that we need to do.

But welcome to the committee and the subcommittee.

Mr. WALDEN. Mr. Vice Chairman?

Mr. GRIFFITH. Mr. Chairman.

Mr. WALDEN. I assume he knows, too, his other responsibilities for all the committee members: getting us each coffee——

Mr. GRIFFITH. We have heard tell of these stories.

Mr. WALDEN [continuing]. Like Mr. Scalise——

Mr. GRIFFITH. That is correct.

Yes. Thank you. We will make sure he is aware of those duties, Mr. Chairman.

Finally, we welcome non-Energy and Commerce Committee members who are with us today or who may show up at a later time. Pursuant to House rules, Members not on the committee are

able to attend our hearings—and we are glad to have them—but are not permitted to ask questions.

I would like now to introduce our panel of witnesses for today's hearing.

First, we have the Honorable Robert Kadlec, the Assistant Secretary for Preparedness and Response at the Department of Health and Human Services. Welcome. Next is the Honorable Scott Gottlieb, who serves as Commissioner of the U.S. Food and Drug Administration. Welcome. Then we have Ms. Kimberly Brandt, who is the Principal Deputy Administrator for Operations at the Centers for Medicare and Medicaid Services. Welcome. We are glad you are here. And finally, we have Rear Admiral Stephen Redd, who is the Director of the Office of Public Health Preparedness and Response at the Centers for Disease Control and Prevention.

Thank you all for being here today and providing testimony. We are looking forward to the opportunity to examine the preparedness for and responses to the recent hurricanes.

Now, as a part of what we do in this committee, we are holding an investigative hearing. And when doing so, it has been the practice of this subcommittee to take testimony under oath. Do any of you have objection to testifying under oath? Seeing none, the chair then advises you that, under the rules of the House and the rules of the committee, you are entitled to be accompanied by counsel. Do any of you desire to be accompanied by counsel during your testimony today?

Seeing none, I will move forward.

In that case, if you would please rise and raise your right hand, I will swear you all in.

[Witnesses sworn.]

Mr. GRIFFITH. Hearing affirmative answers from all, I appreciate it. Thank you very much. You are now under oath and subject to the penalties set forth in title 18, section 1001, of the United States Code.

You may now give a 5-minute summary of your written statement.

And, obviously, we will begin with the Honorable Mr. Kadlec.

TESTIMONY OF 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

TESTIMONY OF ROBERT P. KADLEC, M.D.

Dr. KADLEC. Good morning, Mr. Vice Chairman, Ranking Member DeGette, and members of the subcommittee. It is a privilege to appear before you to discuss our Nation's medical and public health response to a series of unprecedented and nearly simultaneous Cat-

egory 4 and Category 5 hurricanes that hit the U.S. mainland and its territories so far this season.

HHS—and when I include that, it is the ASPR—the CMS, FDA, and CDC, as well as our interagency partners of FEMA, DHS, VA, and DoD, have pushed the boundaries in unprecedented ways to save lives and support the communities and people impacted by these major hurricanes. I recognize that, in some regions in Puerto Rico and the Virgin Islands, people are still facing dire conditions. I recently saw that for myself and the devastation firsthand and can assure you that HHS continues our response at 110 percent and will continue to work as hard as we can until conditions improve.

Since this is my first time testifying before this committee as the ASPR, I will begin with a brief description of my view on the role of this position. After it was created almost 11 years ago in response to Hurricane Katrina by the Pandemic and All-Hazards Preparedness Act, its objective was to create unity of command by consolidating all HHS public health and medical preparedness and response functions under one person, the ASPR. I had the privilege of serving as a staff director of the subcommittee that drafted this legislation. ASPR's mission is simply to save lives and protect America from health security threats. On behalf of HHS, ASPR leads the public health and medical response to disasters and public health emergencies in accordance with the National Response Framework Emergency Support Function No. 8.

Today, the threats facing our country are increasingly diverse and more lethal. Therefore, my main objective is to improve national readiness and response capabilities from 21st century threats. I aim to do that through four key priority areas and efforts: first, provide strong leadership; second, create a national disaster healthcare system; third, sustain robust and reliable public health security capabilities; and, finally, advance innovative medical countermeasure development.

Hurricanes Harvey, Irma, Maria, and, lastly, Nate's near simultaneity and severity created unique challenges. Especially in Puerto Rico, no place, no person, no life was untouched. During my trip there, I was overwhelmed by the resilience of its citizens who are making do in extraordinarily difficult situations. Of the three major hurricanes to date, our strategy has been threefold: first, save lives; second, stabilize the healthcare system; third, restore healthcare services.

In Puerto Rico, we're still responding. In other areas, recovery is underway. Here are just some of the many actions taken by ESFA partners:

In order to save lives, ASPR activated the National Disaster Medical System, or NDMS, and deployed more than 2,500 personnel from 21 states and hundreds of other Federal employees, including U.S. Public Health Service Commissioned Corps personnel, to communities impacted by these storms. In fact, in each of these storms, we deployed teams even before the hurricanes made landfall so they were ready to respond immediately. We cared for more than 15,000 patients in the affected states and territories and more than 10,700 in Puerto Rico alone. HHS has also sent 439 tons of medical equipment and supplies to the affected areas. HHS de-

clared public health emergencies for impacted states and territories before landfall with each storm.

ASPR and CMS proactively utilized the emPOWER tool to identify Medicare/Medicaid beneficiaries in each impacted area who rely on life-maintaining and assistive medical equipment as well as people who rely on dialysis and home health services. We evacuated more than 200 dialysis patients from the U.S. Virgin Islands. In Florida and St. Thomas, for the first time in its history, NDMS personnel joined urban search and rescue teams to locate and evacuate dialysis patients.

HHS activated the Emergency Prescription Assistance Program in Puerto Rico, which provides free medications to disaster victims who cannot afford to pay.

HHS deployed mental health teams and activated behavioral health hotlines, in partnership with SAMHSA, to aid people coping with the psychological effects of these storms.

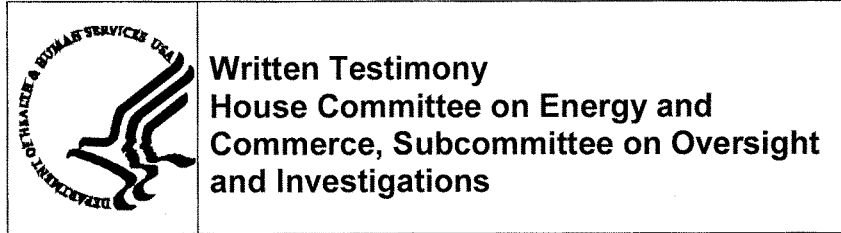
I'd like to show you a map. You can see it on your screens and you have paper copies in front of you. This illustrates the comprehensive approach to providing healthcare and DoD services—pardon me, medical services we implemented together, with our interagency partners at the VA and DoD, as well as the Puerto Rico Health Department.

My overview of activities we took on behalf of Americans in distress is just a fraction of what we actually did. I have not and could not speak to all the work that HHS disaster medical assistance teams and Public Health Service Commissioned Corps personnel did. They are true American heroes who left their families, their medical and clinical practices to render aid, often in arduous circumstances.

We're committed to the long period of recovery ahead. We also reflect on this experience by conducting a comprehensive after-action review to identify ways to improve our capacity to respond to future public health emergencies, be they naturally occurring or manmade.

I thank you again for this opportunity to address these issues, and I'm happy to answer any questions that you may have.

[The prepared statement of Dr. Kadlec follows:]



Hurricane Response

Statement of

Robert Kadlec, MD

Assistant Secretary For Preparedness and Response
U.S. Department of Health and Human Services



For Release on Delivery
Expected at 10:00 a.m.
October 24, 2017

Mr. Chairman and Ranking Member DeGette, it is a privilege and an honor to appear before you and members of the Subcommittee to discuss our nation's medical and public health response to the unprecedented string of hurricanes that have hit the U.S. this season. I am Dr. Robert Kadlec, Assistant Secretary for Preparedness and Response – or ASPR – at the U.S. Department of Health and Human Services (HHS).

After being confirmed in August, I barely had enough time to introduce myself to the ASPR staff before Hurricane Harvey made landfall in Texas. The past few months have been very challenging, testing our capabilities and resources. I can proudly appear before you today and say that HHS, as well as our interagency partners, have pushed forward in equally unprecedented ways to save lives and support the communities and people impacted by three major hurricanes, while at the same time dealing with a fourth hurricane and standing ready to respond to potential requests from California for health (especially mental health) support with respect to the California wildfires and from Nevada health authorities with respect to the mass shooting in Las Vegas. I recognize that in some regions, especially Puerto Rico, people are still facing dire conditions and it feels like the government has not done enough. I saw the devastation first hand and want to reassure you all that HHS will continue working as hard and smart as we can until conditions improve.

Since this is my first time testifying as the ASPR, please let me begin with a brief description of my background and my view on the role of ASPR. Then, I will describe what ASPR has done in leading the medical and public health responses, as well as supporting human services responses, to Hurricanes Harvey, Irma, and Maria. Lastly, I will share some initial lessons learned.

The Role and Vision of ASPR

During my confirmation hearing, I told Senators that assuming the role of ASPR would be both exciting and daunting. It is exciting because I now lead an organization that I helped create in 2006 when I was staff director of the Senate Subcommittee on Bioterrorism and Public Health Preparedness. It is daunting due to the immense responsibility of this position and the increasingly challenging threat landscape we face.

When ASPR was originally established in the Pandemic and All-Hazards Preparedness Act (PAHPA) under the bipartisan leadership of Senator Richard Burr and the late Senator Ted Kennedy, the objective was to create “unity of command” by consolidating all public health and medical preparedness and response functions under the ASPR. This approach was modeled on the Goldwater-Nichols Act that created the Department of Defense (DoD) combatant commands and the impetus was the disorganized and fragmented response to Hurricane Katrina in 2005. Recognizing this, as I took over as the ASPR two months ago, one of my top priorities was to transform ASPR from a policy-centric organization to an operations-centric agency.

ASPR’s mission is to save lives. On behalf of HHS, ASPR leads the public health and medical response to disasters and public health emergencies, in accordance with the National Response Framework and Emergency Support Function #8. HHS also supports other federal entities who lead Emergency Support Function 6, with respect to the human/social services. In addition, HHS leads Federal health and human services recovery support under the Health and Social Services Recovery Support Function. Today, the threats facing our country are increasingly diverse and

more lethal. My main objective is to improve national readiness and response capabilities for 21st century health security threats. I aim to do that through four key priority areas:

- First, provide strong leadership, including clear policy direction, improved threat and situational awareness, and secure adequate resources.
- Second, seek the creation of a “national contingency healthcare system” by better leveraging and augmenting existing programs – such as the Hospital Preparedness Program (HPP) and the National Disaster Medical System (NDMS) – to create a more coherent, comprehensive, and capable system integrated into daily care delivery.
- Third, support the sustainment of robust and reliable public health security capabilities, including an improved ability to detect and diagnose infectious diseases and other threats, as well as the capability to rapidly dispense medical countermeasures in an emergency.
- Fourth, advance an innovative medical countermeasures enterprise by capitalizing on advances in biotechnology and science to develop and maintain a robust stockpile of safe and efficacious vaccines, medicines, and supplies to respond to emerging disease outbreaks, pandemics, and chemical, biological, nuclear, and radiological incidents and attacks.

Medical and Public Health Responses to Hurricanes Harvey, Irma and Maria

The scale and scope of this year’s hurricane season has been unprecedented. Hurricanes Harvey, Irma, Maria, and Nate’s proximity and severity have created unique challenges. For example, while we were responding to Hurricane Harvey, teams had to be mobilized for Hurricane Irma, which devastated the U.S. Virgin Islands, and made landfall again in Florida. In the wake of

Hurricane Irma, Hurricane Maria made landfall in the U.S. Virgin Islands and was extremely destructive to the Commonwealth of Puerto Rico. It took out large portions of Puerto Rico's fragile electrical grid, which impacted the entire island. Additionally, Puerto Rico faced public health and health system infrastructure challenges prior to the hurricane that exacerbated the hurricane's effects. Especially in Puerto Rico, no place, no person, no life was untouched by these hurricanes – the physical destruction was unfathomable. But during my trip there, I was overwhelmed by the resilience of the citizens who were making do in extraordinarily difficult situations.

For the three hurricanes to date, ASPR activated the National Disaster Medical System (NDMS) and deployed more than 2,500 personnel and hundreds of other Federal employees to communities impacted by the storms. NDMS teams were deployed from 21 states outside the affected areas for all three hurricanes. In fact, HHS through ASPR deployed NDMS teams and U.S. Public Health Service Commissioned Corps (USPHS) teams before the hurricanes hit so they were ready to respond immediately. HHS sent tons of equipment and supplies to affected areas and declared public health emergencies in TX, FL, LA, AL, MS, SC, GA, USVI and PR, as well as for California with respect to the wildfires. This enabled the Centers for Medicare & Medicaid Services (CMS), in response to requests from State/territorial public health or health departments, to waive certain Medicare/Medicaid, CHIP and the Emergency Medical Treatment and Labor Act (EMTALA) requirements, in order to expedite patient care in affected areas. We cared for more than 10,000 patients and evacuated patients to facilities that could provide the expert care needed. HHS requested activation of a FEMA national ambulance contract, which provided aeromedical and ground ambulances to move patients from harm's way to hospitals.

HHS activated the Emergency Prescription Assistance Program, which provides medications to disaster victims who cannot afford to pay.

Under the National Response Framework, HHS is the coordinator and primary Federal agency responsible for Public Health and Medical Emergency Support Function #8 (ESF #8). ASPR leads this coordination on behalf of the Secretary. Our strategy in the hurricane response has been three fold: save lives, stabilize the healthcare system, then restore services. In some areas, such as Puerto Rico, we are still in the response mode of saving lives and stabilizing healthcare services.

HHS has 17 core medical and public health functions under ESF #8. One of those functions is to assess medical needs. ASPR worked closely with State, local, and territorial public health departments in each of the affected areas to determine their needs and to best integrate our support. I maintained contact with them throughout our response, and personally visited several of the affected States and territories. Our field personnel worked closely with the Federal Emergency Management Agency (FEMA), and were placed as liaison officers within State and territorial operations centers, in order to provide immediate support and services to local officials. In Puerto Rico, we assessed all 67 hospitals and continue to monitor nursing homes and skilled nursing facilities. And, the Health Resources and Services Administration (HRSA) has been supporting its community based grantees who operate primary care delivery sites in these areas by connecting them to local, state, and Federal resources.

Another ESF #8 responsibility is public health surveillance. Working with the Centers for Disease Control and Prevention (CDC), we supported the monitoring of diseases within the shelters we staffed and responded to State requests for assistance with post-hurricane disease

surveillance. In Puerto Rico, we provided CDC environmental health officers and epidemiologists to support their public health response efforts. Additionally, CDC sent experts to Puerto Rico to assist with restoring and augmenting their public health laboratory capacity. Our HHS team has worked with Puerto Rico to provide testing for waterborne diseases such as leptospirosis, an infectious disease endemic to PR, though traditionally with low case numbers.

Another ESF #8 responsibility is to provide healthcare services. HHS provided medical services in the form of emergency department decompression, hospital augmentation, Federal medical stations, and free-standing medical teams. Through the NDMS, ASPR engaged in the evacuation of patients, when necessary. We proactively evacuated more than 200 dialysis patients from USVI before Hurricanes Irma and Maria struck. Our partners from DoD and the Department of Veterans Affairs (VA) were key components of these moves. Once the hurricanes passed, teams provided on-site medical care through Federal medical stations (FMS) with 50 to 250 beds provided through the Strategic National Stockpile. In Puerto Rico, ASPR developed an innovative approach to providing medical care. Using a “hub and spoke” approach, we were able to cover all seven regions of PR and provide care and evacuation to each region. ASPR collaborated with the VA and DoD to increase the number of patients who could be seen. An important lesson learned from events such as Hurricanes Katrina and Sandy and during the 2010 Haiti earthquake was the impact that disasters have on persons who rely on durable medical equipment (DME), especially energy dependent DME. To rectify this problem, ASPR and CMS created the emPower tool. EmPower provides information to local public health officials about the number of Medicare beneficiaries in each impacted area who rely on 14 types of life-maintaining and assistive equipment, ranging from oxygen concentrators to electric wheelchairs,

as well as data on the number of people who rely on dialysis, oxygen, and home health services. Citizens who use durable medical equipment tend to be at-risk populations with access and functional needs, including the chronically ill and aging populations – those who are the most vulnerable in their communities and most likely to need life-saving assistance in prolonged power outages. EmPower also provides real-time severe weather tracking information from the National Oceanic and Atmospheric Administration to help communities track and plan for emergencies. In Florida and St. Thomas (USVI), for the first time in its history, NDMS personnel joined DoD's Urban Search and Rescue (USAR) teams to locate dialysis patients whom authorities were unable to reach during the initial evacuation, using EmPower data. HHS's Food and Drug Administration (FDA) monitored pharmaceutical supplies impacted by the storms to help prevent hurricane-related devastation from causing drug shortages. ASPR also worked with FDA, Red Cross, and the American Association of Blood Banks to ensure the blood supply was sufficient in the impacted areas. HHS deployed mental health teams and activated behavioral health hotlines in partnership with the Substance Abuse and Mental Health Services Administration (SAMHSA) to aid people in coping with the effects of the storm and help those in impacted areas connect with local behavioral health professionals. HHS created and distributed information and education on carbon monoxide poisoning, worker safety, food safety, vector control, and other health related topics. Our partners at CDC provided expertise in controlling mosquitoes. CDC and FDA also provided technical expertise with potable water ranging from municipal systems to individual wells. Finally, HHS provided mortuary affairs teams that assisted with respectful re-interment of human remains uncovered by flooding of cemeteries.

ASPR coordinated these broad range of activities through daily ESF #8 Federal interagency calls across all departments and agencies that play a role in health and medical responses, including Federal Emergency Management Agency (FEMA), DoD combatant commands (e.g., NORTHCOM, TRANSCOM, and SOUTHCOM) and other DoD entities, VA, and all HHS operating divisions such as CDC and FDA.

Conclusion

ASPR is still actively in response mode with respect to the impact of Hurricane Maria in Puerto Rico. Now that much of the response effort is concluding, the recovery effort will continue for years. We will continue to partner with FEMA over the next several years during this long period of recovery.

We have a team who has been tracking information throughout the response for an after action report. This report will be critical to future operations. We will be building on things we performed well, and fixing areas that need improvement.

The Pandemic and All-Hazards Preparedness Act (PAHPA) was designed to improve our nation's public health and medical preparedness and response capabilities for emergencies, whether they are naturally occurring disasters, infectious disease outbreaks, or acts of terrorism.

ASPR's forward leaning response during this challenging hurricane season was made possible thanks to PAHPA and its 2013 reauthorization. Indeed, our nation is better prepared thanks to this landmark legislation, which has brought cohesion and efficiency to the Federal public health and health response. PAHPA is due for reauthorization in 2018, and I look forward to working closely with you to move this important legislation forward. Together, we can continue to strengthen our nation's readiness and response capabilities for 21st century health security threats. I thank you again for this opportunity to address these issues and am happy to answer any questions.

Mr. GRIFFITH. Thank you. Thank very much.
Now 5 minutes for an opening statement for the Honorable—

TESTIMONY OF SCOTT GOTTLIEB, M.D.

Dr. GOTTLIEB. Thank you, Chairman Griffith, Ranking Member DeGette, members of the subcommittee. I appreciate the invitation to discuss the FDA's response to Hurricanes Harvey, Irma, and Maria. My remarks today are going to be focused on the impact of Maria on Puerto Rico because of the unique role the FDA has in the island's recovery and because of the enormous magnitude of the devastation that Maria caused to our fellow citizens.

First and foremost, our commitment is to the people of Puerto Rico as they begin the long recovery from the overwhelming devastation. But FDA also has a broader mission in Puerto Rico: A substantial portion of the island's economic base is comprised of facilities that manufacture medical products. This includes many critical medical products. There are currently more than 50 medical device manufacturing plants in Puerto Rico. Collectively, they produce more than 1,000 different kinds of devices. To date, we are especially focused on about 50 types of medical devices manufactured by about 10 firms in Puerto Rico. These devices are critically important to patient care because they may be life-sustaining or life-supporting or the island may be the only manufacturing site for these devices.

At the same time, we're focused on about 30 different medically important drugs and about 10 biological devices or biologics that are solely or primarily manufactured on the island. Fourteen of these products are sole-source, meaning they're manufactured only in Puerto Rico.

To avert shortages of critical medical products, we have been working closely with our partners at FEMA, DHS, and, of course, HHS to troubleshoot challenges related to getting fuel for generators and raw ingredients for manufacturing processes, as well as the logistics to move finished products off the island. Our interventions have evolved as the nature of the risk has changed, and our response progresses. Early on, we helped individual firms secure landing rights for planes to ferry off finished products that were, in some cases, at risk of being destroyed by flooding warehouses. As days went on, we started to get more actively involved in helping facilities secure diesel fuel for generators. In the last week, we have been actively engaged in helping a few facilities that manufacture products critical to the blood supply secure small quantities of medical-grade gases that they use in their manufacturing processes. As the recovery efforts proceed, a lot of these challenges are being solved through better logistics and no longer require our active intervention.

That's the good news. We have processes in place now that are helping guarantee supply of diesel fuel, raw manufacturing ingredients, and medical gases, and other critical components. But there will be other challenges that arise as this crisis evolves.

The one that concerns us the most is long-term power. Many generators weren't meant to function for months on end. Moreover, a lot of the facilities can't return to full production on generator power alone. Most are producing at anywhere from 20 to 70 per-

cent of their normal capacity based on our informal survey. They won't be able to resume full production until they get back on the power grid. And if they don't return to the grid by the end of this year, we're concerned that we could face multiple potential shortages unless we can also help these facilities temporarily ship more of their manufacturing off the island.

But with my remarks, I'd like to give you a perspective on the human factor that we're seeing every day where we see the island's residents taking often heroic steps to keep supplies and critical products flowing and where the firms that manufacture these items are taking their own extraordinary steps as good corporate citizens to support these efforts. If we're going to avert major product shortages, it's going to be as a consequence of these efforts. I want to take a moment to take note of these activities and to support them.

First and foremost, I want to take note of the Americans who reside in Puerto Rico. The medical product industry directly employs about 90,000 Puerto Ricans. And if we do avert critical shortages, it will be primarily because of our fellow citizens who returned to their post at this critical time, even as their own families were displaced and their lives devastated. We owe them all an enormous debt of gratitude.

I also want to use this chance to take measure of the good corporate citizenship that FDA has been witness to. Even as we watched some companies take extraordinary efforts to maintain their production, they took equivalent steps to support their employees and the families of their workers, using their facilities as a way to deliver direct assistance to those harmed by Maria. Many of these manufacturing facilities are serving as disaster relief stations across the island. They are helping distribute FEMA aid to the outlying towns. Companies are distributing gasoline to their employees and general relief items like water, food, and batteries. Facilities have been using their cafeterias to feed employees and their families. One multinational drug company told us that they shipped thousands of generators to the island for distribution to their employees as part of hundreds of tons of relief aid and emergency supplies that they shipped by air and sea. We know of companies that have created financial programs to help employees rebuild their homes and resume their lives. Some of these programs include cash grants or matched donations they accept from employees across the globe as a way to help Puerto Rico employees rebuild their homes.

I want to take a moment to recognize these efforts. These kinds of commitments are going to be a key part of helping Puerto Rico fully recover. We all need to do our part.

Most of all, I want to recognize the resilience of the people of Puerto Rico and the fidelity to our public health mission. The FDA has a long history of operating on the island. It has been an integral part of our work. We owe the island's residents our steadfast and long-term commitment to a full recovery. Thanks a lot.

[The prepared statement of Dr. Gottlieb follows:]



**TESTIMONY
OF
SCOTT GOTTLIEB, M.D.
COMMISSIONER OF FOOD AND DRUGS**

**BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES**

**“EXAMINING HHS' S PUBLIC HEALTH PREPAREDNESS FOR AND
RESPONSE TO THE 2017 HURRICANE SEASON”**

OCTOBER 24, 2017

RELEASE ONLY UPON DELIVERY

Mr. Chairman, Ranking Member, and Members of the Subcommittee, I am Dr. Scott Gottlieb, Commissioner of Food and Drugs at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to testify today on FDA's response to the hurricanes that have devastated parts of our country.

First, I would like to extend my thoughts to all those who have been affected by these storms. I traveled to San Juan, Puerto Rico, shortly after Hurricane Maria devastated the island. The ruin left in the storm's path was overwhelming. I saw long lines for gasoline and banks, and very little commercial activity on the city's streets. Homes were completely destroyed. I met with about 50 members of FDA's staff in San Juan, and heard many stories of extreme hardship. People were worried about how they would safely tend to the basic needs of daily living in a city without electricity. By every measure, this was an epic event of historic destruction that will require our sustained commitment to our fellow citizens on the island, as well as to the public at large as we maintain our mission to protect and promote the public health.

This hurricane season has left other regions devastated, as three major storms have made landfall on the United States. This combination of major catastrophic events is unmatched in recent history. FDA has longstanding experience responding to natural disasters and is dedicated to supporting the U.S. response in the interest of public health. In the 2017 hurricane season, beginning with Harvey, the Agency has played an integral role in the hurricane response efforts with a multifaceted approach, including providing on the ground support and making recommendations regarding food and medical products that may have been affected by the

storms. We perform extensive preliminary work in advance of storms to help prepare for the potential impacts. For example, we utilize storm protection data, Geographic Information Systems (GIS), and firm registration databases to prepare maps to identify FDA-regulated firms, including those that manufacture critical products that could be impacted by the storms. Where necessary, we may take contingency steps to help ensure a continuous supply of critical medical product manufacturing.

But often the most significant role that FDA plays comes after the storm, as facilities come back on line and may need remediation, and farmers seek to put crops or farmland that were damaged back into commercial use. For example, since Hurricane Harvey devastated the rice fields around Houston, FDA has been working with local producers and states to help determine which crops can be used commercially, including diversion into animal feed based on review of supportive scientific data. More information on animal food can be found at:

<https://www.fda.gov/animalveterinary/resourcesforyou/ucm575263.htm>. The devastation brought by the 2017 storms goes beyond the manufacturing of medical products. The storms hit hard in areas where there are a significant number of farmers, including Texas, Florida, Georgia, Louisiana, Alabama, South Carolina, North Carolina, Puerto Rico, and the U.S. Virgin Islands.

However, Puerto Rico was a singular tragedy that challenges FDA in unique ways that the Agency has not confronted in other storms. Puerto Rico is home to a substantial base of medical product manufacturing. This includes both pharmaceuticals and medical devices. At least 33 percent of Puerto Rico's gross domestic product is from its pharmaceutical sector. About 8 percent of the medicines consumed by Americans (based on the dollar value of pharmaceuticals)

are manufactured in Puerto Rico, with major categories including blood fraction products, cardiovascular drugs, and treatments for cancer and HIV. On the medical device side, there are about 50 medical device manufacturing facilities on the island that supply products to Americans, with many sophisticated and medically-necessary products manufactured in Puerto Rico, including cardiovascular devices such as pacemakers and blood collection devices.

As a consequence of the devastating impacts to the island, the people of Puerto Rico, and the facilities that manufacture these critical products, FDA has been working around the clock to help troubleshoot individual challenges associated with maintaining a continuous supply of the most critical medical products. To give you some data: when it comes to pharmaceutical products, there are hundreds of drugs manufactured on the island and many of these drugs made on the island are critical medicines. We are monitoring closely a list of about 40 products that are critical and either manufactured solely or primarily in Puerto Rico. Of those 40 products, 14 are sole-source products, meaning there are no alternative drug products available. The impact of Puerto Rican manufactured medical products to the public health of all Americans is significant, and we will continue to monitor all pharmaceutical manufacturers on the island to identify other opportunities where the Agency can assist, such as additional imports.

In Puerto Rico, even while we work to restore manufacturing, our first priority continues to be our fellow citizens who live on the island. FDA and its Federal partners are coordinating with health care service companies located in Puerto Rico. We are working to provide Puerto Ricans access to medical products and helping medical product manufacturers that supply the island recover after the storms. We have undertaken sweeping, Agency-wide actions to provide direct assistance to our staff and fellow citizens on the island. This includes efforts to help get food and

medical products onto the island, and help hospitals get back to full operation. FDA is also working in partnership with the AABB Inter-organizational Task Force (ITF), to facilitate access to safe blood products for the people of Puerto Rico.

Each natural disaster brings unique challenges. But the magnitude of these storms, and their historic impact, has required FDA to engage in ways we have not before, in order to minimize the effects on consumers, healthcare delivery, and the U.S. medical supply, in addition to addressing the direct challenges faced by our fellow citizens. Below, I will address in more detail some of the steps we are taking in respect to these challenges, and the impact they have on the different products that we regulate.

Medical Products

Even before the storms hit, FDA reached out to pharmaceutical and medical device firms with facilities in the path of the storms to determine what products might be impacted. Approximately 9,000 medical product firms in the path of the storms were identified for follow-up by FDA. Calls have been placed to approximately 5,000 firms to assess the impact of the storms; the Agency has reached 60 percent of those firms and more than 200 site visits are planned. In many cases, owing to downed communications, we have not been able to reach certain firms. But we have been in contact with all of the firms that manufacture medical products that we consider critical, where a falloff in production and an ensuing shortage could have public health implications. We believe we have a good understanding of the potential risks that we face, and are taking steps to mitigate them.

I was grateful for the opportunity to accompany the Acting Secretary of Homeland Security Elaine Duke on her trip to Puerto Rico on October 6 to meet with FDA staff on the island and bring them supplies. We have 100 people on staff in our San Juan headquarters. This footprint is a reflection of the significant medical manufacturing presence on the island. As I mentioned earlier, the devastation in Puerto Rico presents a broader challenge because it is home to a large medical product manufacturing base for both drugs and medical devices and supplies. Some of these facilities produce products that could be in shortage if production is sharply diminished or pushed offline. Approximately 80 percent of the drug products that are manufactured on the island are consumed by U.S. citizens in Puerto Rico and across the 50 states. Puerto Rico plays a pivotal role in supporting the public health of all Americans. In total, there are about 50 firms in Puerto Rico that manufacture drug products, and about 40 that manufacture devices.

Shortages have traditionally been handled by individual centers within FDA, which have unique approaches to address potential shortages. Given the magnitude of this crisis, coupled with the unique logistical challenges in Puerto Rico, it was critical to coordinate these efforts across FDA, prioritize our efforts, and organize a larger response to this crisis. We expanded our response capacity through our emergency operations staff, leveraging their expertise and crosscutting perspective to address and prioritize based on the potential for medical product shortages and work toward solutions more effectively with Federal partners and industry.

We organized a new team to work in direct response to the tragedy in Puerto Rico and increased the staff that is working directly on these efforts, as well as staff working part time to support

this response. Understanding how important communications are, we have also created a new task force to make information available, especially to affected consumers, to keep people informed about our response and steps they can take to recover. In all, FDA has hundreds of staff working full or part time in response to these tragic storms.

Some of the medical product facilities in Puerto Rico were hit harder than others. But even the facilities that sustained relatively minor damage are running on generator power. Many firms have requested assistance in securing fuel to keep their generators running. Many of these generators were not designed to run this long and are old. So it is unclear how long they can last. In select cases, we have tried to work with sponsors to secure additional, back-up generators. If the generators fail, and the facilities shut down, re-starting these plants is not always a seamless and fast process. The facility usually needs to be re-inspected. The impact of disruptions on continuous equipment like HVAC and refrigeration of the batches that are in storage is also significant.

You have probably heard most drug and device firms say that their facilities in Puerto Rico are back in operation. It is true that the manufacturing has been restarted, or was never interrupted at most of the major production facilities. Many facilities implemented emergency plans to prepare for the hurricane, mitigating the most severe damage. But these facts do not reveal the true scope of the challenge that we are facing when it comes to the continuation of medical product production in Puerto Rico.

For most facilities, we understand that manufacturing is running at minimal levels, and certainly far from full production. We have surveyed firms and can anecdotally relate that reports of manufacturing running below 50 percent are common, with many firms operating around 20 percent capacity, and some even less. We have found no firm operating above 70 percent of their normal operation. The initial challenge was securing gasoline for employees so they can return to work. The highly skilled workforce has returned to their jobs in high numbers, even as their own lives were devastated by the storm, and even as they had to tend to their families. For those of us concerned about the potential for medical product shortages of critical products, we owe our fellow citizens of Puerto Rico a great debt of gratitude for helping to sustain production.

Now, the major challenges that remain include fuel for generators and the availability of secondary supplies used in the manufacturing processes, such as medical gas that is used in various production steps. Power, in particular, remains a critical concern. Many of the generators were not meant to operate for long periods of time. But, electrical power grid restoration is likely to take many months. For critical manufacturing facilities, we have helped selected firms troubleshoot the issues involved in securing and installing secondary generators that can operate more reliably or back up critical production processes. However, we remain very concerned about a handful of firms whose facilities are vulnerable and manufacture critical products.

In rare cases, we address drug shortages through the careful and selective importation of alternative supplies from other approved manufacturing sites and reliable markets. We have had to do this for one manufacturer, so far, as a result of circumstances related to Hurricane Maria. This involves the importation of an alternative supply of an IV solution product and

metronidazole manufactured by Baxter from multiple sites from around the world. Some of these products were on FDA's drug shortage list prior to Hurricane Maria, but, the existing shortages were exacerbated as a result of the reduction in manufacturing experienced in Baxter's Puerto Rico facility.

When FDA contemplates the importation of an alternative product to address a drug shortage, the Agency often works with the approved manufacturer on securing supplies they produce for overseas markets that they are able to redirect to the U.S. Sometimes these products are manufactured in facilities already inspected by FDA. In the recent case of the Baxter IV fluids importations, for example, the company has supplies they can redirect from their Ireland and Australian sites to the U.S. Our goal is to meet all U.S. patients' needs with the temporary imports until the approved U.S. versions can cover U.S. market demand. To enable these imports, FDA conducts a complex process of review of the foreign facility and product to ensure that the imported products can be safely used interchangeably with the U.S. approved product, and that the production process for the substitute products is safe and reliable.

To do this, we evaluate the overseas formulation, labeling, and other attributes, as well as the quality of the manufacturing sites to ensure that the substitute product poses no undue risks for U.S. patients. Any differences from the approved version are outlined in a letter shipped with the product and posted on FDA's website. If the U.S. approved firms do not have any ex-U.S. supplies that they are able to redirect to U.S. market, FDA will work with our regulatory counterparts in countries such as Canada, Australia, and the European Union on other potential sources. These are typically products that are approved for markets that have good inspectional

histories. FDA's Drug Shortage staff has sanctioned the procurement of products in these ways on 37 different occasions in the past seven years to address shortages. It has been a valuable and successful tool. But it is resource intensive for FDA, and only works because we adopt this practice on relatively rare occasions. It is important to note that in most cases, overseas firms cannot fully meet U.S. needs. In other cases, it takes overseas production sites significant time to ramp up manufacturing capacity to meet the extra U.S. market needs. In the case of Baxter, the company has supplies from the overseas sites, where production will increase over time to meet the needs of the U.S. This is another way we address drug shortage situations.

The ultimate goal is to get all facilities back online at full capacity, both as a public health priority and for Puerto Rico's economic recovery from the hurricane. I discussed this matter directly with the Governor of Puerto Rico and his staff. These sites directly employ close to 90,000 residents of Puerto Rico, and represent more than 30 percent of the island's GDP. Pharmaceutical manufacturing alone accounts for about 16 percent of all the manufacturing jobs in Puerto Rico. These are highly skilled, higher-wage jobs. They are an important element of Puerto Rico's economic base and one of the island's signature industries.

According to analysis prepared by FDA in conjunction with colleagues at the Council of Economic Advisors, pharmaceutical workers in Puerto Rico earn about 60 percent more than the average manufacturing wage in Puerto Rico. Many of these citizens are back at work. But hypothetically speaking, if pharmaceutical production were to shut down for six months, and employees lost their income related to these jobs, workers would stand to lose about \$500 million. This figure is meant only to give you a representation of the magnitude of the

importance of these jobs to the island's residents. In order to help Puerto Rico secure its economic future, getting this manufacturing base back online is a critical step. We need to do our part to help these firms maintain their commitment to operate in Puerto Rico.

I can tell you the leadership of FDA is committed to all of these efforts. We stand with the people of Puerto Rico. I have been personally engaged in troubleshooting these issues, working directly with my colleagues at HHS and the Department of Homeland Security, as well as the Governor of Puerto Rico.

I want to highlight some of the other challenges we have been addressing related to these tragic storms:

Blood Supply

Another critical area is ensuring access to safe blood in the face of so many storm-related injuries. Since the storms' onset, my colleagues have been working closely with the AABB ITF to help ensure that not only are needs being met, but that we maintain the same level of blood safety as we do when we are not amidst three natural disasters. Thanks to the continued donations, blood banks have successfully met the needs across all impacted regions in the continental U.S. to date. We will continue to work with this important group to monitor the needs in Puerto Rico and the U.S. Virgin Islands.

FDA Personnel

In addition to helping the public to recover, we have a responsibility for the well-being of FDA employees in areas ravaged by the storm. FDA staff is fully accounted for across all areas of impact from hurricanes Harvey, Irma, and Maria. I visited with the FDA team stationed in San Juan, where we have about 100 full-time staff, who worked hard to prepare and secure our facilities ahead of the storm. And I deeply appreciate the work of all FDA staff preparing for and responding to these disasters, including over 400 FDA staff who have deployed or are ready to deploy as part of the U.S. Public Health Service Commissioned Corps, and those who put in countless hours in support of FDA's response on top of other mission-critical work at FDA. I am proud of their work and dedication to help our fellow Americans. I was also deeply moved by the more than 150 FDA civilian staff who responded to the Federal Emergency Management Agency's (FEMA) request for volunteers. My staff and I are fully committed in our support of the nation's efforts to recover and rebuild over the months that follow.

Agriculture and the Food Supply

FDA plays an integral role, working with states, in protecting the safety of the food supply – both human and animal. We recognize that these hurricanes have presented unique challenges for farmers, and FDA is committed to working with farmers, as well as with our Federal and state partners, so that the food we serve our families is safe and that consumers have confidence in the products they consume.

FDA has been providing support to farmers and food producers who have been impacted by these storms, and in particular, disseminating information about the proper handling of crops that have been exposed to floodwaters, and when these products can be safely diverted into animal feed uses.

Both human and animal food must meet well-established safety requirements. We have recently updated our public documents on these matters in response to the flooding in Hurricane Harvey, to make sure that our well-established scientific principles are accessible to producers and purchasers. Some of the major concerns for crop safety are heavy metals, chemical, bacterial, and mold contamination. Crops may be submerged in flood water, exposed to contaminants, or susceptible to mold, resulting in crop losses. In many cases, it is challenging to determine what contaminants may be in crops that were submerged by floodwaters. We are working to address these issues.

We have been in close consultation with farmers, consumer representatives, and state officials regarding concerns about how crops may be impacted. The direct discussions we are having with state officials and with farmers are aimed at providing our most up-to-date, science-based information on which crops can enter commerce without creating risks to consumers or animals. We have experts in the affected regions who can help provide direct assistance and we are taking additional steps to support recovery efforts. We also understand that state Departments of Agriculture may have specific requirements regarding any attempt to clean, process, test, use, or sell crops for human or animal food. In many of these efforts, we have worked closely with our counterparts at other Federal agencies.

Our primary mission is the protection and promotion of the public health. We are committed to making sure food is safe for consumers and animals. But, we recognize there are hard questions that must be quickly answered about crops affected by these storms, or else crops that might be safe – because they were not exposed to contaminated floodwaters – could age past their point of use. We recognize the significant impact these storms have had on farming families. We are working hard to provide them with timely guidance. My staff and I are committed to doing our part to help farmers get back to work.

This will be a long recovery. The devastation was significant. But we are in this for the long run.

All of these storms present FDA with hard challenges. We have committed ourselves to provide relief to affected Americans. This has been our highest priority at FDA since these storms struck. I have been personally engaged, on a daily basis, in these efforts. The devastation in Puerto Rico – owing to its unique role as a base for the manufacture of many sophisticated, complex, and vital medical products – presents FDA with especially complex challenges. We are committed to the people of Puerto Rico, their recovery, and their efforts to maintain their jobs and their proud and vital manufacturing history.

Thank you for inviting FDA to testify today. I would be happy to answer any questions you may have.

Mr. GRIFFITH. Thank you. I thank you for your testimony.
And now I recognize Ms. Brandt for a 5-minute opening statement.

TESTIMONY OF KIMBERLY BRANDT

Ms. BRANDT. Thank you. Chairman Griffith, Ranking Member DeGette, and members of the subcommittee, thank you for the opportunity to discuss efforts by the Centers for Medicare and Medicaid Services, or CMS, to respond to the recent hurricanes.

CMS plays an integral role in emergency response during these natural disasters. I have almost 20 years of experience working on Medicare and Medicaid issues. And even with that perspective, I was surprised at the depth and breadth of CMS' involvement in the hurricane response efforts.

This is a role our agency takes very seriously, as evidenced by, even while I am here today, CMS Administrator Verma is in Puerto Rico assessing our on-the-ground efforts and gaining valuable insights from patients, providers, and local officials. Many people think of CMS, firstly, as a payer, reimbursing for the care delivered to our over 100 million Medicare/Medicaid and CHIP beneficiaries, and, secondly, as a regulator, overseeing and enforcing standards for the care delivered by millions of providers and suppliers. While CMS does not directly provide care to our beneficiaries, we do have a direct impact on the care they receive. And the last several weeks have allowed CMS to demonstrate the important role we can play in emergency preparedness and response efforts.

One of CMS' most valuable emergency response tools is our ability to waive or modify certain program requirements, which CMS can do after the President declares a major disaster and the HHS Secretary declares a public health emergency. CMS is using the full breadth of this authority to ensure our beneficiaries have access to the care they need by providing flexibility to Medicare and Medicaid providers so they can deliver high-quality care to those who need it, when they need it, and where they need it. For example, we use waivers to allow Medicare providers to move patients between facilities and administer care in alternative locations and to expedite Medicaid enrollment for out-of-state providers. Already, we have approved nearly 100 waivers in total across the impacted disaster areas.

Last month, I joined Administrator Verma on a visit to Houston, Texas, where we are able to speak to several of those impacted, including beneficiaries and providers who demonstrated how important these flexibilities were to them following an emergency. We want beneficiaries and providers to be able to focus on their immediate needs to provide urgent care without worrying about reimbursement policies, and we heard firsthand during our visit what a difference those flexibilities make.

That is why CMS is taking an active listening approach and meeting and talking with stakeholders in all of the impacted areas on an ongoing basis to make sure we understand their needs and are able to meet them.

One of the Administrator's top priorities has been to provide access to necessary care for one of our most vulnerable beneficiary groups, dialysis patients, during these challenging circumstances.

One of the ways we have done this is using our authority to temporarily designate dialysis facilities licensed in locations impacted by the hurricanes—but that are not yet certified—to serve as a special-purpose renal dialysis facilities so they can provide care for Medicare beneficiaries. In fact, we were able to designate one of these facilities in Florida before the storm hit to ensure that patients were dialyzed in anticipation of the storm.

In Puerto Rico and the U.S. Virgin Islands, CMS has been working closely with ASPR, the Kidney Community Emergency Response Program, and the End Stage Renal Disease Networks to monitor conditions before, during, and after the storms to predict and assess the impact to these extremely fragile patients. Here are two examples of our combined efforts: Under the direction of one of our CMS Commissioned Corps members, we are working with these partners to daily track the operational status of dialysis facilities in Puerto Rico and their status with respect to fuel, water, and other supplies, as well as developing delivery schedules for those supplies necessary for the facilities to treat the nearly 6,000 dialysis patients on the island.

CMS also partnered with several of our Federal and local partners to arrange support for approximately 120 dialysis patients evacuated from the U.S. Virgin Islands to Atlanta when conditions were no longer safe in the Virgin Islands. This included working with staff on the ground in Atlanta from day one to greet and medically assess each patient as they arrived.

Unfortunately, these recent events will not be the last public health emergencies our Nation faces. Making sure providers and suppliers are prepared for future disasters, whether it is a hurricane, wildfire, or disease pandemic, is essential to ensuring patient safety. That is why CMS requires all Medicare and Medicaid facilities to comply with basic health and safety requirements, including emergency preparedness standards, which we updated last fall. The updates include a more comprehensive approach to emergency planning and requiring facilities to more thoroughly address location-specific hazards. In addition, we required facilities to meet additional emergency training standards for staff and implement a communication system to contact patients, physicians, and other necessary persons to ensure continuation of patient care functions.

While much has been done, there's still much to be done, particularly in Puerto Rico, where over 50 percent of the population is covered through a CMS program. Together, we must continue to think creatively about all the ways we can help ensure our beneficiaries have access to needed care, supplies, and prescriptions, even in the midst of emergencies and natural disasters. We appreciate the subcommittee's interest in these efforts and look forward to working with you throughout the recovery process.

[The prepared statement of Ms. Brandt follows:]

STATEMENT OF
KIMBERLY BRANDT
PRINCIPAL DEPUTY ADMINISTRATOR FOR OPERATIONS
CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

EXAMINING HHS'S PUBLIC HEALTH PREPAREDNESS FOR AND RESPONSE TO
THE 2017 HURRICANE SEASON

BEFORE THE
U. S. HOUSE ENERGY AND COMMERCE COMMITTEE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OCTOBER 24, 2017

**U. S. House Energy and Commerce Committee,
Subcommittee on Oversight and Investigations
Hurricane Response
October 24, 2017**

Chairman Griffith, Ranking Member DeGette, and members of the Subcommittee, thank you for the invitation and the opportunity to discuss efforts at the Centers for Medicare & Medicaid Services (CMS) to respond to and prepare for emergencies and natural disasters, including Hurricanes Harvey, Irma, Maria, and Nate. The Department of Health and Human Services (HHS) plays a significant role in emergency recovery and response efforts, and CMS is an important contributor in this work. In the weeks following these devastating storms, CMS has worked tirelessly to anticipate and respond to the needs of the millions of Medicare, Medicaid, and CHIP beneficiaries who have been impacted by these disastrous events. Our job is to make sure that the people served by our programs, in conjunction with the states and territories, continue to receive high quality healthcare even in the face of serious natural disasters.

CMS Emergency Response Efforts

Following a natural disaster, CMS works diligently across the agency to provide immediate relief to those impacted and to ensure those served by CMS programs have access to the life-saving treatments they need. Our approach to disaster preparedness and response has been informed by CMS's experience responding to Hurricane Katrina and the recent significant disasters. Each hurricane presented unique challenges—the flood water in Houston, the wind damage across Florida, and the combination of the two in Puerto Rico. The facts on the ground dictated a unique approach before, during, and after each storm, and our lessons learned helped us tailor our responses accordingly. For example, the devastation of Hurricane Harvey taught us valuable lessons that allowed us to respond even more quickly for Hurricanes Irma, Maria, and Nate. While we worked with states to assess need and grant waivers immediately following Hurricane Harvey, we worked with states and facilities to assess needs and prepare waivers while Hurricane Irma was still underway, and before the onset of Hurricanes Maria and Nate. In the weeks and months following these devastating storms, we continue to be proactive and monitor the needs of the local governments to make sure providers, suppliers, and hospitals and other healthcare facilities can continue to provide care.

Giving Beneficiaries, Providers, and Suppliers Flexibility to Meet Emergency Health Needs

Federal statute allows, at the request of the Governor of an affected State, the President to declare a major disaster or emergency if an event is beyond the combined response capabilities of the State and affected local governments. Federal law also allows the Secretary of Health and Human Services (HHS) to declare that a Public Health Emergency exists in the affected State, and authorize waiver or modification of certain Medicare, Medicaid, CHIP, and EMTALA requirements under section 1135 of the Social Security Act. The HHS Secretary (or Acting Secretary) declared a Public Health Emergency and Section 1135 waiver determination in the areas impacted by Hurricanes Harvey (August 26), Irma (September 8), Maria (September 19), and Nate (October 8) almost immediately upon receiving information regarding the levels of devastation being caused by these storms.

With a public health emergency and a Presidential declaration in effect, there are many things we can do to help. For example, the Section 1135 waiver determination enables CMS to waive or modify certain Medicare, Medicaid, CHIP, Stark Law, and EMTALA requirements, including certain deadlines, quality reporting requirements, conditions of participation, and certification requirements. Providers can now submit waiver requests to the state survey agency or the CMS regional office,¹ and they will be evaluated to ensure that they meet the requirements set out under the law. CMS made all approved waivers and hurricane related information, such as Frequently Asked Questions and Presidential declarations, available on our website.²

In each of these emergency events, CMS is using the full breadth of our waiver authority to maintain access to care for Medicare and Medicaid beneficiaries by supporting the ability of providers, suppliers, hospitals, and other healthcare facilities that participate in those programs to provide timely care to as many people impacted by the storm as possible. For example, using our waiver authority, CMS:

¹ <https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Requesting-an-1135-Waiver-Updated-11-16-2016.pdf>

² <https://www.cms.gov/About-CMS/Agency-Information/Emergency/Hurricanes.html>

- Gave Medicare providers in locations impacted by the hurricanes the flexibility to move patients between facilities, administer care in alternative locations, and approve out-of-network providers as needed to ensure continuity of care.
- Expedited Medicaid enrollment for out-of-state providers. This means providers can be reimbursed for services provided to beneficiaries who have been evacuated from locations impacted by the hurricanes, and allows reimbursement to providers who go into impacted areas to provide relief.
- Lifted the moratoria on non-emergency ambulance suppliers in Texas, to reduce potential access to care concerns.
- Allowed impacted Critical Access Hospitals to exceed their limits on the number of beds (25) and the length of stay (96 hours). This means, for example, a Critical Access Hospital would be reimbursed for services provided to a beneficiary who needed care that was expected to require more than a 96-hour stay.
- Allowed Medicare payments for replacement Part B prescriptions in circumstances where dispensed medication has been lost or otherwise rendered unusable by damage due to the emergency.
- Required Medicare Part D plans to suspend some of their utilization controls, such as prohibiting prescriptions from being refilled too soon, for beneficiaries who evacuated their homes without their prescription medications.
- Established a hotline to assist healthcare providers in Texas, Florida, Louisiana, Puerto Rico, and the U.S. Virgin Islands in receiving temporary Medicare billing privileges, making sure providers will be appropriately reimbursed for their critical services.
- Coordinated with local emergency response and public health officials and organizations to provide beneficiary access to life-saving services by temporarily designating dialysis facilities licensed in locations impacted by the hurricanes, but not yet certified to provide care for Medicare beneficiaries, as Special Purpose Renal Dialysis Facilities so they could serve as Medicare dialysis facilities for a limited period of time.

- Temporarily suspended certain requirements necessary for Medicare beneficiaries who lost or realized damage to their durable medical equipment, prosthetics, orthotics, and supplies as a result of a hurricane. This is helping make sure that beneficiaries can continue to access the needed medical equipment and supplies they rely on each day.
- Expedited Texas's request to allow officials to adjust CHIP enrollment, redetermination policies and cost-sharing requirements for families living in, or evacuated from, areas impacted by Hurricane Harvey. For example, these provisions, retroactive to August 25, 2017, will extend children's eligibility so they can receive healthcare services beyond their usual renewal period.
- Established a Medicare Part C and D special enrollment period, allowing individuals affected by the hurricanes to enroll in, dis-enroll from, or switch, Medicare health or prescription drug plans. It is available at the start of the incident period and runs through the end of the calendar year.

Waivers are a vital tool available for CMS to use in emergency response efforts, but there are also additional steps we can take. For example, CMS made sure that beneficiaries were not discharged to unsafe conditions and continued to receive quality medical care by monitoring discharge appeals and quality of care reviews that arose as a result of the hurricanes. To help clarify billing instructions, we have issued technical direction to the Medicare Administrative Contractors regarding the waivers and have reminded area Medicare Advantage plans of their responsibilities to relax certain requirements during a disaster or emergency.

In response to requests or direction from the relevant state authorities, CMS clarified that issuers participating in the Federal Health Insurance Exchange have the flexibility to extend certain payment deadlines, including deadlines for binder payments to effectuate new policies and grace periods for existing enrollees. CMS also established a Federal Health Insurance Exchange special enrollment period, allowing certain individuals impacted by these hurricanes who experienced a qualifying life event to select a new 2017 Exchange plan or make changes to their existing plan at any time through December 31, 2017. In addition, individuals who reside in, or move from, areas affected by a hurricane in 2017 will be eligible for a special enrollment period that extends the 2018 Annual Open Enrollment Period through December 31, 2017.

Coordinating Relief Efforts with Local, State, and Federal Partners

The massive amount of destruction caused by the hurricanes requires extensive coordination between local, state, and federal public health officials. CMS teams, along with our state/territorial and federal partners, have been working around-the-clock to stay in constant communication with local officials to better understand the changing needs on the ground to help us get Americans the assistance they need to survive. For example, CMS:

- Coordinated with Puerto Rico Department of Health to develop a process for credentialing nurses and technicians from the mainland to provide relief for dialysis facility staff.
- Through the Kidney Community Emergency Response Program and the End Stage Renal Disease Networks, monitors before, during, and after the event to assess the impact to the End Stage Renal Disease Community. The Networks are CMS contractors responsible for working with individual dialysis facilities, the large dialysis organizations, and local officials to arrange for patients to have dialysis prior to a known event such as Hurricane Maria, increasing patients' capacity to wait for evacuation after the storm. Following the recent hurricanes, staff from the Networks, under the direction of CMS Project Officers, have been a critical part of the community effort to make sure patients in affected areas were able to access dialysis services.
- Through the End Stage Renal Disease Network 3, developed and tracked daily the operational status of dialysis facilities in Puerto Rico and their status with respect to fuel, water, and other supplies, and developed delivery schedules for fuel and water supplies.
- Worked with dialysis facilities, End Stage Renal Disease Networks, and the Kidney Community Emergency Response Program to assess the operational status of dialysis facilities, account for patients, and, with federal and state/territorial partners, to assure the delivery of necessary fuel for generators, water for dialysis treatments, and dialysis supplies.

- Through the End Stage Renal Disease Networks, collaborated with HHS partners and several non-government organizations, along with local physicians and providers, to provide transportation, meals, and other support for approximately 120 dialysis patients evacuated from U.S. Virgin Islands to Atlanta. In addition, staff identified hotels near dialysis centers where HHS is paying for these residents to stay until they can return home safely.
- Coordinated across the Agency and with State partners to address questions, provide information, and facilitate payment of services for Medicare and Medicaid beneficiaries who were evacuated across State/territory lines.
- Participated in a series of meetings with top HHS officials to discuss Harvey recovery efforts and the current status of preparation for Hurricane Irma.
- Joined key officials from across HHS, including CMS Administrator Verma, in site visits and/or stakeholder calls to talk with patients and health officials in affected areas, including Texas, Florida, and Puerto Rico to hear firsthand how they have been impacted by the storms and how CMS can help respond.

As the areas impacted by Hurricanes Harvey, Irma, Maria, and Nate continue to rebuild and recover from the devastation caused by these storms, CMS will continue to work hard to provide states, providers, and beneficiaries with the flexibility they need.

CMS Emergency Preparedness Efforts

CMS is committed to ensuring the safety of the millions of Medicare and Medicaid beneficiaries who rely on the U.S. healthcare system every day. This means making sure facilities that provide care are prepared and able to do so, even in emergencies and natural disasters. That is why CMS requires that all facilities seeking participation in Medicare and Medicaid comply with basic health and safety requirements set forth in the Medicare Conditions of Participation (CoPs). For example, these CoPs incorporate requirements for long-term care facilities for infection control, quality of care, nursing services, and many others, including emergency preparedness standards such as requiring Medicare-certified nursing homes to have a generator if they have residents on

electricity-dependent life support systems, and are also required to conduct appropriate installation and maintenance.³

Last fall, CMS updated and improved the emergency preparedness requirements for providers participating in Medicare and Medicaid.⁴ For example, we now require facilities to use an “all-hazards” risk assessment approach in emergency planning to identify and address location-specific hazards and responses.⁵ In addition, we require facilities to develop and maintain an emergency preparedness training and testing program for new and existing staff, including annual refresher training, along with a communications system to contact appropriate staff, patients’ treating physicians, and other necessary persons in a timely manner to ensure continuation of patient care functions. The new standards became effective on November 15, 2016, and surveys to evaluate compliance with the new requirements will begin November 15, 2017. More information, including interpretive guidelines, Frequently Asked Questions, and surveyor training materials can be found on our website.⁶

Moving Forward

The areas affected by Hurricanes Harvey, Irma, Maria, and Nate will continue to encounter significant and unique challenges as they face the task of rebuilding. We must continue to think creatively about all the ways we can help and make a difference for all those depending on us to ensure they have healthcare and access to needed supplies and prescriptions.

This hurricane season has forced us to think outside of the box for creative ways to support and communicate with those serving the communities impacted by the storms, and CMS stands ready to work with our partners across the Federal government and, most importantly, with local communities, healthcare providers, and patients. CMS will continue to build upon our recent experiences from these significant storms to improve our readiness for the next natural disaster. We appreciate the Subcommittee’s interest in these efforts, and look forward to working with you throughout the recovery process.

³ 42 CFR §483.73(e).

⁴ <https://www.gpo.gov/fdsys/pkg/FR-2016-09-16/pdf/2016-21404.pdf>

⁵ 42 CFR §483.73(d)(2), 42 CFR §483.73(e), and 42 CFR §483.73(e)(3)

⁶ <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Emergency-Prep-Rule.html>.

Mr. GRIFFITH. Thank you very much for your testimony.
I now recognize Rear Admiral Redd for 5 minutes for an opening statement.

TESTIMONY OF STEPHEN C. REDD, M.D., RADM

Dr. REDD. Good morning, Vice Chairman Griffith, Ranking Member DeGette, and distinguished members of the subcommittee.

I am Rear Admiral Stephen Redd, Director of the Centers for Disease Control and Prevention's Office of Public Health Preparedness and Response. I appreciate the opportunity to be here today to discuss CDC's efforts and activities in response to the 2017 hurricanes.

To address the impacts of these hurricanes, CDC has provided public health support to the coordinated Federal, State, local, territorial and Tribal responses. The focus of CDC's efforts have been in epidemiology and health surveillance, laboratory support, environmental and occupational health, and health communications.

On August 30, 2017, CDC activated its emergency operation center to coordinate our response to Hurricane Harvey, and subsequently, we've expanded that activation to include Hurricanes Irma and Maria. Since the end of August, CDC has had approximately 500 staff members supporting the response. Additionally, we have deployed over 70 staff to the affected areas to provide on-the-ground support, including 34 to Puerto Rico and 12 to the U.S. Virgin Islands. To address immediate health concerns, CDC deployed Federal medical stations to serve as temporary, non-acute, medical care facilities. Each Federal medical station can accommodate up to 250 patients and includes a cache of medical supplies and equipment. HHS deploys medical teams to staff these facilities, and CDC has deployed six of these to Puerto Rico, four to Texas, and two to Florida.

CDC has used syndromic surveillance to monitor health-related data that may signal disease outbreak. Our National Syndromic Surveillance Program has collaborated with ASPR's disaster medical assistance teams to collect data on patient encounters and works closely with the American Red Cross to monitor data on shelter populations so that health officials can respond quickly when that's called for.

Surveillance during this response has indicated elevations in carbon monoxide poisoning. And this has led to increased messaging to prevent this condition and guidance on the safe operation of generators.

Identifying and controlling public health—diseases of public health importance in Puerto Rico and the U.S. Virgin Islands are a priority. The Puerto Rico Department of Health sustained significant damage during Hurricane Maria, including damage to their laboratories. These laboratories are not able to conduct any public health tests. They're not able to confirm diagnoses of infectious or environmental diseases. CDC is working with the Puerto Rico Department of Health and FEMA to get these laboratories back in operation. And, in the meantime, we have arranged for packaging and shipment of clinical specimens of suspected priority infectious diseases, such as tuberculosis, leptospirosis, rabies, influenza, salmonella, to the U.S. mainland for testing. In fact, the first ship-

ment of diagnostic specimens for leptospirosis recently arrived in Atlanta.

Let me touch briefly on a few other components of our response. We've provided technical assistance to the affected areas to address health issues, such as food safety, water issues, including sewage. We've provided guidance on injury prevention from debris and drowning. We've helped with shelter assessments. We've provided guidance regarding the safety of responders, and we have developed and disseminated key public health messages to individuals in the affected areas.

CDC recognizes that the full recovery from the recent hurricanes will take time, particularly in Puerto Rico and the Virgin Islands, where the damage has been extensive. But we're here to continue to provide that support.

Thank you, again, for the opportunity to appear before you to discuss our response and recovery efforts, and I'd be glad to answer any questions you might have.

[The prepared statement of Dr. Redd follows:]

Centers for Disease Control and Prevention

2017 Hurricane Response

House Energy and Commerce Oversight and Investigations Subcommittee Hearing

October 24, 2017

Testimony

Witness: RADM Stephen C. Redd, MD

Testimony – House Energy and Commerce Committee, Oversight and Investigations Subcommittee

Good morning Chairman, Ranking Member, and other distinguished members of the subcommittee. I am Rear Admiral Stephen C. Redd, Director of the Centers for Disease Control and Prevention's (CDC) Office of Public Health Preparedness and Response. I appreciate the opportunity to be here today to discuss CDC's efforts and activities in response to the 2017 hurricanes.

From late August to early October of this year, the President approved several emergency and major disaster declarations in accordance with the Stafford Act for the hurricane-affected states and territories. This authorized the Department of Homeland Security's Federal Emergency Management Agency (FEMA) to coordinate all disaster relief efforts. Under the National Response Framework (NRF), FEMA is the lead agency and CDC, along with our HHS counterparts here today, is serving in a supporting role to FEMA. As a part of the NRF, HHS leads the Emergency Support Function-8, Public Health and Medical Services, under which CDC operates. CDC's responsibilities include providing public health support to supplement state, tribal, territorial and local resources in response to public health and medical disasters and/or during potential health and medical emergencies.

CDC prepares for emergency events by helping our state, local, tribal and territorial partners strengthen their public health preparedness systems for emergency events. CDC's Public Health Emergency Preparedness Program (PHEP) is our single largest cooperative agreement program that

provides critical funding, guidance, and technical assistance to help partners prepare for public health emergencies. Since August 2002, the PHEP cooperative agreements have assisted public health departments across the nation, targeting the development of emergency-ready public health departments that are flexible and adaptable. Each state and territory impacted by Hurricanes Harvey, Irma, Maria, and Nate are PHEP recipients.

Since 2002, States and Territories funded under PHEP have continued to focus on strengthening critical public health preparedness capabilities. For example, in FY 2017, Texas planned to dedicate approximately 90 percent of their PHEP funding in the critical public health preparedness capabilities of Community Preparedness, Medical Material Management & Distribution and Public Health Laboratory Testing. The State's past experience with flooding disasters has helped Texas ensure the safe evacuation of residents, especially residents in need of special assistance during an evacuation who otherwise would have been left behind. Florida planned to focus approximately 80 percent of their FY 2017 funding to Community Preparedness, Public Health Surveillance & Epi Investigation and Public Health Lab Testing. The US Virgin Islands proposed to use approximately 60 percent of their FY 2017 PHEP funds on Emergency Operations Coordination, Public Health Surveillance & Epidemiology Investigations and Community Preparedness. Puerto Rico planned to dedicate over 60 percent of their PHEP funds to Public Health Laboratory Testing, Information Sharing, and Medical Countermeasure Dispensing.

Immediately following a hurricane, the Federal, state, and territorial response includes coordinating and managing resources to provide immediate relief, in particular restoring physical infrastructure, which includes infrastructure needed to provide healthcare. Once public health and other officials have identified and addressed the immediate public health and healthcare needs, the impacted areas enter the recovery phase when critical capabilities are identified and key activities are

implemented to assist communities with recovering effectively over time. The recovery phase can last from months to years.

CDC continues to work in affected areas from Hurricanes Harvey, Irma, and Maria. Texas was primarily impacted by the flooding caused by Hurricane Harvey and is now in the recovery phase. This is also the case in Florida which was heavily impacted by Hurricane Irma. However, the U.S. Virgin Islands, which sustained severe damage from both Hurricanes Irma and Maria, is just now entering the recovery phase, and Puerto Rico is still in the response phase from the devastation caused by Hurricane Maria.

On August 30, 2017, CDC officially activated its Emergency Operations Center to address the public health impact of Hurricane Harvey and then expanded the activation to include the subsequent Hurricanes, Irma and Maria, as they approached the states and territories. Since August 31st, CDC has approximately 500 staff members who have provided scientific and technical assistance and additional logistics, staffing, communications, analytics, management, and other support functions. Additionally, we have deployed approximately 73 staff to the impacted areas to provide on the ground support. To fully address the impact of the 2017 hurricanes, we are providing a full spectrum of public health technical support to Federal, state, local, territorial, and tribal entities, including on-site support. The focus areas for the effort are epidemiology and health surveillance, environmental and occupational health, and public health communications.

To address immediate health concerns, CDC deploys at the direction of the Department and via the Strategic National Stockpile (SNS), Federal Medical Stations (FMS) to serve as temporary non-acute medical care facilities. Each FMS can accommodate up to 250 people and contains a cache of medical supplies and equipment. HHS deploys medical teams to staff the FMS. As of October 16th, for Hurricane

Maria, CDC/SNS has deployed six 250-bed Federal Medical Stations in Puerto Rico. For Hurricane Harvey, CDC/SNS deployed four to Texas and two to Florida for Hurricane Irma.

CDC applies syndromic surveillance to monitor health-related data that precede diagnosis and signal a probable disease case or outbreak. Syndromic surveillance uses existing data systems as an early warning system of disease outbreaks, water or food contamination or other event, for example, spikes in school absenteeism or emergency department visits. Our National Syndromic Surveillance Program collaborates with the Assistant Secretary for Preparedness and Response's Disaster Medical Assistance Teams (DMAT) to collect all data on DMAT patient encounters. The total number of encounters received for Texas was approximately 5,400 and for Florida, approximately 1,700. Most encounters for Texas and Florida were related to bites, stings, injuries, musculoskeletal pain, various respiratory symptoms, treatment of existing chronic conditions, and medication refills. From Puerto Rico and the US Virgin Islands, CDC has received data from approximately 1,300 total encounters. The common chief complaints have been related to musculoskeletal pain, injuries due to cuts/lacerations, and normal health maintenance for existing chronic diseases. CDC also works closely with the American Red Cross to monitor data on shelter population, so that health officials can quickly detect if health-related issues arise.

CDC is also providing technical assistance to affected states and territories to address various other health issues such as food safety; water issues including sewage and wastewater; injury prevention from debris and drowning; disease or insect vector control; hazardous waste; shelter assessments; and indoor air quality issues such as carbon monoxide and mold. CDC's Geographic Information Systems (GIS) mapping team is working with the Florida Department of Health to identify the total number of private inundated (flooded) water wells. We are also working with FEMA and the Department of Defense to make recommendations to the Puerto Rico Department of Health (PRDH)

for vector control measures post Hurricane Maria. For example, CDC is supporting local vector control in Puerto Rico by providing technical assistance to the Puerto Rico Vector Control Unit (VCU). Through this effort, CDC is advising the VCU on messaging strategies to encourage community participation in the clean-up of trash that may serve as potential mosquito breeding sites. CDC has also recommended safe water storage with lids or screens to prevent egg-laying by mosquitoes and the continued use of repellent. The Puerto Rico VCU will incorporate this guidance into their messaging campaign and consider the dissemination of repellent to the public. We are also working with Puerto Rico and US Virgin Islands on disinfection of water cisterns.

Identifying and controlling diseases of public health importance in Puerto Rico and the U.S. Virgin Islands is a priority. Of concern, the PRDH sustained significant damage during Hurricane Maria, including to their laboratories. To date, the labs are not able to conduct any public health testing including the ability to confirm diagnoses of infectious and environmental diseases. CDC is working with PRDH and FEMA to get the Puerto Rico public health labs back in operation. In the meantime, CDC is assisting with arranging for packaging and shipping of clinical specimens for suspected priority infectious diseases to the continental U.S. for testing and reporting.

CDC has provided guidance and technical assistance regarding the safety of responders, including respiratory protection and immunization recommendations. For instance, in Puerto Rico, responders were informed of safety hazards associated with exposure to carbon monoxide from power generators, use of protective clothing and boots to prevent cuts and exposure to contaminated water, and the importance of personal hygiene and handwashing. We have also provided technical assistance to state and territorial partners and responder organizations who planned to deploy to Puerto Rico or U.S. Virgin Islands on a variety of topics including proper occupational health and safety precautions for handling human remains, mold remediation, and preventing heat stress.

Another critical component to a successful recovery is the ability to quickly disseminate potential lifesaving public health messages, tools and resources to a wide and diverse audience. CDC's Health Communications Task Force has the responsibility of developing and disseminating key messaging and resources to individuals in the impacted areas. In coordination with federal partners, CDC is disseminating social media messages and public service announcements over operating radio stations and flyers to all residents and mainstream media in English, Spanish, and other languages as requested. CDC and our HHS colleagues are amplifying each other's messages.

CDC developed a suite of safety messages covering several critical topics, including generator safety and carbon monoxide poisoning. CDC is in the process of providing safety fact sheets and flyers to Puerto Rico and the US Virgin Islands for a communications campaign. These messages were also distributed electronically through partners, friends, family, and social media. The Health Communications Task Force also focuses on reaching key clinician audiences with Health Alert Notices and clinician outreach newsletters, and has been successful in reaching approximately one million people in a short period of time. For example, given that many healthcare providers are not familiar with signs and symptoms of carbon monoxide poisoning, CDC provided clinical information about how to diagnose carbon monoxide poisonings.

CDC continues to respond to requests from federal, state, tribal, territorial, and local partners on critical public health recovery efforts. For example, the Texas Department of State Health Services requested CDC's assistance for an investigation to explore possible invasive mold infections following widespread flooding and indoor mold growth from Hurricane Harvey. CDC will assist the investigation by: (1) identifying cases of invasive mold infections at Houston area medical centers to help inform the response; (2) characterizing mold exposures of immunocompromised patients in flood damaged areas

to improve public health and clinical messaging; and (3) assessing the extent of mold in households of immunocompromised patients, to the extent possible. CDC is in communication with public health officials in each area to determine short and long-term gaps and requirements to support their recovery activities.

CDC recognizes that the full recovery from the recent hurricanes will take some time, particularly for Puerto Rico and the Virgin Islands where the damage is extensive, but we are here to continue providing support. We will continue to work with FEMA, and all of our federal partners, over the next several years during this long period of recovery. Thank you again for the opportunity to appear before you today to discuss CDC's hurricane response and recovery efforts. I would be glad to answer any questions you may have.

Mr. GRIFFITH. Thank you all very much for your testimony.

And I will now begin questioning by recognizing the chairman of the full committee, Chairman Walden, for 5 minutes for questions.

Mr. WALDEN. Thank you, Vice Chairman.

And I thank all of you for your testimony and the work that the people that you represent are doing in these terrible tragedies.

And we all know there's more to be done, and it's hard, in the aftermath, to get it right. And we sure appreciate what you're doing.

On behalf of the at-large Resident Commissioner from Puerto Rico, Jennifer, thank you for joining us today. I know you're not able to ask questions as part of our committee rules, but I can on your behalf. So I appreciate your submitting some of these because I think they're really important to get on the record.

So, Dr. Kadlec, I'm going to start with you. Puerto Rico remains in the response mode of saving lives and stabilizing healthcare services. What major milestones must be completed to progress from the response phase to the recovery phase? If you can just be fairly brief on that because I've got a couple other—

Dr. KADLEC. Yes, sir, I think it has been highlighted by members of your committee. The power situation on the island does represent a significant limitation. Right now, we have about 60 percent of the 67 hospitals that are on the power grid and have reliable power. But there are 36 percent, total of 24, that still do not. And that's an important benchmark in terms of our ability. The other—

Mr. WALDEN. What do you think the timeline is to get them the power they need?

Dr. KADLEC. Sir, I really wouldn't be in a position to answer that. I think the U.S. Army Corps of Engineers is trying to move as aggressively as possible to do that. They have prioritized hospitals, health clinics, and dialysis centers on the top of the list to, basically, re-electrify with the grid. So I think the intent is to get them up as quickly as physically and humanly possible.

The other part of the sustainment is also knowing about the operational status of those hospitals, because some of them have physical damage, to ensure that they can basically resume full functionality. It is, again, working closely with FEMA and with the Army Corps of Engineers. We performed assessments of those hospitals to identify which ones need physical repair.

And then there are also issues that relate to supply-chain restoration, things like oxygen, which I think is a matter of topical interest here.

Mr. WALDEN. All right. Thank you.

Rear Admiral, thank you for being here and, again, for the work you're doing.

How is the CDC Dengue Branch in Puerto Rico being utilized during this recovery effort? And then I have one more for you.

Dr. REDD. Yes. The Dengue Branch was affected just like every other location in Puerto Rico. As of October 10th, the laboratory is back in operation. It's functioning at a low level under generator power right now. So I think it's more in the affected than in the response zone of the efforts at this point.

Mr. WALDEN. When do you think it might be up to full operation?

Dr. REDD. I think some of the issues that Dr. Kadlec raised would be germane to the full activation and operation of the Dengue Branch lab as well.

Mr. WALDEN. All right. Particularly concerning is the damage to Puerto Rico Department of Health public health labs. To date, the labs are not able to conduct any public health testing, including the ability to confirm diagnoses of infectious and environmental diseases. What will it take to get them up and running? And, in their absence, what is happening to do this kind of lab work?

Dr. REDD. Yes, sir. So restoring power is the first step. There is work with the Army Corps to identify the generator capacity needed to bring the laboratories back to power. There will be a second level of effort to determine what equipment can be salvaged and what equipment can't be salvaged. So we don't know the results of that assessment until the power is back. So it is going to be some time.

Mr. WALDEN. You don't know a timeline on power?

Dr. REDD. I think, for generators, we're talking weeks at the most.

Mr. WALDEN. That they'll be running on generators or before they get them—

Dr. REDD. Generators. Yes. And maybe less than that. So I can't say about the back on the grid. But there should be power to the labs within a relatively short period of time.

In the meantime, we are working with the Department of Health in Puerto Rico to ship specimens to Atlanta for testing. And that's where the first shipment of leptospirosis cases has been shipped.

Mr. WALDEN. And are you comfortable with that kind of arrangement to do the lab testing? Is that quick enough? Is it adequate enough?

Dr. REDD. It's certainly not optimal. I think it's the best that we can do at this point in time. I think that what we really need is to be where those tests can be done in Puerto Rico and having the lab back up to full speed.

Mr. WALDEN. But if it's going to be weeks before that can happen, is there a temporary sort of lab that could be flown in there?

Dr. REDD. We've had quite a bit of discussion on that. I think that, in general, the feeling is that getting specimens to Atlanta for testing is going to be, since it's not going to be a very, very prolonged period of time, that this is a temporizing measure. It's not optimal, but it's the best that we can do under the circumstances.

Mr. WALDEN. It works? You feel it works?

Dr. REDD. Yes, sir.

Mr. WALDEN. All right. My time has expired.

Mr. Vice Chair, thank you for this hearing.

Again, thank you for your testimony.

Mr. GRIFFITH. Thank you, very much, Mr. Chairman.

I now recognize the ranking member of the subcommittee, Ms. DeGette of Colorado, for 5 minutes.

Ms. DEGETTE. Thank you, so much, Mr. Vice Chairman.

I just want to remind the panel: You all know very well it's now been over a month since Maria hit both the U.S. Virgin Islands and Puerto Rico. And, even now, there was just an article in The New York Times today which is entitled "Like Going Back in Time":

Puerto Ricans Put Survival Skills to Use.” And it’s a very powerful article that talks about how people still don’t have power. People are still eating canned foods. Elderly people are afraid to go outside because of gangs. And what it talks about is the way everybody is helping themselves is the neighbors are bonding together. And there’s a fellow, the director of a local nonprofit, said most of the aid—the neighborhood, which appears to be in San Juan, not in the remote mountains, had received was from private citizens and celebrities. Quote: “The government hasn’t arrived here.”

As I mentioned in my opening remarks, having been on this subcommittee when we investigated Katrina, it’s wonderful to reflect back on what we’ve done. But it’s more important to think about, A, how quickly we can do more. And, B, what we can do to improve our efforts in the future. And I just want to remind,, everybody, listening to a lot of this testimony, you’d think that everything was just swell. And I hope none of you intended to intimate that. And I know we’re going to have a lot of questions about that.

But, Commissioner Gottlieb, I kind of wanted to hone in with you about your testimony because, as you said, there are a lot of drugs and devices that are produced in Puerto Rico. There’s 13 of them that are—drugs—that are only produced in Puerto Rico. Is that correct?

Dr. GOTTLIEB. There’s more than 13. There’s probably somewhere in the nature of 40 sole-source drugs but only 14 that we think are critical insofar as they are medically important and we couldn’t find a therapeutic alternative. So we’re focused on about 14 products.

Ms. DEGETTE. About 14. And most of the plants where those drugs are being manufactured are relying on generators. Is that right?

Dr. GOTTLIEB. That’s right. I believe almost all, if not all, of the plants are on generator power.

Ms. DEGETTE. On generator. Now, I think you testified that this is not a long-term solution. Is that right?

Dr. GOTTLIEB. That’s right, Congresswoman. There are some facilities that have substantial generators and probably could operate for a sustained period of time.

Ms. DEGETTE. What do you mean by “a sustained period of time”?

Dr. GOTTLIEB. Some of them are very hardened. So I don’t want to say that there aren’t facilities there that couldn’t operate, perhaps indefinitely, on generators. But that’s the exception. Most of those facilities will not be able to operate for a sustained period of time.

And if we get into the first quarter of next year and these facilities aren’t back on the grid, we’re going to have some concerns. And so we’re trying to think now how we can work with our partners at HHS and the Army Corps of Engineers to prioritize a handful of the facilities that are critical.

Ms. DEGETTE. And the reason you’re going to have concerns is sort of twofold. Number one, the generators don’t produce the kind of energy that they need to produce these products, right?

Dr. GOTTLIEB. That’s right.

Ms. DEGETTE. And, number two, even if you can use it, it's going to be a reduced supply.

Dr. GOTTLIEB. That's right. I know of one firm that's producing at 100 percent output right now, but they've dialed back certain portions of the facility. In most cases, these facilities can't operate at 100 percent production on their generators——

Ms. DEGETTE. Right.

Dr. GOTTLIEB [continuing]. And they certainly can't operate 100 percent of their facilities on the generators.

And the other point is that the generators themselves are going to start to break down. These weren't meant to operate——

Ms. DEGETTE. That's right. They are not meant to operate.

Dr. GOTTLIEB. That's right.

Ms. DEGETTE [continuing]. These plants.

Now, let me just ask you quickly. On Friday, you released a statement that said the FDA is monitoring about 50 types of medical devices manufactured in Puerto Rico that are critically important to patient care, including everything from insulin pumps to pacemakers. Is this the same kind of problem that we're seeing with the drug manufacturers?

Dr. GOTTLIEB. Same challenge. So these are 50 devices that we're monitoring, manufactured by 10 different firms. And it's a similar challenge. In some cases, the device manufacturing is more energy dependent and the facilities themselves need a more reliable flow from the grid. So, even as these facilities get put back on the grid, if the grid itself is unreliable, they might prefer to stay on their generator power for a longer period of time. And many of them also are going to want dual feeds off the grid. So it could be a while before some of these facilities could get the kind of connection to the grid that they need.

Ms. DEGETTE. Mr. Chairman, let me just say, if anybody has any concern this is impacting all American families, my daughter, who is a Type 1 diabetic, just got a letter from Medtronic last week saying her new insulin pump was not going to arrive because of the problems we're having in Puerto Rico. So this is impacting every American, not just the Americans in the U.S. Virgin Islands and Puerto Rico. Thank you.

And I'd like to ask unanimous consent to put that New York Times article into the record.

Mr. GRIFFITH. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. GRIFFITH. I now recognize the vice chairman of the full committee, Mr. Barton of Texas, for 5 minutes for questions.

Mr. BARTON. Thank you, Mr. Chairman.

I want to extend my personal welcome to our newest member, Mr. Duncan. He's an outstanding member of the Republican baseball team that I manage, like Mr. Costello. And I'm sure he'll do just as good, if not a better, job on the committee. So we're glad to have you, Jeff, and look forward to a bright future with you.

Mr. Chairman, I appreciate this hearing. I know the primary focus is Puerto Rico and the Virgin Islands, but we had a hurricane in Texas too. We're a little bit more developed as a state, so our ability to endure it was possibly somewhat stronger. Having said that, there's still issues in Texas.

My first question, I think, will be to Mr. Redd. In a normal year, there's a lot of mosquitoes in the Houston area. But, given the amount of water that was sustained and we still haven't had a freeze, so we still have that issue, what cooperation, if any, have you and your agency had on helping to minimize that problem in the Houston area specifically but the Gulf Coast generally?

Dr. REDD. Yes. We operate as part of the combined Federal response here. We've worked with DoD through the FEMA managed response system to provide advice on what kind of mosquito control efforts would be most appropriate. And we've worked with that system. We don't do spraying ourselves, but we provide that expertise on mosquitoes.

Mr. BARTON. As far as you know, there's not an issue of not enough insecticide?

Dr. REDD. That's correct. This is a problem that happens after virtually every hurricane which has a rain element to it. The types of mosquitoes that follow a hurricane typically aren't the ones that transmit disease. And there's pretty much a standard approach to that with CDC providing technical advice, DoD providing the equipment and actually doing the spraying in consultation with the local mosquito control districts.

Mr. BARTON. Similar question. I guess this would be to Dr. Kadlec.

Is that correct?

Dr. KADLEC. Yes, sir.

Mr. BARTON. Lots of Medicare patients in the Texas Gulf Coast area, and many of them have had to go to hospitals for treatment. Under current regulations, does CMS have the authority to reimburse these hospitals for the emergency treatment of Medicare patients?

Dr. KADLEC. Sir, since we have a representative from CMS, I'll ask Ms. Brandt to maybe respond to that.

Mr. BARTON. Well, that's my fault. I should have directed it to her to start with.

Ms. BRANDT. No problem, sir. Thank you.

We are currently working with state officials to work with them on the uncompensated care issues and to develop a plan so that we can make sure to appropriately reimburse those providers.

Mr. BARTON. Is there anything the State of Texas needs to supply CMS to get that put together fairly quickly?

Ms. BRANDT. Currently we are working with the State officials to do what's called a multistate 1115 waiver to allow them to request Federal matching dollars for an uncompensated care pool, and that would be for those people who have been displaced or who needed to receive care within the disaster area. So we are working with the state and hope to complete that in the foreseeable future.

Mr. BARTON. Well, I'm the co-chairman of the Texas Congressional Delegation Harvey Task Force. My Democrat co-chairman is Henry Cuellar. If there's anything the delegation needs to do to assist in that, if you'd let his office or my office know, we'll make sure that you get whatever information that you want.

Ms. BRANDT. We will certainly do so, and we will keep you apprised of that, sir.

Mr. BARTON. Thank you.

And with that, Mr. Chairman, I yield back.

Mr. GRIFFITH. The gentleman yields back. Appreciate that.

I now recognize the chairman of the full committee, Mr. Pallone of New Jersey, for 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman.

At a recent press event with the Governor of Puerto Rico, President Trump said that he would give his administration a 10 on its response efforts in Puerto Rico. But I have to be honest with you, from what I hear from my mayors and council people and people that are coming into my district from Puerto Rico, I would give at best a 2 on a scale of 1 to 10.

And my concern is, as I expressed a little bit in my opening statement, that this isn't only an issue of what's happening on the island, but also the people that are coming to the United States that have needs. And I don't think they would be coming here if they were able to stay in Puerto Rico.

Just as an example, I'm looking at the Home News, which is my daily in New Brunswick, which is one of my towns in my district, and it says that when the Puerto Rican Governor visited with President Donald Trump on Thursday to ask for aid, he said that without immediate help from the United States to rebuild the island there would be a mass exodus to the mainland of the United States.

And then we have a professor at Rutgers, which is in my district, who said that the number of Puerto Ricans who will move to the Garden State due to the storm will likely spike once people determine they can't stay on the island longer if power and access to running water, food, and Medicare do not improve.

Now, I obviously would like people to come here if they can't get basic necessities on the island. But, I mean, this is—you know, the fact that the President would call this a 10 is absurd, in my opinion.

So let me start with Dr. Kadlec. Recent reports still indicate that nearly 80 percent of the Americans on the island are without electricity. One mayor reported that his city's ambulances had responded to at least four calls where a patient who had lost power for oxygen tanks or ventilators had died. Other reports have stated that hospitals have had to take in patients from medical centers where generators have failed.

I'll tell you, when we had Sandy, I think our power was out for 2 weeks and it was impossible. I can't imagine going for months without power.

So, Dr. Kadlec, a lack of reliable electricity has created serious risks to the health of American citizens in Puerto Rico. Would you agree with that?

Dr. KADLEC. Sir, it's decremented the whole society there. So the answer is, yes, it is a risk to people.

Mr. PALLONE. All right. Well, I appreciate your honest response.

Last Friday, CNN reported that a million Americans on the island or about 35 percent of all residents still lack access to running water. And I understand that without adequate drinking water or safe running water to provide basic hygiene, affected populations run the risk of serious gastrointestinal and related diseases. Again,

in Sandy, I think I only went a couple days without a shower and I couldn't deal with it.

So let me ask, I guess, Dr. Redd, would you agree that if nearly a million Americans lack access to reliable clean water that this poses a major health concern?

Dr. REDD. Yes, sir.

Mr. PALLONE. All right. Thank you.

This morning an article in The New York Times described the situation in Puerto Rico like going back in time. And WIRED Magazine previously reported that the breakdown in electricity and telecommunications systems had pushed Puerto Rico "back a century or so."

Just yesterday, the FCC reported that nearly 70 percent of the island's cellphone towers are still out of service. Again, lack of communication, lack of cell towers, you can't even address emergencies if you can't communicate.

So let me go back to Dr. Kadlec. Would you agree that a functioning communications system is also an essential component to reaching and communicating with Puerto Ricans to ensure that healthcare needs are met?

Dr. KADLEC. Sir, it is. And we've done a lot to basically ensure that we have positive communications with those hospitals on the island, either by radio, cell communication, or landline.

So we've really worked hard to maintain—we actually deployed National Guardsmen with satellite phones initially when there was no cell service on the island to ensure that we could keep positive contact.

And to your point about the generators, sir, I think that's a fair one. But, quite frankly, sir, we've created a whole system to basically address that.

And, in fact, when I was there the first week after the storm, Humacao, one of the hospitals where one of our DMAT teams was located, co-located, lost generator power. And they had several patients in the intensive care unit, actually a couple having surgery at the time, and we were able to transfer those patients safely without loss of life not only to our shelters where our DMAT teams were, but transport them through ambulances, Medevac helicopters.

Mr. PALLONE. Well, I appreciate that.

Dr. KADLEC. The point is, so that we've gone to extraordinary steps to basically help—

Mr. PALLONE. All right. Well, I appreciate it.

Let me just issue one thing as my time runs out. The President said it's a 10. I gave it a 2. Would you give me a number between 1 and 10?

Dr. KADLEC. I'm not in the business to give you marks, but I can tell you we're working 110 percent even today to help those people, help our fellow Americans on that island.

Mr. PALLONE. I appreciate that.

Thank you, Mr. Chairman.

Mr. GRIFFITH. Thank you so much.

I now recognize the gentlelady of Indiana, Mrs. Brooks, for 5 minutes for questions.

Mrs. BROOKS. Thank you, Mr. Chairman.

And thank you to all of our panel members for being here.

Dr. Kadlec, I want to talk a little bit more about the National Disaster Medical System that you've described. And I know you've only been on the job for a few months now. In fact, how many months have you been on the job?

Dr. KADLEC. Sixty days.

Mrs. BROOKS. Sixty days. Tough first 60 days.

Dr. KADLEC. It has been a baptism.

Mrs. BROOKS. And obviously you were very familiar with the organization prior to becoming in charge of ASPR. Are there reforms to the National Disaster Medical System that you're already considering, or are there challenges you've already faced, whether it's on the deployment, whether it is on the number of resources you have or the authorities you have? And if so, what are they?

Dr. KADLEC. Ma'am, all the above. I think one of the things that this event demonstrated, because of the extraordinary nature, and to Representative DeGette's point, to go down there and actually see the devastation is pretty extraordinary. I've made five combat tours in Iraq, and I never saw anything like what I saw in Puerto Rico, number one.

Number two is, that would kind of simulate what we'd probably expect if we had a nuclear detonation without the fire or the radiation. So the physical destruction to that island, as I said, affected everyone, and the psychological and physiological effects are pretty extraordinary.

To that point, we were stretched in terms of our DMAT capabilities or NDMS capabilities to deploy. I give a lot of credit to those DMAT physicians, nurses, paramedics, pharmacists from your states who basically deployed down there on numerous occasions. We had people from Colorado who were at Harvey, Irma, and now Maria.

And so the answer is, is that we probably need to do some creative thinking how to do that. We worked very well with the VA in Puerto Rico. We need to probably work better with DoD on that.

But I think there are a lot of things we need to do to remove dependencies that require us to basically do "Mother, May I"s for transportation. We probably need a larger supply capability. And we need to move things faster and better.

That said, we deployed before landfall, we had 150 people from our DMAT teams in San Juan riding out that storm. So we have extraordinary people doing extraordinary things. They're from your jurisdictions. They're American heroes. And we probably don't give them enough credit, and we certainly don't give them enough resources.

Mrs. BROOKS. And, Dr. Kadlec, with respect to the authorities of ASPR, has it been clear as to who is actually in charge of the response efforts, or do there need to be additional operational capabilities provided to ASPR?

Dr. KADLEC. Ma'am, I think that's something that we're going to do an after-action and look at that. I'd like to say we were able to do pretty well. I think we can do better. But I'd like to hold an answer on that to work with your staff to identify those things. Again, to remove those dependencies, the "Mother, May I"s for am-

balances, for air transportation, for a variety of things, are things that we need to resolve.

Mrs. BROOKS. Thank you.

Ms. Brandt—and, again, I have some questions also provided by Representative Gonzalez—apparently, prior to the hurricane, retention of medical personnel has been a challenge to Puerto Rico. And so prior to Hurricane Maria, according to my colleague, almost a physician a day would leave the island, would not be practicing there, and it affected a number of specialists left in the territory. How is that impacting the short-term and long-term recovery efforts?

And I actually received communication from a constituent of mine whose cousin was a specialist overseas at the time that it hit, and she had difficulties getting back on to the island to help her people.

And so what is CMS doing relative to the physician retention issue?

Ms. BRANDT. Thank you for the question, and that is something that CMS is very concerned about and very aware of.

In terms of the retention issue, we've been working with the Department of Health on the island and seeing what flexibilities we can do administratively to be able to lift any requirements that would make it easier for people to stay on the island or to work with them, to see what other types of programs that we have that would provide incentives for physicians and other medical personnel on the island. But ultimately that is a decision by the government of the island.

In terms of allowing people to come in to assist with the efforts on the island, especially in wake of what has happened, we have waived many different regulations and other authorities that we have that would have limited out-of-state—or out-of-territory in this particular instance—providers to be able to come in and provide care, and have been working with the Department of Health on the island to see what else we can do to ensure that they have as much access to as many personnel as we can get them.

Mrs. BROOKS. Thank you for that flexibility.

My time is up. I yield back.

Mr. GRIFFITH. I thank the gentlelady.

I now recognize the gentlelady of Florida, Ms. Castor, 5 minutes for questions.

Ms. CASTOR. Thank you, Mr. Chairman.

Over a month later, folks in Florida and all across the country are still reeling from the avoidable deaths in the nursing facilities in Florida. There are now criminal cases. There are civil cases. We're trying to figure out why in the heck Florida's governor has deleted voicemails that came directly from the center to his cellphone.

But there's an important backstory here. In 2005, after Hurricane Katrina and the 215 deaths in nursing homes there, CMS and everyone determined, well, many skilled nursing centers are not prepared. So you went into rural development then to try to ensure that there is going to be an alternative power source available. I understand that it will be November when a CMS rule relating to

alternative power sources for skilled nursing centers will come into being, will become effective.

Why has it taken so long? And are you confident that it will do what we need to do?

And I want to recognize my colleague, Congresswoman Wasserman Schultz from south Florida, and thank Congresswoman Wilson and the Florida delegation that has been pressing this issue as well.

Ms. BRANDT. Well, first of all, let me just state that from CMS's perspective, we share everyone's concern about the tragedy that happened at Hollywood Hills. That's an event that should not have occurred. And from a CMS perspective, our first and ultimate priority is ensuring that we have patient safety and patient protection at every one of the facilities that accepts Medicare and Medicaid beneficiaries.

With respect to the rule itself, to clarify, the rule went into effect last year. We will begin serving against it in this November. So the rule actually went into effect last year, it's just that the actual surveys against it will go into effect starting next month.

However, it is something that we think does go a long way toward addressing a lot of the concerns that have been raised by Hollywood Hills. But in light of the event there, we want to continue to look at it to see if we could do more.

But some of the things it does that were pointed out as part of the problem at Hollywood Hills are ensuring that there is an emergency preparedness plan at every facility, ensuring that every facility has adequate backup supplies, such as generators and others, to be able to provide that there's a temperature between 71 to 81 degrees within the facility and that it doesn't go beyond that.

We also are working to make sure that the appropriate staff are trained so they know what to do in the case of an emergency. Based on the reports that I've read of the incident at Hollywood Hills, several of the failings that led to the unfortunate set of circumstances were that the personnel did not respond to the emergency preparedness plan. The personnel were not adequately trained on the plan, and they weren't able to take steps accordingly. And those are things that we are going to be working with to ensure that, as I said, we survey people going forward, starting in November, that that's happening.

Ms. CASTOR. Thank you. And I encourage you to do that on an expeditious basis because that timeframe is not acceptable.

And, Ms. Brandt, health services provided under Medicaid play a critical role in how quickly families are able to recover from natural disasters. Following Katrina, the Bush administration took a number of actions to ease barriers to health insurance coverage through Medicaid. For example, CMS allowed for a temporary expansion of Medicaid eligibility in affected areas, a moratorium on eligibility redetermination, self-attestation of all Medicaid eligibility factors, and various waivers. And Congress in the Deficit Reduction Act acted to ensure that states were fully reimbursed at 100 percent FMAP.

Does CMS intend to take similar actions in response to Harvey, Irma, and Maria? What exactly, and what, if any, difference will

there be between Puerto Rico and the U.S. Virgin Islands and the states and the mainland?

Ms. BRANDT. So multiple parts to the question.

So with respect to the self-attestation in the eligibility requirements, we have already put in place all of those same flexibilities that were in place for Katrina to allow it, so that people have the flexibilities to self-attest, if they don't have their appropriate documentation, if it was lost in the floods or the winds or any of the other natural disasters. So that is already taking place.

With respect to the uncompensated care pools that you mentioned, that is something that we're working with the Office of Management and Budget to work with Congress on because that is something that only Congress can address from a funding perspective.

And then, with respect to how the states are treated differently than the territories with respect to that, we've basically been holding them all to having the same amount of waivers and the same amount of flexibilities across the board. But one of the things that we are watching is, as has been mentioned, the number of people leaving Puerto Rico and going to the states and making sure that we're working with the states that they're going to, to make sure those states are compensated for the care that they're providing to those evacuees.

Ms. CASTOR. Good. I'll look forward to working with you more on it.

And thank you to the panel.

Mr. GRIFFITH. Thank you very much.

I now recognize the gentleman from Michigan, Mr. Walberg, 5 minutes.

Mr. WALBERG. Thank you, Mr. Chairman.

Thanks to the panel for being here.

I have a few questions as well that Congressman Jennifer González-Colón has asked to address, and they're important, because I think they address some concerns now, but even for future consideration.

The first, would it be beneficial to postpone the Medicare Advantage enrollment period to January of 2018—I ask this of Ms. Brandt—given that 80 percent of the population is without electricity and telecommunications remains largely down throughout the island? What would be your answer to that?

Ms. BRANDT. We have been working to establish a special enrollment period for the citizens of Puerto Rico so that they have flexibility because we recognize that many of them may have trouble meeting the current enrollment period.

Mr. WALBERG. OK. So that is viable with that?

Ms. BRANDT. Yes.

Mr. WALBERG. OK. How are you ensuring that Puerto Rico has the medicine it needs?

Ms. BRANDT. On that one, I would defer to Dr. Kadlec because that's more of a supply chain issue. We simply pay for the prescriptions.

Mr. WALBERG. OK.

Mr. Kadlec.

Dr. KADLEC. So there have been several approaches to basically address medicines on the island. Probably the most important thing we did with the principal medical supplier on the island was provide them fuel to maintain their generator so they could keep refrigerated products and basically maintain their supply chain as well as making sure their trucks had gas to deliver it.

We've also been monitoring the availability or the functionality of pharmacies. There are over 700 pharmacies on the island; 92 percent, 93 percent of them are open at the present time.

We have worked with mainland distributors of temperature-sensitive items to ensure that they can basically push in there. Insulin is a very big one that we've worked with people as well as with the major transporters of materials in to make sure that those issues are—materials are prioritized.

I'd also turn to Dr. Gottlieb because his agency has been very influential as well as working with mainland suppliers to bring in products. But we've been working at a variety of different ways.

Our DMAT teams have caches that they take and provide pharmaceutical resupply to not only hospitals, to patients they see anywhere. We've done tailgate medicine where we've actually gone into areas that are rural, remote, and have been cut off. Done so by helicopter and altering vehicles to ensure that we can deliver medicines to people who need them.

So we've gone through a variety of different lengths, some very straightforward and some pretty exotic to do so, but we've tried to meet whatever need is out there.

Mr. WALBERG. OK.

Commissioner Gottlieb, could you respond to that as well, especially in context with the power problems and how we're keeping up with the pharmaceuticals?

Dr. GOTTLIEB. The point that I'd add to the comments is just that there's a number of facilities that manufacture largely and predominantly for the island of Puerto Rico on Puerto Rico and we've prioritized those facilities.

So in terms of how we've thought about our mission, we have prioritized manufacturers who supply critical products to the people of Puerto Rico. So there are some local manufacturers that, for example, provide sterilization services to the hospitals that fall within FDA's regulatory scope. And so early on we worked to prioritize getting those back online.

Mr. WALBERG. Mr. Gottlieb, one more question. It's been reported that medical oxygen production and access continues to be a challenge in Puerto Rico. Could you please update the committee both on the actions the FDA is taking to ensure that all patients and facilities that require oxygen are able to receive it as well, as the agency's actions to guard against a potential shortage of medical oxygen?

Dr. GOTTLIEB. Yes, we've worked with our partners at HHS. I'm going to defer to them on this because they've played a more active role directly with these facilities.

Dr. KADLEC. Sir, there are two principal suppliers of oxygen on the island. Both of them are back operational on the grid right now. There was a smaller supplier and then a very large supplier

of oxygen, and they both suffered loss of electricity in the immediate aftermath of the storm.

Again, barging in oxygen cylinders, it's not something you can fly in necessarily. But oxygen is not the only gas that's needed. CO₂, nitrogen, argon, are all medical gases that are needed by manufacturers as well as the clinics out there.

So we basically have been trying to move what we could. The USS Comfort, which is floating around the island on the western side, can produce oxygen. And so we were actually filling cylinders of oxygen using the Comfort's capabilities to basically provide that, as well as bring in liquid oxygen generators so that we could actually provide temporary filling.

So right now I think we're on the right side of the oxygen problem. Both facilities are operational. And I think the supply should be sufficient as we go over time as the capacity and particularly the larger manufacturer comes full steam.

Dr. GOTTLIEB. Just to build on that, I'll tell you there's a number of medical product manufacturers who use oxygen and nitrogen in their manufacturing processes. They've been able to secure the supply they need. In a few instances, historically, we had to prioritize getting some of those supplies onto the island or from the island.

But in most cases they're sourcing that outside the island. That seems to be stable right now. We've moved past what I think is the critical phase of trying to work through this. Most of the facilities that need access to medical gases for their manufacturing processes are getting them now.

Mr. WALBERG. Thank you. I yield back.

Mr. GRIFFITH. I thank the gentleman.

I now recognize the gentleman from California, Dr. Ruiz, for 5 minutes.

Mr. RUIZ. Thank you, Mr. Chairman, for holding this hearing.

By way of background, I'm a board certified emergency physician. I was trained by the Harvard Humanitarian Initiative on humanitarian disaster aid, including the International Committee of the Red Cross.

And I was one of the first responders after the earthquake in Haiti and the medical director for the largest internally displaced camp in all of Port-au-Prince after that earthquake and worked hand in hand with the 82nd Airborne.

I have seen firsthand the challenges that arise in the middle of a humanitarian crisis and the importance of having clarity and a plan and have clarity in coordinating among agencies, local government officials, and NGOs in the field.

So while I am grateful that we are having a hearing on this issue with HHS, we need a fuller, more accurate view of what is happening in Puerto Rico with all stakeholders from all levels of government and all the different agencies, including clinical workers and NGOs and people that are actually on the field.

Two weeks ago, I flew down to Puerto Rico to see the conditions for myself and do a needs assessment based on my training and my experience. I'm here to report to you what I saw and give you some helpful recommendations.

One, the people of Puerto Rico are very hardworking, humble people with respect for themselves and their dignity, and they're

doing everything possible to help one another, to get the job done, to take care of one another.

Number two, the people who work in your agencies are giving 110 percent. I have to give kudos to the DMAT teams that I spoke with firsthand. California 11 from Orange County and Sacramento did fabulous jobs. The HHS liaison was there doing an amazing job.

I went further into the community and did not stay in San Juan and listen just to leaders. I listened to pediatricians on the ground, shelter coordinators, patients that were on the ground. And what I can tell you, these are the problems.

One, there's a lack of clarity of leadership. I'm talking to high-level officials from all the different agencies, and I'm not going to mention names, but the folks in the Puerto Rican Government are saying that FEMA is running the show. People at FEMA are saying that we're taking orders from the Puerto Rican Government. I talked to people from HHS, and they're saying, we don't communicate very much with the needs with the DoD. And so there's a lack of clarity with who's actually running the show in Puerto Rico.

Two, there's a lack of coordination. You're not going to get the full picture, folks, if you stay in San Juan. You're not going to get the full picture if your leadership and people making decisions are based in San Juan in a convention center with air conditioning and food and drinks and everything. You've got to get your butts out of San Juan into the remotest areas in Puerto Rico to talk to people and see firsthand.

So the problem is that there's a lack of priorities and clarity in the metrics that you're using and what you're telling the American people what your efforts are.

What does it mean when you say that bottles and food were delivered to all municipalities for PR purposes so that people get a sense that you're doing your job, when, in fact, what you should be talking about is capacity for food supply chains, capacity for electrical grid repairs, capacity to deal with the need?

All of you have mentioned numbers and the numerators and the number of clinics and the number of people on the ground. But what you haven't mentioned is a denominator, the actual need. So of your hospital capacity, what is the capacity to the overall need that the people on the ground actually need?

So this is my one recommendation. And I strongly agree that you will be able to better handle the situation on the ground with a lot more sense of urgency and realtime flexibility.

Yes, keep your command center in San Juan, but create command posts on the ground with representatives from the HHS, the Army Corps of Engineers, the DoD, Department of Housing, Department of Homeland Security with FEMA, the representatives from the local grid, Federal and state counterpart, including NGOs and local mayors, so they can have daily briefing and problem solving as they arise on the ground.

Let me give you an example. I went to one clinic. They had a generator fixed by FEMA. The local clinic didn't know that that generator that FEMA installed went down. They were without power for 2 days turning patients away. They didn't have a number to call the Army Corps of Engineers to determine whether they were on the queue.

I went to a temporary shelter at a local school in one of the communities. They were going to close their doors on October 23 when school starts. The mothers tell me their children needed bottled water. There is a Department of Defense Army guy saying, "Doc, we have a caseload of bottles, can we get authority to move them down?" Hell, yes.

So having command posts on the ground in every municipality where NGOs, local mayors, and everybody can hold each other accountable to address needs and realtime actions and cut the "Mother, May I"s, like you suggest, Dr. Kadlec, and just get the food and get the transportation, get the medicines that people need in realtime, addressing problems realtime, is what the people of Puerto Rico need, and there's a lack of sense of urgency when we talk about these issues.

Your folks on the ground are doing an incredible job, but the urgency to meet the needs of 3.4 million people, water, food supply chain, electrical grids, those are your top three priorities to prevent unnecessary loss of life of Americans on the island.

I feel very passionate about this because I took care of a woman who in front of me in a shelter had a seizure. I protected her airway. I tried to get her to emergency care. There was no oxygen. There was no medicine at this temporary shelter. We need to do a better job on the ground coordinating with different agencies so that we can save more lives and do what all your mandates are about to do.

So I thank the people on the ground. They're incredible, incredible workers.

Mr. GRIFFITH. And we appreciate your passion.

Mr. RUIZ. And I look forward to working with you more to make sure that we have command posts out in the field.

Mr. GRIFFITH. And we appreciate your passion and agree that we probably ought to get down there and get out and see things, and appreciate you and Dr. Burgess having both visited down there, and look forward to your input as the committee works further on these issues.

I now turn to Mr. Costello of Pennsylvania for 5 minutes for questions.

Mr. COSTELLO. Thank you, Mr. Chairman.

Dr. Kadlec, in your written testimony you mentioned that Puerto Rico faced public health and public health infrastructure challenges prior to Hurricane Maria's arrival, which exacerbated the hurricane's effects. Could you describe what some of these challenges were and how they adversely impacted the public health response efforts?

Dr. KADLEC. Well, sir, I mean, I'd just make a quick comment. Remember that Puerto Rico sustained two hurricanes, not one. So the first, Hurricane Irma, took a wallop, again, on the northern side of the island where a lot of their public health infrastructure is, laboratories. I'll have to defer to Admiral Redd to talk more about some of the particulars there. But remember that there were two events on Puerto Rico, not one, and that was the challenge right there from the get-go.

Admiral Redd.

Dr. REDD. Thanks.

I think that the nature of the event really is what stressed the system so much that it was so destructive. I think also some of the things that have been talked about earlier, about the migration of physicians and the overall waning of the number of providers, is really a risk factor for damage to the public health system.

Mr. COSTELLO. So are you saying that the infrastructure was sufficient and that even if the infrastructure was more improved than the condition that it was in, it wouldn't have mattered because the storm was so devastating?

Dr. REDD. Well, I think whatever amount of destruction you sustain, it is changed from what you had before. So a stronger system before an event would mean you'd have a stronger system afterward. It wasn't 100 percent destruction. But the—

Mr. COSTELLO. I guess what I think I'm trying to drive at—I didn't mean to cut you off—was what kind of infrastructure improvements are necessary to make moving forward so that maybe a storm of lesser destructive magnitude, but still nevertheless damaging, there be a better response—there would be the ability to have a better response because better infrastructure was in place?

Dr. REDD. Sure. Well, I think that some of the instances of damage, for example, if the laboratory had been constructed in such a way that it wouldn't have sustained as severe damage, if there had been a generator capability there that could have been stood up more quickly than what's going on now, those are the kinds of things that would have been able to bring the system back online more quickly.

Mr. COSTELLO. Could I ask you to supplement your answer in writing with any additional type of infrastructure elements?

Dr. REDD. Sure. Happy to do so.

Mr. COSTELLO. Thank you.

Dr. Kadlec, can you elaborate on how some of the lessons learned from previous natural disasters, such as Hurricane Katrina, improved HHS' response to the recent series of storms? And see, I just said series of storms, so it was more than one.

Dr. KADLEC. Thank you, sir.

I think one of the things from Katrina was basically unity of effort. To capitalize on Dr. Ruiz's comments earlier, one of the things that created the ASPR was the idea of a fragmented medical response.

And so while I can't dispute the issues of field command posts, I can just say certainly and with great authority that throughout our efforts we were trying to work very closely not only with the Department of Health in Puerto Rico, which kind of sets the requirements for what they need that we try to service and satisfy, but working across not only the Department of Health and Human Services, as we show here our solidarity with CDC, FDA, and CMS, and other entities within HHS, but across the Federal Government with VA and DoD.

So the uniqueness of that is displayed in Puerto Rico that wasn't displayed in Katrina where you had Veterans Affairs clinics and hospitals basically providing for not only veterans and their families, which is not typical, but also the general population, and doing so with combined DMAT assistance with our National Disaster Medical Service teams.

So that just gives you a flavor of that. I think the other part of it is, is the lessons learned, that we saw it in Texas and we saw it in Florida that there are hospital preparedness grants, these grants that basically help hospitals prepare. First it was initially for hospitals, then it was coalitions of hospitals, that basically were able to demonstrate communications and capabilities within those coalitions that made them more sufficient and resilient to these effects.

I'll give you an example, one in particular, which is pretty extraordinary, which is in Houston with Ben Taub Hospital, which, if you recall back several years ago, there were very bad floods, I think 2008 in Houston, that basically flooded out a lot of the hospital infrastructure in downtown Houston.

Well, they took hospital preparedness grants that you authorized and appropriated against and basically ensured that they could not only withstand flooding, as they did, they developed water-tight doors to basically prevent that, but also a whole set of procedures and communications, that they could continue operations despite hurricanes, despite floods.

And that was not only the case in Houston, but in Beaumont, Texas, where some of those same grants basically made sure that the hospital personnel had waders so they could go recover patients from the Cajun Navy that went out there to recover patients.

So there are a lot of great lessons learned in this. One thing is about the capacity of Americans to not only help, but to volunteer, as we are witnessing in Puerto Rico right now. But the idea is that we're going to do a little bit more of a formal one to take advantage of these terrible events to see what we can do better.

Mr. COSTELLO. Thank you. And such a thorough response that you actually answered the question that I didn't get to ask as part of the answer to that question.

Could I just ask you to supplement in writing any additional lessons learned, not an admission that you didn't do anything right, but sort of consistent with Congressman Ruiz's comments relative to what moving forward can be done in order to improve the next time a tragedy like this might occur so that we're better prepared. Because that's what we all want to do, be better.

Dr. KADLEC. Sir, be happy to.

Mr. GRIFFITH. I thank the gentleman.

And I now will recognize Ms. Schakowsky of Illinois for 5 minutes for questions.

Ms. SCHAKOWSKY. Thank you very much.

Fourteen people died at the rehabilitation center in Hollywood Hills in Florida when it lost power and overheated from September 11 to September 13.

Ms. Brandt, as seniors went into distress, workers struggled to provide 911 with basic information, including the address. It was also reported that the same facility had previously laid off hundreds of workers, including nurses.

The nursing home stated that it employs "full-time and part-time employees," but did not state if a nurse was present when those patients went into cardiac arrest.

You could give me yes or no to these simple questions—did CMS find that there was a nurse onsite at this nursing facility from the 11th of September to the 13th?

Ms. BRANDT. We have a full report on that, Madam Congresswoman, which I'd be glad to get you. I don't know the specifics of if there was specifically a nurse. I can't answer that.

Ms. SCHAKOWSKY. Is a nurse required to be present in a nursing home?

Ms. BRANDT. We have conditions of participation which require clinical staff to be present.

Ms. SCHAKOWSKY. And are the requirements for nursing home disaster preparedness plans, is that a requirement?

Ms. BRANDT. That is a requirement, yes.

Ms. SCHAKOWSKY. And were they followed?

Ms. BRANDT. According to the report that we got from our state facilities, they were not followed in this instance, and that is why the facility has been terminated from accepting Medicare and Medicaid patients.

Ms. SCHAKOWSKY. So that's the consequence?

Ms. BRANDT. That is the consequence.

Ms. SCHAKOWSKY. OK.

I wanted to talk to Dr. Kadlec about the hospitals. A week after Hurricane Maria, HHS told the committee staff that most hospitals were damaged, faced major challenges in getting food, water. We've talked about that. And then, of course, more than a month after Hurricane Maria, Slate reported that surgery is being done by cellphone flashlight. There's pictures that show that, so, I guess, it's pretty well documented.

And so what I wanted to know is do hospitals connected to the electric grid have access to the full regular power, or is it only being provided intermittently?

Dr. KADLEC. Ma'am, it depends where those hospitals are. There have been some issues with reliability. I would have to turn you over to the U.S. Army Corps of Engineers to talk about what specific areas—

Ms. SCHAKOWSKY. OK. So when you say all hospitals now are corrected to the grid, that doesn't mean that—

Dr. KADLEC. No, ma'am. There's only 60 percent of the hospitals that are connected to the grid currently as of today.

Ms. SCHAKOWSKY. And the others, are they operating on—

Dr. KADLEC. They're operating on generators. And we're basically working with FEMA to actually have what we call N-plus-one, where they have two backup generators—they have a generator, a principal generator and a backup, so that if they need to switch, if the generator fails, they can go immediately to the next one. And, again, the plan is, is to basically have a 911 FEMA generator repair team to come out and fix the primary generator.

Ms. SCHAKOWSKY. But as a consequence of all this, you would say that there is not 24/7 power at what percent of the hospitals?

Dr. KADLEC. Well, 60 percent right now are on the grid, which would have regular power, and even then sometimes there's some reliability issues as it relates to transmission wires and distribution, that I have very little understanding of because I did very badly in electrical engineering. But I think the point is, is that

there are hospitals out there that are on the grid and even those hospitals have generator backups.

Ms. SCHAKOWSKY. OK. I wanted to turn for a minute to the Virgin Islands, Dr. Kadlec. I understand that Hurricane Maria tore the roofs off of the two largest hospitals in St. Croix and St. Thomas. So what is HHS doing to ensure that Americans in the Virgin Islands are receiving the healthcare that they need?

Dr. KADLEC. Ma'am, immediately after the storms passed, both Irma and Maria had effects on both St. Thomas and St. Croix, where the hospitals are located. And then with the passing of those storms, the initial storm Irma, we basically just set up a DMAT team with its temporary shelter there. And that was replaced with a more capable Army support clearing medical station, which is a 40-bed mini-hospital that's there.

And now we're in the midst of basically deploying a western shelter assembly so that would allow the physicians and nurses and healthcare practitioners on the Virgin Islands to go back to work and take care of their patients while the hospitals are being assessed by the Army Corps of Engineers to either be repaired or replaced. I think in the case of St. Thomas it's going to need to be replaced.

So we've provided immediate care, we're providing the intermediate support, and then we're basically transitioning to a capability that would allow the healthcare workers on the Virgin Islands to go back to work, and then with that give time to basically repair or replace those hospitals.

Ms. SCHAKOWSKY. Thank you. I yield back.

Mr. GRIFFITH. I thank the gentlelady.

I now recognize Mr. Collins of New York for 5 minutes for questions.

Mr. COLLINS. Thank you, Mr. Chairman.

Thank you, all the witnesses, for coming.

So, Dr. Kadlec, while we're operating the hospitals under generator power and the like, as people are being transitioned out of the hospitals, in many cases, in fact probably in most cases, the residents don't have power at home and they don't have running water.

Could you perhaps explain what's going on relative to these patients leaving? And how are you and others now dealing with the fact that they're moving into an environment without power, and in many cases without running water?

Dr. KADLEC. Sir, just to highlight a comment made earlier by Admiral Redd, there are six Federal medical stations that have been deployed to Puerto Rico. At the present time two are operational, two 250-bed facilities that are being staffed by VA workers as well as volunteers.

In one case, from the Greater New York Hospital Association, a great example of a combined effort between our Federal and volunteer partners that are basically providing those kind of transition places for people who need additional medical support or care, don't need to be in the hospital but can't get home, go home for whatever reason. So we've set up those and have more in position as required to do so.

Mr. COLLINS. Well, that's reassuring that you're basically assessing patients one by one to make sure that when they're released they're getting the care they need.

Dr. KADLEC. Yes, sir.

Mr. COLLINS. Another question, again back to the individual situations, is the report that the pharmacies are asking for cash payments because of a lack of ability to connect into insurance companies and the like. Yet, in many cases, the folks needing prescriptions filled don't have that cash.

So whether the question should go to you or Dr. Gottlieb, how are we handling what at least has been reported?

Dr. KADLEC. So in Puerto Rico there's a program called the Emergency Pharmacy Assistance Program, which provides free medications to individuals who can't pay for it. So that's been invoked so that people who don't have cash, would need medicines, can get it. That's one way.

The other way is if they were to go to one of our DMAT facilities that are colocated in seven of the regions in Puerto Rico. They can get medicines from there as well. We'd provide prescriptions or medications as required.

Mr. COLLINS. That's reassuring as well.

Now, in some cases someone that's been on prescriptions, I'm assuming there's some difficulty even in a pharmacy contacting the physician's office. I know if I go to fill one and it's expired, they say, "OK, we'll contact the physician. We'll get back to you." But, again, because of the lack of infrastructure, how is that being handled?

Dr. KADLEC. Well, not only medicine but prescriptions are being basically filled out for people who seek them out. They have to basically present themselves either to one of our DMAT teams or military facilities or VA facilities and they will get a prescription, if not the medication itself.

Mr. COLLINS. Again, I appreciate this is—you're basically taking what I would call a one-by-one-by-one approach, every situation is somewhat different, but I'm getting comfortable that you're taking care of people as best we can, given the limited infrastructure and in some cases doing things in an unusual way.

Dr. KADLEC. Yes, sir.

Mr. COLLINS. So, Dr. Gottlieb, Representative Gonzalez has asked me to ask you, on the FDA issue related to food and agriculture, what would be your overall assessment? And are there cases where the FDA is granting waivers and things of that sort, understanding it's not business as usual at all?

Dr. GOTTLIEB. Thanks for the question, Congressman.

We would typically grant waivers, for example, if crops that were damaged in a hurricane, if the producer was looking to divert crops intended for human consumption into animal feed. And we do process those waivers.

In terms of what we're doing right now, we've already conducted, I believe, 20 not inspections, but site visits to various agricultural facilities and food production facilities to help them get back online.

We've done this in the last week or so, even as our own employees down there have been devastated by the hurricane. We have about 100 employees on the island. We've conducted a total of, I

believe, about 36 right now inspections of various medical product facilities and food production facilities to help them get back into production.

Mr. COLLINS. Well, I want to thank you.

And, Mr. Chairman, I'll yield back, but I guess I need to say, I'm really happy to hear of the response that we have in Puerto Rico given the fact that the island was devastated. It is an island nation. And while it's always easy to criticize response, what I'm hearing is a lot of actions have been taken one by one to make sure people are getting the services they need. We can't snap our fingers and rebuild an electric grid overnight, but everything I'm hearing is.

And I would disagree with the member that was going to give them a 2 on a scale of 1 to 10. I also don't like to give grades, but I think that's a bit harsh, considering the devastation that the island withstood and the fact we've never seen anything like this before.

So, again, I want to thank all four witnesses for coming here today. And I certainly am leaving today feeling much more comfortable about what's being done to take care of the tragedy that did occur on Puerto Rico.

I yield back.

Mr. GRIFFITH. I thank the gentleman.

I now recognize the gentleman from California, Mr. Peters, for 5 minutes for questions.

Mr. PETERS. Thank you, Mr. Chairman.

When you get down at the end like this, a lot of questions have been asked already. So I wanted to ask you an open-ended kind of question from a perspective of prevention.

So I think a lot about what we might do with respect to preparing communities to deal with earthquakes or fires or floods. But from a health perspective, I haven't really given that much thought. Do you have any thoughts about what you would have liked to have seen the Federal Government do or Puerto Rico do before this that would have mitigated the need to respond to the extent that we had? Anybody?

Dr. KADLEC. So I would just comment that in all the three hurricanes, the major ones, Harvey, Irma, and Maria, that we were very aggressive in deploying our assets—people, capabilities, logistics—as far forward as we could safely in the case of Puerto Rico, actually putting people in harm's way to be there when things happened.

You can never anticipate how things will unfold. And particularly Florida, if you recall, the turn of Irma that went from the east coast to the west coast, thankfully, and then that kind of deceleration of the storm just before it hit Tampa. That's a little bit of good luck. You can't always count on that.

But I think one of the things that comes out of this is the importance for community resilience, individual resilience. Those are things that somehow, again, are not necessarily the domain of HHS, but I think FEMA and Department of Homeland Security often use October as preparedness month and ask people to see if they have a plan, if they have supplies, if they have the necessary things at home.

I think these events highlight that element, that individual preparedness. No matter how good we may be, it's always going to be a circumstance that we may not be able to get to you immediately and you're going to have to provide for yourself and your family in the immediate term.

Mr. PETERS. From your perspective, though, so as the health agencies, including CDC, do you feel like you have input into what is the content of the outreach that's happening around October to tell people how to be ready, from your perspective?

Dr. KADLEC. I'll have to defer to Admiral Redd to talk about CDC, but we do participate in these kind of interagency conversations. But, again, if you just wonder what kind of messaging you need, I think as we look to the threats of the 21st century and my role in preparedness and response, the circumstances that we found ourselves in after 9/11 are clearly different today. The circumstances that we find ourselves in when this position, my position was created in 2006 are different today than they were then. And so I think the thing is, is part of it is keeping up with the rapidly changing threat environment.

Mr. PETERS. That is the premise of my question. My question is, are we keeping up with it? Is there something we need to be doing? Is there something reflecting back on?

Dr. KADLEC. I'm going to take advantage of an opportunity to point out that the Pandemic and All Hazards Preparedness Act will be reauthorized hopefully in the spring of 2018, and I believe there should be things that reflect that changed threat environment.

I think Mrs. Brooks mentioned the issue about the structure of the National Disaster Medical System. I've called for the idea of a national disaster healthcare system that would be basically built potentially on what has been proposed with the national trauma system to basically ensure that we have the capabilities the country needs to face whatever the threats may be in the future, whether they're natural or manmade.

Mr. PETERS. Right. Thank you.

Let me turn to the admiral real quickly.

Dr. REDD. Yes. The answer to your question, I think, is different depending on the horizon. I think that certainly since 9/11 there have been remarkable improvements in our ability to respond in a coordinated, cohesive way.

One comment that I'd make is that these three different hurricanes were actually very different events, that in Texas was really a flooding event with not very much wind damage in the most populated areas. In Puerto Rico it was primarily a destructive wind event.

And so I think the lesson from that is that really being adaptable is a critical capability. And I think that we are continuing to get better at being adaptable to the circumstances that we're confronting.

Mr. PETERS. Great. I want to thank the witnesses and yield my remaining time to Dr. Ruiz.

Mr. RUIZ. Quick, because I just have a few seconds, but the idea of peripheral field command posts, would that be helpful to better coordinate on-the-ground realtime with all the stakeholders, Dr. Kadlec?

Dr. KADLEC. Sir, it is, and we have that communications capabilities with our DMAT teams.

Mr. RUIZ. So it can happen?

Dr. KADLEC. It can happen. As it is, you defined a joint——

Mr. RUIZ. So, Dr. Redd, would that be a solution that would be worthy of pursuing?

Dr. REDD. Yes, it would. And I think, just in a narrower way, from a surveillance standpoint, having hubs that could report in would be something that would be helpful to understand what the facts on the ground are.

Mr. RUIZ. So I'm going to highly suggest that we start doing that as well.

And another metric to count is unnecessary deaths, epidemiology. It's one thing to be killed by a falling branch or drowning from the river. The other thing is to die from not having medications that they could have had if it wasn't for the hurricane.

So there's a lot of unidentified bodies and there's a lot of deaths occurring. We need a better way to count how many are due primarily and secondarily from the hurricane.

Thank you.

Mr. GRIFFITH. Thank you for yielding back.

I now recognize the gentleman from Texas, Mr. Olson, for 5 minutes for questions.

Mr. OLSON. I thank the chair and welcome the chair as our new chairman of this subcommittee. I thank you for allowing me to participate in this hearing even though I'm not a member of the subcommittee. I'm here to talk about three aspects of Hurricane Harvey, I'll call them the three M's: mental health, mold, and mosquitoes.

I moved to the Texas Gulf Coast in the summer of 1972. If you were there at that time and since then you hear of the legends of Hurricane Galveston in 1900. The worst natural disaster in our country's history, over 6,000 lives lost, probably 8,000 to 10,000 if you count them all. I was there for Hurricane Alicia in 2001, Ike in 2008.

Harvey did more damage than those hurricanes combined. It hit us twice. It hit us once, got stopped, then came and hit us again.

We faced many health challenges. The San Jacinto Waste Pits with Dioxin were breached, leaked out in the San Jacinto River. There were chemical spills, raw sewage spills, floating walls of fire ants, toxic smoke fires that got out of control. Flesh-eating bacteria took two lives, one in Galveston and one in Kingwood. A first responder in my district was infected but beat it with heavy, heavy antibiotics.

Mental health became a big issue. I saw this firsthand. I was at a school there, elementary school hit by the tornado that hit Sienna Plantation called Scanlan Oaks. Talked to parents, school kids come to class. One young man came, very proud.

"The tornado hit my home. Knocked out my window as I was sleeping."

Mom came back, and I said, "Man, he's doing great."

And she said, "No, he's not."

He's greater at school. It's a great story. I beat the hurricane, the tornado. But since that hit his house, he can't sleep in his own bed.

He crawls in with Mom and Dad just for security and safety because he fears for his life after what happened with Hurricane Harvey. And that's just one example of how our kids are traumatized by these events.

And also the adults. We went through days and days of tornado warning, flood warning, the whole night for 3 nights, probably slept 4 hours over 3 days. Four days after Harvey cleared there was a little flash flood. Those alarms went off. People all around said, "I kind of freaked out hearing those alarms again."

So my question is, what resources—probably you, Admiral Redd, and maybe you, Mr. Gottlieb—what resources are you providing our communities to address the mental health issues that they face because of Hurricane Harvey? What can be done for these people?

Dr. GOTTLIEB. Well, I'll defer to my colleagues on the panel.

In my role as FDA Commissioner with respect to what we've been focused on coming out of Hurricane Harvey in addition to there being some medical product facilities in the region, the predominant issue has been related to crop destruction and issues related to requests for waivers, for diversion of crops into animal feed.

And going forward, we will probably have to take some steps to help with remediation of certain fields that might have been exposed to heavy metals from the flooding. But we're primarily focused on issues related to the crops that were damaged in the aftermath of the hurricane.

Mr. OLSON. Thank you.

Admiral Redd, do you have any comments on that, sir?

Dr. REDD. On the mental health question in particular, I think that there are maybe three points. Well, four points.

One is that these events are devastating and they have effects on everyone. Most of those effects are relatively short-term for most people. And I think for people, when those effects are not short-term, we need to be able to make sure that there is availability of services.

The second point is really understanding the magnitude of that group of people that need long-term help.

Let me think if I could remember my third point. I think that's it for me, is the two points.

Dr. KADLEC. Sir, I'll add to his point, though, really quick, which is just simply that we've used the Public Health Commissioned Corps. They have behavioral health teams that basically are going out. They've been most recently deployed in the Virgin Islands.

But also SAMHSA has provided a hotline to call for people who have had it. They've had 11,000 calls. And basically you can speak to a counselor on the phone to ask about their emotional issues and find some assistance and solace in that way.

So there are some capabilities out there, and we've been working with—and, again, it's dependent on the local authorities to basically initiate these things. But we certainly stand ready to assist when it is appropriate.

Mr. OLSON. Thank you, sir.

Come on, Admiral Redd, you are ready for your third point.

Dr. REDD. Well, actually, there may be a couple more.

But let me talk about mold. We're working closely with the Department of Health. When there's a flooding event, structures that are flooded will become moldy.

We're actually doing three different things in mold. One is training of responders. The other is working on communication materials. And the third thing is working with the Department of Health to investigate the potential for an increase in infections due to invasive mold.

Mr. OLSON. I thank the witnesses and my chairman.

Also remind me about our region, there's one thing that unites us: Beat L.A.

I yield back.

Mr. GRIFFITH. I thank the gentleman.

And I now recognize the gentlelady from New York, Ms. Clarke, for 5 minutes for questions.

Ms. CLARKE. Thank you so much, Mr. Chairman.

I'd also just like to remind everyone that we're talking about territories that are in tropical climate and that these are tri-island territories. I hear people talk about Puerto Rico as though it's a monolith. There's also Vieques and there's Culebra. There's also three islands with respect to the U.S. Virgin Islands, and that is St. John, St. Thomas, and St. Croix.

So I don't want us to see this as a monolith because each of these islands have their own identity, their own inhabitants, and I'm not hearing enough of a deep enough dive into what is happening with the inhabitants of all of these territories. Because it's not one singular event. It's an event that hit three separate geographic territories.

I'm putting that out there because I'm going to want to hear more about what has happened in terms of response to those territories. We're not hearing at all about how the people of St. John are receiving healthcare, the people of Vieques are receiving healthcare. We're not hearing that information, and that is just as important.

I'd like to start my question about the evacuation process. What assistance was provided to prepare and implement an adequate and efficient evacuation plan for those whose health are compromised? And was there coordination assistance provided to the local health departments in the wake of the hurricanes to track evacuees who were sent to other islands and/or the mainland?

Dr. KADLEC. Ma'am, I can probably address that. In deference to your question, I would also just highlight our map that we provided which identifies where HHS has basically been providing augmentation support to St. John, as well as St. Croix and Virgin Islands. And also we had a presence on Vieques as well.

But to your point about evacuation, again, for the complexity of this event—and, again, Irma struck St. Thomas first, and for which we were doing some unprecedented things.

Using CMS' emPOWER database, we actually were able to send in our DMAT teams with urban search and rescue and identify dialysis patients on the island, which we recovered 120 of them and then evacuated them to relative safety in Puerto Rico until Maria hit, at which point in time we evacuated them literally the day of landfall of Maria, evacuated those patients to Miami, to a medical

shelter there, where we could ensure that they were being cared for.

In the cases of other patients who were evacuated from the Virgin Islands, they were evacuated through Atlanta, and, again, receiving care through there, through the local resources.

And so throughout, the intent here is not only did we evacuate those dialysis patients, but sent them with a nonmedical attendant, a family member, so they would have someone to assist them along the way.

At the present time, there's only been a handful of evacuations off the island to the mainland. There were two pediatric patients, intensive care patients, that were evacuated from San Juan to Miami soon after landfall.

But what we've tried to do is basically maintain the health infrastructure on Puerto Rico, because we're hopeful that those people get better, and they need to be closer to family and support units there.

So the way we addressed the problem in Puerto Rico is we created these seven regional hubs of hospitals that we augmented with our disaster medical assistance teams.

We took the benefit of a level one trauma center in Centro Medico in San Juan, where we made it one, if you will, the eastern hub, a receiving hospital for high acuity or intensive care patients, and then used the USS Comfort as the other hub, the western hub, a mobile hub that we could basically run from basically from the top of Arecibo down to Ponce to collect patients, depending on their acuity, as required, and then have been able to use DoD assets, both ground ambulances and Medevac Dustoff helicopters, to provide response on the island, and then using Naval medical assets and rotary-wing and fixed-wing assets to fly them.

Ms. CLARKE. If there is a document that you have that just sort of outlines all of that, that would be great.

Dr. KADLEC. Yes, ma'am.

Ms. CLARKE. If you can provide it to the committee.

Dr. KADLEC. I can make that available to you.

Ms. CLARKE. I also wanted to talk about the public health challenges of these island territories. The islands will need the assistance of the Federal Government in the weeks, months, and years to come. What is the agency's position of the Medicaid cap as it relates to the Virgin Islands with its already-limited resources? And do you support a full Federal contribution as the Federal Government did for Katrina?

Dr. KADLEC. Ma'am, I'll defer to Ms. Brandt.

Ms. BRANDT. Thank you for that question.

That is certainly something that we are looking at, and we are exploring whether or not we would have the flexibility to do that. But the Federal match is set by Congress. It's statutory.

Ms. CLARKE. Yes. I'm asking about your recommendation. Right now you have these islands, island territories, where in one case, the U.S. Virgin Islands, their major employment is through tourism, right? No one's working. So are we requiring that government come up with a match or are we going to suspend it and do a full Federal contribution as we did for Katrina on the mainland?

Ms. BRANDT. Excuse me for not answering directly. We are pursuing that. We are working with the Office of Management and Budget to pursue that with congressional approval.

Ms. CLARKE. Wonderful. Thank you.

I yield back, Mr. Chairman.

Mr. GRIFFITH. I thank the gentlelady.

I now recognize the gentleman from Georgia, Mr. Carter, for 5 minutes.

Mr. CARTER. Thank you, Mr. Chairman.

And thank all of you for being here today. I appreciate your presence.

I'm going to assume this goes to CMS, and that's Ms. Brandt.

Can you help me here? I know the situation that exists with the nursing home situation in Florida. Are you going to now require nursing homes to have generators? Is that going to be a requirement? And can you very briefly tell me how that's going to work?

Ms. BRANDT. Sure. We actually have an emergency preparedness rule which was finalized last year that is going to be surveyed again starting next month. So that's when the state surveyors go out. It requires generators, it requires emergency preparedness plans, and it requires training on a continual basis.

Mr. CARTER. Will there be any kind of reimbursements for nursing homes? I've spent much of my professional career as a nursing home consultant, and I can tell you, they are pushed for trying to stay solvent as it is. Is there going to be any kind of help for them or is this just another government mandate?

Ms. BRANDT. That is certainly something that we are looking at, but I can't speak specifically to that at this time.

Mr. CARTER. OK. Thank you.

Mr. Kadlec, there was an article in The Wall Street Journal the other day about the USN Comfort, the Naval ship, that was a medical ship, and how it was off the coast of Puerto Rico but it wasn't being utilized. And I just wanted to get your input on how we could do a better job in the future of making sure—from what I understand, it's a 250-bed hospital on the water, but only 150 beds were being utilized at one time?

Dr. KADLEC. Yes, sir.

Mr. CARTER. What can we do to make that better? It's costing us \$180,000 a day just to have it there. And those people desperately off of Puerto Rico need help.

Dr. KADLEC. Yes, sir. And, again, to allude to Ms. Clarke's question before, part of our plan was basically to use the Comfort as a capability to deal with high acuity patients, intensive care patients, particularly in circumstances where hospitals on generators would fail, where we would need to urgently transfer critically ill patients somewhere. And so we were basically using the 50-bed ICU on the boat, sir.

Mr. CARTER. And we understand and appreciate that. But it seems like we could have made better use of it. And have we learned anything? Is there anything we can do differently to make it more accessible in the future?

Dr. KADLEC. And so we are in the midst of actually looking how we can utilize it more, as more of a stationary platform, probably berth in one of the ports in Puerto Rico.

Mr. CARTER. Exactly. Make it more accessible.

Dr. KADLEC. That has been an ongoing conversation with the Department of Health in Puerto Rico to assess how we can use that more to their needs.

Mr. CARTER. OK. Thank you.

Dr. Gottlieb, it's my understanding that the FDA can declare on a shortage list medications that are not available and that they can be compounded. Is that true, they can be compounded by pharmacies if they're put on the FDA shortage list?

Dr. GOTTLIEB. We don't typically look at the opportunity to compound as an alternative or solution for shortages. Our drug shortage staff would typically try to work to help get the approved product back in supply and might look to help source the same products from overseas manufacturing facilities that might be inspected by FDA.

It is the case that in certain situations you might see practitioners go to approved compounding facilities, facilities that are compounding within the confines of the statute, to source certain products.

Mr. CARTER. OK. So you're actually increasing access to alternative medications? Is that what you're trying to do?

Dr. KADLEC. Thanks to some of the new authorities that Congress gave us with respect to our drug shortage staff and our ability to identify shortages further out from the actual occurrence of a shortage, we've been taking steps to try to mitigate the shortages that have occurred, but also situations where we see the potential for products to tip into shortage.

So we're looking out typically 1 to 2 months for what we think could potentially happen if production doesn't resume and taking steps to, for example, move temporarily certain manufacturing out of facilities that might be damaged or not up to full production to facilities in other markets that could help supply the U.S. market.

Mr. CARTER. Right. OK. I would ask you, as you continue on your process for the memorandum of understanding dealing with compounded medications, that you would take into consideration natural disasters and that there would be exceptions put in there where compounding pharmacies could be utilized so that they could get those medications to those patients in the case of natural disasters such as this.

Dr. GOTTLIEB. And we would be happy to work with the Congressman as well. It might be something more appropriately addressed in the statute. I certainly look forward to working with you on that.

Mr. CARTER. And I will be glad to work on that if it needs to be addressed in the statute.

One final question. I will just ask you, Dr. Gottlieb. Is the CDC supporting vaccinations to prevent Leptospirosis?

Dr. GOTTLIEB. Well, I would defer to my CDC colleague.

Mr. CARTER. OK. Excuse me. I'm sorry.

Dr. REDD. There's no vaccine for Leptospirosis.

Mr. CARTER. There is no vaccine for that right now?

Dr. REDD. No.

Mr. CARTER. What about treatment for it?

Dr. REDD. It's very treatable. It works better the earlier the disease is identified. So earlier treatment is more effective.

Mr. CARTER. Is that being supplied to Puerto Rico now?

Dr. REDD. It is. The antibiotics that are used for treatment, they're not—

Mr. CARTER. Pretty common?

Dr. REDD. Yes, they are. They're not anything special.

Mr. CARTER. OK.

Dr. REDD. Penicillin and tetracycline.

Mr. CARTER. OK. Great. Well, tetracycline is not available as much as it ought to be.

Dr. REDD. Depends on which variety.

Mr. CARTER. As Dr. Gottlieb will attest, unless you're getting it for fish tanks. I'm serious. Nevertheless, it is a problem.

But thank you very much. And thank all of you again.

And I yield back.

Mr. GRIFFITH. I now recognize the gentleman from New York, Mr. Tonko, for 5 minutes for questions.

Mr. TONKO. Thank you, Mr. Chair.

As ranker on the Subcommittee of Environment that reports to the standing Committee of Energy and Commerce, I have made clean drinking water a major effort to focus that I'm very appreciative the committee is responding to. We have recently reported a bill from the subcommittee and then standing committee. So, therefore, I want to address that concern, clean drinking water.

There are many reports about a lack of safe drinking water in Puerto Rico. Unfortunately, neither FEMA nor the EPA is before us today. So, Dr. Redd, I'm hoping that you might be able to share some insights into the water situation in Puerto Rico and the Virgin Islands.

Recent news reports have stated that roughly one-third of Puerto Rico has no reliable access to potable water at home. Because of this, we have heard reports of people drinking and bathing in rivers and streams in Puerto Rico.

Last Tuesday, Puerto Rico's state epidemiologist, Carmen Deseda, announced that there have been some 74 cases of Leptospirosis reported on the island so far this month. Puerto Rico usually sees only 60 cases of this disease, as I'm informed, in a given year. Some reports have connected this outbreak to public use of contaminated water sources.

So I ask, can you tell us about this whole concern about Leptospirosis, and what are its symptoms?

Dr. REDD. Certainly. Leptospirosis is a bacterial infection. It's acquired, as you described, by drinking or being exposed to water that's contaminated with those bacteria. They infect many species of animals. And animal urine is the vehicle for transmission of the disease. So situations where there's a shortage of potable water or exposure to floodwaters that are contaminated with the bacteria are the settings for exposure.

We are working closely with the Department of Health in Puerto Rico to determine whether those suspected cases actually are cases. We have specimens in the laboratory at CDC right now doing those tests. We are aware of one confirmed case that was diagnosed in

a patient at the VA. So how large this outbreak actually is—if it's an outbreak—is something that really remains to be determined.

The best way to control the outbreak is to prevent exposure to contaminated water, and that really is an issue that you've started with, with wider availability of potable water and then early treatment for people that have symptoms of fever, weakness, exposure to those things. And then, in the later stages, more characteristic is jaundice, yellowing of the skin, because of liver damage.

For the question about the extent of the water supply system, I might refer to Dr. Kadlec on what the situation is, proportion of people that have access to potable water.

Dr. KADLEC. So I can give you just basically down that we've been following: 25 out of the 115 public drinking water facilities are out of service. So, again, that's an intense issue of concern. And, again, prioritization in terms of reelectrification.

But significantly, too, is 10 out of the 51 wastewater treatment facilities are out of service. So that gives you a rough estimate of what the situation for water is. But that's being followed by the U.S. Army Corps of Engineers.

Mr. TONKO. Then back to the disease itself, like, is it normally treatable?

Dr. REDD. It is treatable. It does have a significant mortality rate for severe cases, 5 to 15 percent fatality. So it's a serious disease that we need to take steps to try to prevent and when it's recognized treat promptly.

Mr. TONKO. And how critical is it that patients be treated in a matter of days or hours after—

Dr. REDD. Well, like many bacterial infections, the sooner treatment can be started, the more effective it is. So early recognition is very important. And some of that has to do with access to medical care.

Mr. TONKO. Yes. And are there any other diseases or hazards associated with drinking and bathing in rivers and streams, particularly after these heavy rains and floodings that we saw in Puerto Rico? Are there other health concerns?

Dr. REDD. There are. There are. So the conditions that can cause gastrointestinal illness are going to be more common in floodwater, wastewater that has sewage in it. There are also skin infections that could be more common when people become exposed to that. So really it's a variety of diseases, as well as something that's been alluded to earlier, the inability to wash your hands, do things that will have many other beneficial effects.

Mr. TONKO. Thank you very much. I yield back.

Mr. GRIFFITH. I thank the gentleman.

And I appreciate everybody bearing with me. I am going to reserve to go at the end.

I now recognize Mr. Bilirakis from Florida for 5 minutes for questions.

Mr. BILIRAKIS. Thank you, Mr. Chairman. Thank you for allowing me to sit in on the subcommittee.

Secretary Kadlec, does the Hospital Preparedness Program currently allow states to use grant funds to help defray costs associated with procurement and maintenance of generators for assisted

living facilities and skilled nursing facilities to support the development and sustainment of regional healthcare coalitions?

Dr. KADLEC. Sir, the way the grants are structured, it is principally for healthcare facilities and for coalitions thereof. So as part of a plan of a coalition, that could be considered as part of it, but we don't dictate that as being part of it. We are looking to identify how these hospitals and hospital systems can become more resilient.

But, in fairness to your question, sir, if I may get back to you on that, I can give you a more fulsome followup on that.

Mr. BILIRAKIS. Yes. Please, that's very important, to see whether it's permissible.

Dr. KADLEC. Yes, sir.

Mr. BILIRAKIS. Because, again, in our area, there are small nursing facilities, but also ALFs, that do not have generators. And that's a priority, and that's what I'm concerned with.

Dr. KADLEC. Sir, I'll get back to you on that.

Mr. BILIRAKIS. Maybe they have 10 patients or less, and we've got to make sure they have the generators, the backup.

And, Ms. Brandt, last Friday the committee sent a bipartisan letter to the owner of the rehabilitation center at the Hollywood Hills in Florida raising concerns, again, about the nursing home in Florida where 14 residents eventually died after the facility lost air conditioning in the wake of Hurricane Irma.

There was apparently a fully functional hospital across the street. Unbelievable. And according to the Florida Agency for Healthcare Administration, the facility administrator and medical professionals didn't know to call 911 in an emergency.

I can't understand this. What's wrong with these people? How could a nursing home be so unprepared for a medical emergency that 14 residents lost their life, especially when there's a hospital across the street? Can you answer that question, please—

Ms. BRANDT. Well, thank you for the question, sir.

Mr. BILIRAKIS. Attempt to.

Ms. BRANDT. And, as you're aware. Hollywood Hills has been terminated from participation in the Medicare and Medicaid program.

We make patient safety our number one priority for the residents of all of our Medicare and Medicaid facilities, and this was a complete management failure at Hollywood Hills, which is why they were terminated. They did not meet our conditions of participation for keeping the temperature at a reasonable level. They did not provide adequate care to the patients. As you mentioned, there was a hospital right across the street which they could have availed them.

So they had several levels of what we call immediate jeopardy for patients, which is why they were terminated.

Mr. BILIRAKIS. OK. Who is ultimately responsible for their safety?

Ms. BRANDT. In terms of the patient safety, the facility has the responsibility and the management of the facility has the responsibility to ensure that they are meeting emergency preparedness requirements, that they are providing adequate care to the patients. And we survey and hold the facilities accountable to those requirements.

Mr. BILIRAKIS. OK. That's very important, the accountability, obviously, the supervision, is so important.

What can CMS do to ensure a tragedy like this never happens again?

Ms. BRANDT. Well, one of the things that we have done, as I mentioned in my opening statement and in the written testimony, is that we have instituted an emergency preparedness role which requires that facilities have an emergency preparedness plan, that they train on that plan and make sure all employees are aware of it, and that they have adequate backup in place to allow—you mentioned the discussion of generators and other things—to ensure that they have adequate power supplies and other things to ensure that patient care can be provided, and that they have a plan for where the patients can go if it cannot be provided.

Mr. BILIRAKIS. Well, what about Puerto Rico now? I understand that there are nursing homes operating without air conditioning and people are very unsafe. Who's responsible for this? Who's supervising this? Is it CMS? HHS? And, obviously, it's unacceptable. Can you respond to that?

Ms. BRANDT. Well, so, in situations like in Puerto Rico, where you have an almost unheard of position, where you have no water, you have no power, you have really no ability to provide it, we work with all of our partners.

Dr. Kadlec and the ASPR team, as well as the FEMA teams and everyone on the ground works with not only Federal and state, but also the territory officials in Puerto Rico to pull together to get patients to a safe place.

If they don't have the ability to provide that care, then we work together to get them transported to a safer place, such as the evacuees that Dr. Kadlec was talking about earlier from the Virgin Islands.

Mr. BILIRAKIS. Thank you very much. I appreciate it.

And I'll yield back, Mr. Chairman.

Mr. GRIFFITH. I thank the gentleman for yielding back.

I now recognize Mr. Green, the gentleman from Texas, for 5 minutes.

Mr. GREEN. Thank you, Mr. Chairman.

And coming from the Houston area, again, a very urban area, I heard today that we had our second death from a flesh-eating bacteria in Galveston County. That's to the south of us, where I'm at. But, also, to the north we had a 77-year-old lady in the Kingwood area, up in Congressman Poe's district, pass away. We have some great medical facilities. And that gentleman was actually at UTMB because it's infectious disease.

Has that been prevalent in Puerto Rico or the Virgin Islands? Because I know we have a lot of standing water or at least we did have. And I'd like to ask if CDC—

Dr. REDD. I'm not aware of cases that have occurred in the other hurricane-affected areas.

The condition that you're describing is pretty infrequent in the U.S., about 600 to 700 cases per year over the last 4 or 5 years of that disease occur. So it's not common. But the exposure to floodwaters is a risk factor for that condition.

Mr. GREEN. OK. Thank you.

Hurricane Harvey created so many serious environmental and public health issues, including evidence of compromised Superfund sites, and toxic spills, chemical fires, and high levels of air pollution. EPA confirmed that in the aftermath of Hurricane Harvey—we have a location called the San Jacinto Waste Pits in Harris County that's now in Congressman Babin's district—but welcome to the redistricting in Texas. It was in my district. It was in Ted Poe's district. So we changed those, but our constituents still contact all three of us.

The analysis found that it was concentrations of 2,000 times higher than the level in which the EPA required a cleanup. And the EPA administrator was there literally 2 weeks ago to visit that site, and the decision has been made to permanently clean up that facility there in east Harris County. So I was glad of that.

Dr. Redd, what are the types of risks associated with substances such as this? It's a dioxin facility. It was dumped there in the '60s by a paper mill. We have responsible parties.

But in both the State of Texas, Harris County and city of Baytown that's there, put signs up in both English, Spanish, and Vietnamese not to eat the crabs or the fish—but when I go out there, you can't find anybody that doesn't have a fishing pole—because the signs say, if you're an expectant mother or a small child, you shouldn't digest these crabs, but a lot of people still do.

What are the types of risks that are associated with that other than problems with eating it?

Dr. REDD. I'd like to respond to that question in a followup. I don't want to say anything that's incorrect here, and I think especially with the levels that we're seeing in that setting.

Mr. GREEN. OK. Like I said, the decision has been made to clean it up. But my concern is a lot of my constituents who go out there and fish and crab, and I keep explaining to them, you need to pay attention to those signs.

According to the Houston Health Department, there are millions of contaminants in floodwaters covering most of the city. Arsenic, lead, heavy metals in floodwater sediment also were repeatedly found.

Dr. Redd, following Hurricane Harvey, what role did the CDC play in warning affected communities of possible water-borne risk and other public health risk.

Dr. REDD. So, in general, in that part of the response, we were working in support of EPA. The kinds of things that we would do would be to try to make the kinds of warnings that you described, make sure people know those things. So, really, public health communications because of the flooding.

Mr. GREEN. OK. Additionally, not just from industry, but about 50 drinking water systems were shut down following Hurricane Harvey and more than 160 systems issued boil water advisories. This is an issue also we're seeing in Puerto Rico, which is still issuing boil water notices. However, given the lack of power, some people are not able to boil the water.

Dr. Redd, given that boiling water may not be an available option, what are some of the hazards of drinking potentially contaminated drinking water without boiling it? And how does the CDC communicate these hazards?

Now, we may be over it, I hope, at least in southeast Texas, but, again, in the Virgin Islands and Puerto Rico.

Dr. REDD. So the hazards that one would be exposed to drinking water that could be contaminated with sewage would be the things we've talked about before, gastrointestinal illnesses, the inability to do hand hygiene that prevents a lot of other diseases. And if there's Superfund site contamination, exposure to some of the materials in those waters.

Just to bring back one other point, that's one of the reasons that having the public health laboratory in Puerto Rico online again is so important so that that testing can be done, and when water is safe to drink, it will be easier to confirm when that testing is available.

Mr. GREEN. Thank you, Mr. Chairman. I know I'm out of time. But, you know, every year the upper Texas coast—I mean, every 7 or 8 years we get a hurricane or a tropical storm. So, you know, hopefully it will be that long a time.

But are we learning any lessons from Hurricane Harvey, both in southeast Texas, Louisiana, that could be applied in Puerto Rico or the Virgin Islands now? Or, hopefully, we are learning to be better prepared, particularly for our water system, because when they shut down, that's really a human need that we have to have.

And, Dr. Kadlec, you had mentioned that.

Thank you, Mr. Chairman, for letting me run over time.

Mr. GRIFFITH. I appreciate that, and thank you.

That being said, I now recognize myself for 5 minutes, and this will be the end. So you're almost done.

Dr. Gottlieb, black mold. All of the areas we've talked about, everybody knows there's going to be some black mold issues. But here's one of the issues that I'm not sure most Americans know. What are the symptoms? Because, obviously, if you see it, you're going to do something about it, or try to do something. But often-times it's a hidden concern.

So what should people be on the lookout for? You want to take it.

Dr. GOTTLIEB. I'd probably defer to CDC, if that's—

Mr. GRIFFITH. All right. That's fine.

Dr. REDD. You're absolutely correct, Chairman, that flooding leads to mold contamination.

There are two different hazards from exposure to mold. One is the worsening of allergic conditions. And that can be quite serious in the case of somebody that has asthma that's sensitive to mold. The other is, particularly for people who have weakened immune systems, infection from mold, that also can be very serious.

Mr. GRIFFITH. But how are they going to know? I recognize the seriousness. What are they going to be seeing?

Dr. REDD. Well, I think when building materials have been damaged, if mold can grow on it, it will. And so really it's a question of remediation. In other words, for porous surfaces, removing those surfaces and rebuilding. And for surfaces that aren't porous, cleaning them. That's the guidance in those areas, is what CDC has been providing, working with the Texas Department of Health.

Mr. GRIFFITH. All right. I guess I'm concerned that if you don't see it, you don't know it's there. I know that you're going to start

having some rasping, particularly if you have asthma. But what if you don't? Or what if you don't know about that? Isn't that one of the first ways you tell, is you start having some chest congestion?

Dr. REDD. Well, I think for areas that have floodwaters, you can tell where that floodwater has been.

Mr. GRIFFITH. OK. So you just do remediation. All right.

Dr. Kadlec, it's been a month. We have any hospitals in Puerto Rico that are not accepting patients?

Dr. KADLEC. Sir, there are about three that were closed. So there are some that have been—

Mr. GRIFFITH. That aren't open.

Dr. KADLEC [continuing]. Physically damaged to the point where they could not—

Mr. GRIFFITH. OK. And the ones that are open, are any of them refusing to accept patients?

Dr. KADLEC. Sir, on a daily basis, I don't know what their census are, but it could be the circumstance where they defer/divert patients. So I can't give you an affirmative answer.

Mr. GRIFFITH. We've talked about dialysis before. Any other specialized treatments that are currently unavailable at various hospitals?

Dr. KADLEC. Well, sir, dialysis is available through 46 of the 48 clinics on the island. Depending on the hospital, there may be some services that are not available. So I can't give you an affirmative, if I can take that for—

Mr. GRIFFITH. Let me ask you this. Because I read a report somewhere that even though dialysis was available, they were cutting short the treatment time period from what it normally would be. Is that still the case?

Dr. KADLEC. Sir, it is, and we're looking to actually work that problem out in terms of lowering the stress on some of those clinics where they see fewer patients or defer patients to places that have more functionality.

Mr. GRIFFITH. All right. And that brings up the United States Navy Ship Comfort.

Dr. KADLEC. Yes, sir.

Mr. GRIFFITH. It's sitting out there, hadn't had a whole lot of patients. And this is a question my colleague gave to us earlier—what is the approval process or the admission process to get on or to be approved for the Comfort?

Dr. KADLEC. Yes, sir. The plan is very simple, is that the island was not cut in half, but based on the swath of the hurricane that came through, westward side, eastward side, on the east side referrals of any high acute patients, intensive care patients, that need to be made from hospitals that are on the east side of the island would go to Centro Medico, which is their level one trauma center, and that would be done through ground or rotary-wing transportation.

The determination of whether those patients would be moved to Centro Medico, same as to the Comfort, would be based on decisions by the clinicians at Centro Medico that would review and talk to the doctors at the local hospitals to say: What is this patient suffering from? What kind of care do they need? What kind of service do they need?

Mr. GRIFFITH. And I appreciate that.

Dr. KADLEC. So based on that, then they would be transferred to eastward—

Mr. GRIFFITH. One of my concerns, I recognize some might argue that it's good that you haven't sent more to the Comfort, I think we have got an asset down there we're not using.

Dr. Gottlieb, biggest long-term concern that you have, both for Puerto Rico and otherwise? What's your biggest concern that FDA may be having?

Dr. GOTTLIEB. Well, our biggest long-term concern right now from a public health standpoint is that we may face product shortages of critical medical products heading into the first quarter. We are going to do everything we can to head them off.

My biggest long-term concern for the island of Puerto Rico is that if we don't do our job and help these facilities stand back up in a timely fashion we could start to see some of the production move out of the island, and I think that would put a strain on the Puerto Rican economy. And so part of our solidarity to the people of Puerto Rico is to make sure we maintain that production down there. It's an important part of the island.

Mr. GRIFFITH. And I appreciate that.

I see that my time is up. I yield back.

Ms. DEGETTE. Just following up on that. Also, it would take away good jobs from the island if those facilities start to close down. Is that right?

Dr. GOTTLIEB. That's right. About 90,000 people are directly employed by the industry. These are very high-paying manufacturing jobs relative to other manufacturing jobs on the island. It's an important part. Depending on the estimates, it's anywhere between 20 to 30 percent of the GDP of Puerto Rico, a very important part of the island.

Mr. GRIFFITH. In conclusion, I want to thank all of the witnesses and the members who participated in today's hearing. I remind members that they have 10 business days in which to submit questions for the record. I ask that the witnesses all agree to respond promptly to the questions that they may receive after the hearing from members.

I have to tell you, I learned a lot. This was a good hearing. Thank you all for participating. You all contributed greatly, and I think I have a better understanding.

I do look forward—and maybe you all can suggest where we should go—but I do look forward at some point to the committee and the subcommittee perhaps visiting the islands to see what we've got and, perhaps, as well, the other areas that have been affected by the recent hurricanes.

With that being said, the committee is adjourned.

[Whereupon, at 12:38 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

The New York Times

<https://nyti.ms/2zAren3>

'Like Going Back in Time': Puerto Ricans Put Survival Skills to Use

Using generators, rationing and even bonfires, Puerto Ricans have had to get creative to survive weeks without power or regular water and food after Hurricane Maria.

By CAITLIN DICKERSON and LUIS FERRÉ-SADURNÍ OCT. 24, 2017

SAN JUAN, P.R. — A grandmother turned a school bathroom sink into a bath. Neighbors are piling into a garage for communal meals prepared on an old gas stove. A 79-year-old man made a bonfire out of fallen tree branches to cook.

More than a month after Hurricane Maria tore through Puerto Rico on a path of destruction that spared no region, race or class, residents of the island have found their creativity stretched to the limit as they try to function without many amenities of the modern world.

It is not just water and electricity that are in scarce supply. Cellphone service ranges from spotty to nonexistent. Cars are damaged and roads blocked. For many, work and school still have not resumed, so they wander the streets, play board games and sit around telling stories by candlelight.

"It's like going back in time," said Kevin Jose Sanchez Gonzalez, 25, who has been living in darkness since Sept. 5, the day before a previous storm, Hurricane Irma, began to chip away at Puerto Rico's electrical grid.

Crammed into homes three or four families at a time, living on canned and freeze-dried food without any means of turning it into a hot meal, and sleeping in shelters, Puerto Ricans have been learning to make do, sometimes in extreme ways.

A Home in a Tool Shed

As the sun set in the shantytown of La Perla in Old San Juan, Ramón Marrero, 79, slumped onto the unwashed cot inside his brother's tool shed, where he had lived since Maria claimed his home.

A single light bulb illuminated the other contents of the bare, musty room: two plastic chairs piled with clothes, canned fruit and vegetables, and a single gas burner.

Mr. Marrero, a community elder known to his neighbors as Don Ramón, draped a towel over his bare back to fend off the mosquitoes. Earlier, he had walked to the post office to charge his cellphone and mobile battery pack.

The only electricity he had seen since the storm came from an extension cord connected to a shared generator donated by Luis Fonsi, the Puerto Rican pop singer who filmed the video for the hit song "Despacito" in La Perla.

Mr. Marrero was hesitant to plug in the light bulb or his electric fan — only one could be used at a time — because he was afraid to overheat the machine or take energy from his neighbors.

Residents of the barrio say they were left to clear garbage and other debris on their own after the storm because municipal workers had failed to show up. Like Mr. Marrero, they were using fallen branches to fuel bonfires for cooking.

Lorel Cubano, the director of a local nonprofit, said most of the aid the neighborhood had received was from private citizens and celebrities like Mr. Fonsi. "The government hasn't arrived here," she said.

Fear in the Darkness

Georgia Lopez Ortiz, 92, is one of many elderly residents of the Luis Lloréns Torres housing project who have been too scared to walk outside since Maria wiped out the streetlights. The notoriously crime-ridden development is the largest in the Caribbean, and is dominated by rival gangs. Residents say it has become even more dangerous in the dark.

Ms. Ortiz's washing machine does not work, so she has been hand-washing clothes in a bucket. She cannot cook, so her daughters bring her food every few days.

When aid groups visit, she throws a rope through the security bars that enclose her patio, and uses it to pull up packages of water and dried goods.

Raquel Mercado, 69, lives in a cramped one-room apartment with her 37-year-old son. Her car has not worked since it was flooded during the storm, so she has not been able to get to a bank to withdraw cash or to a pharmacy to refill her prescriptions.

She is selling snacks out of her apartment to bring in some money.

"What else is there to do?" Ms. Mercado said. "We're stuck here."

Baseball, Wine and Long-term Guests

A baseball game blared from speakers connected to a projector screen in Maricarmen del Llano's living room. The adults drank red wine as they cleaned up from a dinner of fried chicken and mashed potatoes.

Even in the well-off parts of the island, though, life is not quite normal.

For the last month, seven extended family members, including a newborn, have been living with Ms. del Llano, a school psychologist; her husband, a veterinarian; and their two children, ages 7 and 9.

The whole house is running off a powerful generator. Overnight, they use the machine to run air-conditioning in each bedroom.

Tangie Sobrino, Ms. del Llano's cousin and the newborn's mother, is getting ready to move back home with her husband, a lawyer, and their two other young children. They were preparing to purchase a \$5,200 generator.

"Our reality is not the norm," Ms. Sobrino said, referring to the many Puerto Ricans for whom recovery was much further off.

From Good Life to Discomfort

The storm also revealed what had been carefully hidden cracks in the upper echelons of Puerto Rican society, which has been imploding during a decade-long recession.

Inside her two-story home with multiple balconies and a pool, Maria Julia Martinez's stainless-steel refrigerator, espresso machine and toaster oven have been gathering dust. The family's flooring business had tanked in recent years, and they could not use the appliances because they did not have \$2,000 to fix their broken generator in the backyard.

They have a much smaller generator that could support a couple of small appliances at a time, but to save gas money and prevent it from breaking down, the family runs the machine only at night. They use a propane camping stove and a barbecue to prepare food.

When Ms. Martinez's husband cranked on the small generator one night last week, she ran off to do a couple of laundry loads on the efficiency cycle. Afterward, the entire family, including their pets, went to sleep on mattresses set up on the floor of their upstairs master bedroom. A small air-conditioning unit in the room provided a respite from the rest of their home, which felt like a dark and steamy cave all day and night.

"This is living in hell," Ms. Martinez said. She acknowledged that despite their discomfort, her family was still much better off than most people on the island. "I feel bad for feeling bad."

A New Level of Poverty

Inside the elementary school classroom that has become their temporary home, Iris Perez and her two adult daughters sat in plastic chairs, slapping mosquitoes on their exposed arms and legs and staring blankly, as if it was too hot to speak.

Like nearly half of Puerto Ricans, they had been living in poverty before the storm. But Maria swept away their ocean-side home, and banished them to a new level of destitution.

This emergency shelter was better than the last; here there were showers and the family had the classroom to itself. Before, the women — along with Ms. Perez's brother, son-in-law, and two young granddaughters — had slept next to other families and bathed with cups of water, filled up in the bathroom sinks.

Hand-washed clothing hung from fluorescent lights on the ceiling. A bookshelf had become a medicine cabinet, with deodorant and baby shampoo stacked in front of school books. Filing cabinets were diaper changing stations.

Nashali Reyes, Ms. Perez's oldest daughter, was seven months pregnant, and worried about contracting the Zika virus. Her 2-year-old daughter Charyliz bobbed around the classroom with a blanket and bottle in her hands, seemingly unbothered by the bug bites on her face, which had become swollen and infected because she was allergic.

"It doesn't matter what we do," Ms. Reyes said, gesturing to a bottle of repellent. They had to keep the windows and doors open, they said, to maintain a livable, if extremely uncomfortable, temperature.

A message written on a whiteboard reminded them to keep their temporary home clean. "Welcome," it said in Spanish, "May God bless you."

Communal Living

Felix Cruz was holding court for his neighbors at a dining table in his garage. His home had been transformed into a motel and soup kitchen of sorts, because of his two extra bedrooms and large furniture, including a couple of sofa beds where people were crashing.

Most of the neighborhood's residents are retired and living on fixed incomes. They cook and eat communally using a 40-year-old gas stove that has been dragged out of storage and scraped clean of cockroach eggs and mold.

They have been cramming their food into a small freezer in Mr. Cruz's backyard, opening it as little as possible to preserve the cold air.

The neighbors pooled money to pay for gas to power a small generator that could support a couple of fans, and are eating two meals a day, usually rice and whatever meat is on sale.

They eat on fine china, even though doing dishes in the dark is a pain, to try to distract themselves from their discomfort.

"It was difficult before because food was expensive, electricity was expensive, and now it's even worse," Mr. Cruz said. He pointed to Alma Gonzalez, 67, one of the neighbors he said had become like family. "When she has money, she pays. When I have money, I pay. That's life."

Correction: October 24, 2017

An earlier version of this article contained an imprecise translation of a message at a shelter that was written in Spanish. The message said "May God bless you," not "God has blessed you."

You can follow Caitlin Dickerson on Twitter @itscaitlinhd, and Luis Ferré-Sadurní at @luisferre.

The New York Times

Connect the dots all year.

Save up to 75% on the subscription of your choice and gain unparalleled insight from reporters in 140+ countries worldwide.

Basic

\$10 \$8/month

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

November 9, 2017

The Honorable Robert P. Kadlec, MD
Assistant Secretary for Preparedness and Response
Department of Health and Human Services
200 Independence Avenue, S.W., Room 639-D
Washington, DC 20201

Dear Dr. Kadlec:

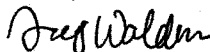
Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, October 24, 2017, to testify at the hearing entitled "Examining HHS's Public Health Preparedness for and Response to the 2017 Hurricane Season."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Tuesday, November 28, 2017. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Ali.Fulling@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Greg Walden
Chairman

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

Questions for the Record

Robert Kadlec, MD

**U.S. Department of Health and Human Services
Assistant Secretary for Preparedness and Response**

House Energy and Commerce Subcommittee on Oversight and Investigations

Examining HHS's Public Health Preparedness for and Response to the 2017 Hurricane Season

Tuesday, October 24, 2017

Unless Otherwise Noted, Responses Accurate as of December 19, 2017

Rep. Greg Walden:

- 1. Does the U.S. Department of Health and Human Services (HHS) have access to real-time information about the status of hospitals and other health care providers in the affected regions?**

HHS uses multiple sources of information to gain information about the status of hospitals and other healthcare facilities.

Because a national health care facility monitoring and reporting system does not exist, state and local officials often times have the best source of information. In some states like Texas, the reporting system is highly developed. In other areas, like Puerto Rico, it is not. When state and local governments do not have real-time information, HHS must rely on a wide range of resources to provide as near real-time information as possible.

For example, the Centers for Medicare & Medicaid Services' (CMS) Kidney Community Emergency Response (KCER) Program coordinates regular calls with the dialysis community. This call includes dialysis facilities, renal networks, private sector partners, and Federal, state, territorial, and local officials. Through this effort, HHS can learn about the real-time status of dialysis facilities directly from the providers and via renal network administrators in the impacted area.

CMS also reaches out to state survey and certification offices to obtain an updated report on the status of facilities. This includes hospitals, skilled nursing facilities, dialysis, and others as deemed appropriate based on the emergency. The information that CMS collects is geospatially mapped to the Office of the Assistant Secretary for Preparedness and Response's (ASPR) GeoHEALTH platform to provide all responders and leaders with a consistent update about health care infrastructure.

In addition to the role CMS plays, the ASPR's Division of Fusion captures, analyzes, and interprets information before, during, and after an emergency, to ensure that decision-makers receive timely and updated situational analysis and information. Fusion's efforts related to this specific effort included monitoring social media to determine status of facilities. The Health Resources & Services Administration (HRSA) maintains contact during and after emergencies with health centers.

While maintaining true real-time information remains challenging, HHS pursues all avenues to get the most timely and accurate information to ensure patients receive the care they deserve.

a. How does HHS obtain information about the status of health care providers in the affected regions?

With data from CMS, ASPR's Geographic Information System (GIS) shares information with state and local partners through static maps or by directly networking with their own GIS tool, if available. Additionally, ASPR uses open and social media sources for health care facility status updates and provides this information through a social media report. This information is currently used only for situational awareness purposes and not for designating an official status.

b. Can you provide information about: (a) whether the health care system in Texas is stabilized; and (b) the percentage of hospitals in Texas that are fully operational?

While Hurricane Harvey presented significant challenges to the health care system in Texas; the system proved very resilient. Lessons learned from previous storms combined with Federal and private investments in resiliency programs prevented significant damage.

The health care system in Houston, Texas, has remained stable since October 2017. Of its 652 licensed general and specialty hospitals, two are still closed post-Hurricane Harvey with no immediate plans to reopen. This means that 99.7 percent of hospitals in Houston are fully operational at this time.

Information about the two hospitals that remain closed:

- East Houston Regional Medical Center is a Hospital Corporation of America (HCA) facility that has sustained damage from multiple flood events in recent years. HCA closed the facility, moved physicians and staff, and redirected patients to other area HCA facilities. They are assessing how to best serve the community going forward and may build a new facility, but have no plans to reopen the currently vacated facility.
- Care Regional Medical Center in Aransas Pass remains closed. The

facility was damaged during Harvey's initial landfall and has not reopened. There have been multiple discussions between the Federal Emergency Management Agency (FEMA) and HHS about available support to help it reopen. While the facility was insured, it is a privately-owned, for-profit hospital. The regional health care coalition in the area, Coastal Bend Regional Advisory Council, has worked with the local emergency medical service (EMS) provider and other area facilities (including a free-standing emergency department associated with Corpus Christi Regional Medical Center that is 12 miles away from the Care Regional site) to address any gaps that may have emerged as a result of Care Regional's closure.

- c. Can you provide information about: (a) whether the health care system in Florida is stabilized; and (b) the percentage of hospitals in Florida that are fully operational?**

Florida's health care system has stabilized since Irma, but the state continues to face an increased demand for care and bed space as a result of the evacuees from Puerto Rico, including dialysis patients evacuated to Florida to receive specialized care. One hospital in particular, Fishermen's Community Hospital in Marathon, Florida, is still recovering from significant hurricane impact. It anticipates operating from a mobile hospital unit for the foreseeable future. At least one small hospital in the state was damaged by the hurricane and did not re-open. However, it was in the process of closing prior to the storm.

- d. During the hearing, the Office of the Assistant Secretary for Preparedness and Response (ASPR) testified that 60 percent of hospitals in Puerto Rico were connected to the grid as of that date. Can you provide information about: (a) the percentage of hospitals in Puerto Rico that are now connected to the grid; and (b) the percentage of health care providers in Puerto Rico that still do not have power?**

As of April 2, 2018, only one of Puerto Rico's 68 hospitals is operating on generator power. The details on the number of providers remaining without power is not available at this time.

- e. During the hearing, ASPR testified that the U.S. Army Corps of Engineers was assessing the hospitals in the U.S. Virgin Islands that were destroyed by Hurricanes Irma and Maria. Can you provide information about: (a) whether the U.S. Army Corps of Engineers has completed this assessment and, if so, the findings of the assessment; and how long it will take to restore the health care system in the U.S. Virgin Islands.**

At the request of FEMA, via the Mission Assignment (MA) process, and through the Unified Coordination Group (UCG), the U.S. Army Corps of Engineers (USACE) conducted initial assessments of the impacted facilities in the United States Virgin Islands (USVI). These initial assessment reports were provided to FEMA for further

direction. Both hospitals will need significant rebuilds and short, mid, and long-term solutions are being worked out with the local government to restore health care services.

2. **HHS, in coordination with federal partners including the Federal Emergency Management Agency (FEMA), pre-deployed a significant amount of federal assets in response to the recent hurricanes. According to ASPR's testimony, HHS sent 439 tons of medical equipment and supplies to the affected areas. How does HHS decide the type and amount of medical equipment and supplies to send to an affected region?**

HHS decides what type and the amount of medical equipment and supplies to send based on the state, territorial, local, or tribal planning assessments for future operations; and assessments conducted on the ground by HHS officials. State and territorial health leadership must approve assets HHS recommends deploying. HHS equipment and supplies are configured to support HHS response teams and provide full wrap-around services and sustainment for responders. This includes comprehensive health care and services, mortuary support, and incident management support in the affected areas. HHS pre-deployed assets to Texas, Florida, and Puerto Rico so that the materials and personnel were ready to meet the needs of Americans immediately after the storm passed.

- a. **Did HHS send similar types and amounts of medical equipment and supplies to each of the affected regions following Hurricanes Harvey, Irma, and Maria?**

Yes, the National Disaster Medical System (NDMS) and United States Public Health Service (USPHS) officers who deployed to each of the three responses used similar equipment, supplies, and assets for their operation. Equipment and supplies are packaged and maintained as a part of HHS' preparedness posture. ASPR manages and maintains over \$70 million in response materials and supplies including vehicle fleets; medical, laboratory, pharmacy, and mortuary caches; communication kits; and shelter systems.

In addition, HHS's Strategic National Stockpile (SNS) deployed Federal Medical Stations (FMS). FMSs are non-emergency medical centers that can provide care for displaced persons with special health needs. These needs include chronic health conditions, limited mobility, or mental health issues that cannot be met in a shelter for the general population.

- b. **Once the assets have been sent to the affected regions, what, if anything, needs to be done for the affected regions to use the assets?**

HHS response assets are configured for rapid deployment and setup in the field by trained HHS responders. Assets are managed and utilized by Federal responders, not by local officials, during response operations.

- c. **How long on average did it take HHS to get the medical equipment and supplies to the affected regions?**

HHS maintains regional warehouses to ensure resources are available quickly and without delay. During the response to Hurricanes Harvey, Irma, and Maria, initial resources (both equipment and personnel) arrived and were pre-staged in the anticipated impact area prior to the storms making landfall.

- d. **Did HHS encounter any delays in using federal assets to respond to the hurricanes because of paperwork or other administrative issues? If so, are there any areas where the federal government could streamline the processes associated with asset deployment?**

HHS is still working on after action reports that will include successes and challenges encountered in the response. HHS will work to correct these challenges and notify Congress if congressional action is needed.

3. **What are some of the biggest challenges HHS faced in executing the Agency's public health and medical preparedness and response functions following the recent hurricanes?**

ASPR has helped save hundreds of lives, treated thousands of patients, and has provided critical medical response resources and assets to impacted communities as a result of Hurricanes Harvey, Irma, and Maria. After each response, including these most recent response efforts, ASPR conducts a corrective action process to assess lessons learned and to evaluate the implementation of public health and medical activities as part of National Response Framework (NRF) Emergency Support Function (ESF) #8 responsibilities. ASPR is currently engaged in evaluating the most recent response efforts and is developing a corrective action process and lessons learned report. This information is shared through the annual budget justification process.

- a. **What plans does HHS have to address these challenges?**

HHS will execute plans to address any challenges that are identified in the after action reports.

- b. **What can we do to improve health care provider preparedness for these types of emergencies?**

In 2015, ASPR and CMS launched the HHS emPOWER initiative to provide public health and health care facilities, first responders, and emergency managers with timely information about electricity and health care service community-based populations. This information has helped hospitals, emergency medical services, and other health providers better anticipate, plan for, and respond to the needs of these individuals.

ASPR incorporated CMS' conditions of participation for seventeen types of providers and suppliers that are essential for continuity of care in the event of a disaster. Specifically, the CMS final rule 3178-F "Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers," 81 FR 63860 (2016), requires initial onboarding training for health care providers according to their role in response and recovery, as well as follow-up training to ensure provider knowledge of emergency plans remains current. It also requires exercises for both inpatient and outpatient facilities to ensure that providers are readily able to execute and operationalize their emergency and communications plans in the event of an emergency or disaster. The implementation of this rule will make significant progress in preparedness.

ASPR is also open to other potential ways to educate and prepare health care providers for emergencies and disasters. This could include, for example, training as part of medical education programs or through continuing education credits that are required for medical provider certifications. ASPR supports the notion of a standardized, national training program of core competencies in health care and public health preparedness. Such a curriculum would ensure that health care providers receive the same basic, foundational training no matter where they are located and where they work. This would facilitate the ability of health care providers to serve as surge staff at other facilities.

Disaster behavioral health knowledge and skills are limited to mostly health care providers. As such, it is important to ensure that training is available within the disaster context and part of health care provider staff development plans, such as psychological first aid. It is also important to ensure the health and well-being of the health care workforce during and after a disaster. Workforce resilience can be enhanced through training and guidance. For example, ASPR developed a plan with the National Association of County and City Health Officials called *Building Workforce Resilience Through the Practice of Psychological First Aid* (Link: <http://nacchopreparedness.org/building-workforce-resilience-through-the-practice-of-psychological-first-aid/>).

Additionally, at the local level, options included coordinating with local pharmacies and other non-governmental organization partners. For example, CDC coordinated with local pharmacies to support vaccine delivery to affected jurisdictions.

4. In the past few months, we have seen three major hurricanes devastate multiple regions of the United States and its territories. How have these experiences impacted staffing at ASPR?

ASPR staff was stretched to the limit, but performed extraordinary tasks despite the unprecedented hurricane season. Before the storm, ASPR had numerous openings for fulltime employees. This created a situation where some staff hit annual and weekly pay caps responding to the hurricanes. Additionally, some staff worked seven days a week. Filling the emergency response related positions within ASPR is a top priority. In

addition to fulltime staff shortages, there were significant openings in NDMS intermittent Federal employees. Some NDMS members were forced to deploy multiple times with some deploying for over 100 days. Filling the vacancies of NDMS members is also a high priority.

a. Does HHS, and ASPR more specifically, have sufficient resources available to handle future responses?

Under ESF8, HHS has deployed approximately 2,500 personnel to support response and recovery efforts with respect to Hurricanes Harvey, Irma, and Maria. Among the HHS personnel deployed are NDMS team members and headquarters and regional staff who support incident command, logistics, and liaison efforts. While ASPR had sufficient staff to meet requirements, many staff worked well above the 40 hour work week. Currently, ASPR has a number of vacancies (both at headquarters and throughout its NDMS system). ASPR is actively recruiting qualified persons to fill these positions. However, direct hire authority (as requested in the supplemental appropriation delivered to Congress in November 2017 to support ongoing response operations) can help expedite this process.

While HHS has met all requests and requirements of the response and continues to support ongoing recovery efforts in the impacted communities; resource shortfalls are possible for some types of future responses. The threats facing the nation from increased natural disasters to threats from state and terrorist actors force ASPR and HHS operating divisions to prepare for situations that few could have imagined years ago. For the nation to be truly prepared for all threats, additional resources, to include staff, training, supplies/equipment, and supporting information technology systems, are necessary.

5. The Department of Health and Human Services (HHS) is the primary agency for ESF#8 related to public health and medical services, including all-hazard public health consultation, technical assistance, and support and potable drinking water, solid waste disposal, and other environmental issues related to public health.

a. Please detail all activities HHS engaged in under this function regarding potable drinking water, solid waste disposal, and other environmental issues related to public health under this authority for Hurricanes Harvey, Irma, and Maria.

Hurricane Harvey
HHS/CDC provided technical assistance, consultation, and support while serving on a multi-agency working group comprising representatives from the U.S. Environmental Protection Agency (EPA), Federal Emergency Management Agency (FEMA), U.S. Army Corps of Engineers (USACE), and the Texas Department of State Health Services

(DSHS). The purpose of the working group was to identify and discuss post-storm potable water infrastructure challenges and develop solutions for bringing impacted water systems to pre-storm functionality.

HHS/CDC worked with EPA, FEMA, and Texas DSHS to develop guidance for addressing contaminated household water wells that were inundated by Hurricane Harvey's floodwaters. HHS/CDC also worked with the Association of Public Health Laboratories (APHL) to assess laboratory capacity in Texas to process microbial well water samples and develop a written inventory that was used in household water sampling activities. In addition, HHS/CDC worked with EPA, FEMA, and Texas DSHS to convene a working group to plan and oversee efforts to test and disinfect household water wells in the Hurricane Harvey inundation zone. Several thousand wells have since been tested and disinfected under the working group's oversight.

Hurricane Irma

HHS/CDC conducted environmental health and safety assessments of special and medical needs shelters throughout south Florida following Hurricane Irma. Findings and corrective action suggestions were provided to shelter managers and/or appropriate shelter staff.

Per request by the Florida Department of Health, HHS/CDC deployed a subject-matter-expert to provide on-site technical assistance, consultation, and support on a wide range of environmental health recovery issues following Hurricane Irma including, but not limited to, monitoring and controlling selected mosquito-borne diseases in severely impacted counties and extremely active areas; training on mold awareness and mitigation efforts to reduce health impacts; and providing access to potable water by monitoring hurricane-related impacts to drinking water facilities and boil water advisories.

Hurricane Maria

According to FEMA's November 17, 2017 Hurricane Maria report, 83 percent of water treatment plant in Puerto Rico are operational, and 85 percent of clients of the Puerto Rico Aqueducts and Sewers Authority (PRASA) have access to drinking water. However, due to inconsistencies in the power-grid, treatment plant pumps have had difficulty maintaining pressure throughout the distribution lines. Combined with unknown line breaks and potential for contamination entry, Puerto Rico and St. Croix are still under a boil water advisory. The boil water notice has been lifted for St. Thomas and St. John.

- b. Please detail the interactions between HHS and the U.S. Environmental Protection Agency or State/Territorial agencies with primary enforcement authority for Federal environmental laws in support of ESF#8 for Hurricanes Harvey, Irma, and Maria.**

EPA participated in daily coordination calls and provided updates, when applicable, on related issues in communities impacted by Hurricanes Harvey, Irma, and Maria.

- c. **Please detail any funding requests or technical recommendations made to or denied by the Federal Emergency Management Agency for addressing water, waste water, solid waste, or other environmental issues related to public health under this function.**

Hurricane Harvey

A recommendation was made to FEMA to pay for the cost of household well water testing and disinfection in the Hurricane Harvey inundation zone. FEMA approved and provided payment for this request.

Rep. Gus Bilirakis**1. Would you discuss the current DMAT staffing shortage – has this been ongoing or a new development?****a. What is driving this shortage?**

In 2016, ASPR conducted a Threat and Hazard Identification and Risk Assessment (THIRA). The THIRA identified new threats and risks requiring appropriate mitigation strategies and associated training. Using the THIRA as a base, NDMS conducted an extensive analysis of the organization to ensure capabilities could meet missions. Among other items, NDMS reviewed staffing considerations to ensure capabilities could meet requirements. NDMS personnel are now required to meet specific fitness standards to ensure they are able to respond, as required, in austere environments. As NDMS implemented these standards, some personnel resigned. In addition, some vacancies within the NDMS system are due to the natural rotation (NDMS volunteer personnel no longer want to be rostered due to personnel commitments, etc.).

It is important to note that each new NDMS staff member who serves on a DMAT team must go through the normal extensive Federal hiring process. This process as of late, has taken significantly longer within HHS resulting in a large number of vacancies within the system. The hiring freeze also created a backlog.

b. How can we address these problems?

NDMS has completed its analysis of requirements, position description updates, and has initiated the hiring process to fill the current shortages of qualified personnel. However, direct hire authority (as requested in the supplemental appropriation delivered to Congress in November 2017 to support ongoing response operations) can help expedite the hiring process. Direct hiring authority would allow ASPR to fill current vacancies and ensure that an adequate number of personnel can continue to support impacted communities and provide effective real time response.

2. How is priority evacuation status determined?**a. When authorities are deciding which health care facilities to evacuate, do they currently take into consideration locations with a history of violations and ensuring these residents are not sheltering in place with bad actors placing them at a high-risk of sustaining injury or death?**

Patient placement and prioritization is a local decision. ASPR does not determine at which facilities patients are placed. The Federal Government *supports* the response efforts of the states and territories according to the needs and direction of the states and territories.

b. If no, should they?

Under federalism, these issues fall under the decision making authorities of the state, territory, local, and tribal governments.

3. Are there disaster Memorandum of Understanding between agencies like the US Postal Service and ASPR to deliver important health information following a crisis?

The U.S. Postal Service (USPS) and the Office of the Assistant Secretary for Preparedness and Response (ASPR) do not have a memorandum of understanding to address this area of health information delivery. The USPS will deliver materials for a fee based on the number of addresses. CDC was able to contract with USPS to hand deliver a one-page flyer with public health messaging to every residence on the U.S. Virgin Islands (USVI). The flyers were very well received by the residents of USVI. CDC sought to replicate this activity in Puerto Rico, but the cost of printing and shipping flyers from Atlanta at that time was cost prohibitive.

However, HHS has a number of internal public health communication platforms across its various operating divisions (OpDiv) and staff divisions (StaffDiv), such as the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), the Centers for Medicare & Medicaid Services (CMS), and the Health Resources and Services Administration (HRSA), for sharing important health information during disasters. ASPR also facilitates a number of voluntary partnerships with private sector health care partners who also communicate regularly with their clients.

4. Would you discuss how we can best streamline agency coordination to prevent bureaucratic overlap and redundancies which can lead to waste and unnecessary delays and hamper the effectiveness of response?

- a. ASPR leads, on behalf of HHS, the National Response Framework ESF#8 Public Health and Medical Service responsibilities. As part of those responsibilities, ASPR is responsible for coordinating the Federal response. After action reports will provide more detailed information on the changes that may be needed; however ASPR is already working with the Department of Defense, Department of Veterans Affairs, and other partners within HHS to better coordinate activities for future responses.
- b. **With a coordinated, interagency response, are there interagency goals that drive response and preparedness strategies?**

Interagency goals are driven by the National Response Framework (NRF) and its associated Emergency Support Functions (ESF). ASPR leads ESF #8 on behalf of HHS, which focuses on public health and medical aspects of the response, including the nation's health care system. The Administration for Children and Families (ACF) leads HHS's support of

FEMA-ARC led ESF #6, which concentrates on mass care and sheltering services. ASPR also supports ESF #6 in coordination with ACF.

c. If so, what are these goals?

The shared goal of the interagency is “a secure and resilient nation with capabilities required across the whole community to prevent, protect against, mitigate, respond to, and recover from the threats and hazards that pose the greatest risk.”

Rep. Frank Pallone

1. **As the Committee considers preparedness issues in light of hurricanes and other recent mass casualty events, can ASPR please confirm whether the Agency believes that existing competitive grant funds for trauma care are sufficient to allow us to adequately respond to these events or should the Committee consider reimbursement through CMS to provide these critical resources?**

Grant programs are an essential part of developing a health care system that is prepared and ready to respond to disasters and public health emergencies. However, grant funding is modest compared to the overall budget of key stakeholders including emergency medical service (EMS) providers, home health providers, and hospitals. Health care systems are primarily focused on creating value for patients with chronic medical conditions and are not focused on high consequence, low probability events. It is important to align regulation, certification, payment, and quality measurement initiatives with grant funded efforts to develop a community based approach.

Trauma systems are the foundation upon which a broader system of care to manage all-hazards can be built. Aligning grant funded efforts to develop coordinated community responses with regulatory and payment reform efforts could strengthen the preparedness of the nation's health care system.

2. **What has HHS done to ensure that rural communities and the islands of Culebra and Vieques have access to proper medical attention?**

For the more rural parts of Puerto Rico, HHS provided tents, generators, and air conditioning units to allow diagnostic and treatment centers to move out of their damaged structures and into safer locations. HHS also leads a task force to connect these centers with the Federal Emergency Management Agency (FEMA) to ensure they have access to assistance. Lastly, HHS worked with the Department of Defense (DoD) and the U.S. Corps of Engineers (USACE) to ensure they had communications access and an adequate number of generators early in the disaster. In regard to Culebra, Puerto Rico, HHS connected the community with the non-governmental organization (NGO) health care task force to ensure medical teams visited the island and provided medical care as needed. However, there was no formal request from Puerto Rico for the community of Culebra.

3. **The widespread devastation in Puerto Rico caused by Hurricane Maria had a direct effect on pharmaceuticals and medical device manufacturing facilities located on the Island. Has HHS partnered with the suppliers of life-saving medicines to treat Puerto Rico's residents? What has the agency done to ensure facilities are well-equipped to ensure consistent production for residents in Puerto Rico and the rest of the nation?**

During the initial response to Hurricane Maria, HHS staff from the Critical Infrastructure Protection (CIP) team worked at HHS headquarters and deployed to Puerto Rico to serve as private sector liaisons. These responders worked closely with staff on the HHS Incident Response Coordination Team, Puerto Rico's DOH, the Puerto Rico Electric Power Authority (PREPA), the Food and Drug Administration, National Voluntary Organizations Active In Disaster, the FEMA National Business Emergency Operations Center, and the Department of Homeland Security's (DHS) Office of Infrastructure Protection staff in order to find resources to assist the unique needs of the private sector. Many of the needs concerned the health care product supply chain, including drug and medical device manufacturing; product distribution in Puerto Rico; and product distribution from Puerto Rico to the continental United States and other markets. Examples of activities the team coordinated include:

- Prioritizing the landing of aircraft carrying medical supplies and drugs for both donations and normal distribution networks;
 - Finding space onboard departing aircraft to move supplies and drugs off the island;
 - Coordinating civilian and military resources to transport liquid oxygen supplies to the island after loss of power to local medical oxygen manufacturing facilities;
 - Sharing information with Puerto Rico's electric utility, PREPA, to recommend prioritization of key health care infrastructure including hospitals, clinics, manufacturing facilities, and blood distribution hubs; and
 - Coordinating private sector entities on the island to share resources with each other.
4. **There are varying reports on the total amount of hospitals in Puerto Rico. For instance, FEMA has reported a total of 67 hospitals. DOD has indicated there are 69. Can you confirm the total number? How many of those are fully operational? How many hospitals, dialysis centers and civilian health facilities have power fully restored and how many are relying on generators?**

ASPR's health care facility database identified 69 hospitals in Puerto Rico. This number matched the Puerto Rico DOH's list, and was used in the very early stages of the response. Through a significant amount of work conducting on-site assessments, it was determined that one of those hospitals was not a hospital but a specialty ward within a hospital. As assessments were completed, the last number reported was 68.

- a. **Follow-up: are there sufficient health care personnel in each of these hospitals and facilities to treat patients?**

The best source of current information regarding staffing issues would be the Puerto Rico DOH and the Puerto Rico Hospital Association.

5. **The amount of patients being treated by the USNS Comfort as compared to its capacity is dismal. The USNS Comfort can receive up to 1,000 patients. How many patients has the ship served on a daily basis since arriving on Puelto Rico? Why is one of the largest medical facilities in the United States fleet being underutilized?**

Although the *USNS Comfort* can be configured and staffed as a 1,000-bed trauma hospital for combat missions, it was deployed to Puerto Rico in a Defense Support of Civil Authorities (DSCA) mission in a tailored humanitarian 250-bed configuration. The *USNS Comfort* could have expanded to 1,000 beds if additional support was needed; the U.S. Government and DoD never received a request to increase *USNS Comfort*'s operational 250-bed configuration. The ship was sent to support civilian authorities (the Puerto Rico Department of Health [DOH] in coordination with Centro Medico and HHS).

Shortly after arrival, the *USNS Comfort* promptly received multiple high-acuity, critical care/ICU patients from two Puerto Rican hospitals that had catastrophic generator failures. Additionally, the presence of *USNS Comfort* in San Juan after October 27, 2017, enabled a disaster medical assistance triage area with HHS and the Puerto Rico DOH that provided care to patients. Over the course of a 44-day relief mission (October 3 – November 15, 2017), 6,003 outpatients were seen in both tents and onboard the ship at the *USNS Comfort* location. The ship saw an average of 139 patients per day. A total of 1,993 patients were seen onboard the ship due to levels of care that exceeded initial triage capabilities, conditions requiring levels of care that exceeded the onshore treatment capabilities, or because they were directly referred to the ship via the Puerto Rico DOH medical operations center. A total of 290 patients were admitted to the *USNS Comfort* as inpatients.

- a. **When did the USNS Comfort arrive in Puerto Rico?**

October 3, 2017.

- b. **When did the USNS Comfort begin accepting patients?**

October 3, 2017.

- c. **Follow-up: What is the process for patients in need of medical care to be treated there?**

Upon *USNS Comfort*'s arrival to San Juan on October 3, 2017, the JFO Medical Operations Center (MOC), located in the San Juan Convention Center, was established in order to unify all patient related agencies in one location. Led by Joint Forces Land Component Command (JFLCC), it was also used to expedite requests from the Puerto Rico DOH through Centro Medico to HHS and the DoD. The MOC was manned 24/7 by members of Puerto Rico DOH, HHS, the Joint Force Maritime Component Commander (CTF-189), and the Joint Force Land Component Commander.

The initial agreed upon protocol was for all requests to be funneled through Puerto Rico's Level 1 Trauma Center, Centro Medico, which would analyze its capability/capacity to care for patients. If the request was to exceed Centro Medico's capability/capacity, the patient transfer request from Centro Medico's administration would come to the MOC for action. The MOC, with all its personnel, would assess the request and coordinate with *USNS Comfort* for acceptance and receipt of patient. This was done to ensure that the *USNS Comfort* had the medical capability to care for the patient. This protocol lasted for a period of two weeks and was modified due to Centro Medico's inability to keep up with local demands, hence the establishment of a new protocol.

The primary intent of the new protocol was to gain flexibility, responsiveness, and efficiencies required to expeditiously address patient movement requests to the *USNS Comfort*, the U.S. Army Combat Support Hospital, and the U.S. Air Force Expeditionary Medical System in Puerto Rico. The new procedure, approved by the Puerto Rico DOH, allowed all operational regional hospitals to bypass Centro Medico and call the MOC directly. This new process improved DoD's ability to accept patients.

The MOC, when notified that a patient needed to be moved, always reviewed a patient condition to determine which DoD or civilian hospital was best equipped for further treatment.

d. How has FEMA communicated this information to Puerto Rico's Department of Health, hospitals, and other health facilities?

Defer to FEMA

6. What are HHS, CDC, and other involved federal agencies doing to ensure local Puerto Rico government employees have the necessary health and safety equipment to protect themselves during their ongoing relief and recovery work?

HHS is coordinating with the Occupational Safety and Health Administration (OSHA) to support occupational safety and health issues that arise during the response. HHS is aware that OSHA's National Alliances agreed to donate personal protective equipment (PPE), including gloves, hard hats, and reflective vests, to help protect volunteers and workers performing hurricane recovery and clean-up efforts in Puerto Rico and the U.S. Virgin Islands (USVI).

Within HHS, the Centers for Disease Control and Prevention (CDC) developed health communication materials that provide information to employers, workers, and volunteers responding to Hurricane Maria on ways to stay protected from a variety of response and recovery hazards. Shortages such as the low number of respirators in the USVI had been reported. HHS is working to understand the reason for the shortages. HHS engaged the commercial supply chain partners to better understand

current personal protective equipment (PPE) shortages and inform commercial decision making and activities to improve access in Puerto Rico and USVI.

a. Which federal government agencies are responsible for providing needed Personal Protective Equipment (PPEs) to relief and recovery workers?

Federal Medical Station (FMS) sets include PPE as part of the equipment and supplies necessary to establish and operation each station, and the FMS sets deployed for the 2017 hurricane responses were fully stocked and included PPE. There is no single agency officially responsible for providing PPEs during an emergency. The employers of health care workers are responsible (and accountable by OSHA regulations and state and local laws) to ensure that their employees have access to necessary PPE. To support the needs of relief and recovery workers, HHS has provided training to worker camps and larger work sites to ensure the workforce understands the requirements and what it can do to protect themselves. In addition, local health departments and OSHA conduct periodic site assessments about the use and provision of PPE for relief and recovery workers.

7. If power is still out in January, how would this impact the following areas?

a. Hospital services

As of December 12, 2017 (the last date where this data was reported) all 68 hospitals in PR are open with seven operating on generator power. Hospitals operating on grid power may lose grid power if the grid remains unstable. Of the hospitals running on generator power, the generators may need to be replaced if they are operating for long periods of time.

b. Health clinics

As of January 24, 2018, 69 of 83 (83 percent) non-mobile HRSA-funded health center service delivery sites were operating on grid power. Health centers operating on grid power may lose power if the grid remains unstable. Of the 14 sites running on generator power, the generators may need to be replaced if they are operating for long periods of time.

c. Water filtration

HHS defers to EPA.

d. Wastewater

HHS defers to EPA.

8. What is the current status of the following services in Vieques, Culebra, St. Croix, St. Thomas, and geographically remote parts of Puerto Rico in each of the following areas:

a. Hospital Services

Schneider Regional Medical Center on St. Thomas and Governor Juan F. Luis Hospital on St. Croix are both operating on grid/utility power and water, but at significantly reduced capacity and capability. An interim/temporary facility is being explored in order to allow each facility to effect repairs/replacement, but no solid timeline has yet been established.

b. Health Clinics

As of January 24, 2018, HRSA-funded health centers on Culebra, Vieques, St. Thomas, and St. Croix report that they are open.

- Healthpromed (HPM) Foundation Inc. (Culebra) and HPM Foundation Inc. Municipality (Vieques) are both open and operating on generator power.
- St. Thomas East End Medical Center (St. Thomas, USVI) has one HRSA-funded health center service delivery site in scope, which is open and operating on grid power.
- Frederiksted Health Care, Inc (St. Croix, USVI) has five HRSA-funded health center service delivery sites in scope, and all are open. Four are on grid power, and one (St. Croix Education Complex School Health Center) is on generator power.

As of January 24, 2018, six other geographically remote HRSA-funded health center service delivery sites are operating on generator power.

- Concilio de Salud Integral de Loiza, Inc (Loiza)
- Corporacion de Servicios de Salud y Medicina Avanzada (Las Piedras)
- Salud Integral en la Montana, Inc (Toa Alta)
- Neomed Center Inc (Aguas Buenas)
- Prymed Medical Care, Inc. (Ciales)
- Prymed Medical Care, Inc. (Vega Baja)

All other geographically remote sites are operating on grid power.

c. Water Filtration

HHS defers to EPA on this issue.

d. Wastewater treatment

HHS defers to EPA on this issue.

9. If roads and transportation infrastructure remains disrupted through next year, how would that impact the supply of products in the following areas to geographically remote areas in Puerto Rico as well as Vieques and Culebra:

- a. Pharmacy services**
- b. Medical supplies**

For both pharmacy services and medical supplies, the transportation issues that barred the delivery of medical products and pharmaceutical products have been cleared. However, a handful of facilities in central Puerto Rico have had roadways washed away and are awaiting bridge repairs to reduce future impacts.

10. When do you expect all medical services to be fully and readily available on St. Thomas and St. Croix?

- a. How long will HHS staff be on the ground in these areas, providing medical services?**

ASPR will remain on the ground as long as it takes to fulfill the mission, as requested by USVI.

- b. What medical services are currently available? What medical services available before the hurricanes are not available, and when will those services be restored?**

The DOH for USVI has the most up to date assessment of what is available and needed. HHS is available to aid efforts and specific tasks as requested by USVI.

11. Mental and behavioral health impacts of the storm:

- a. What actions have been taken to address the mental and behavioral health impacts of the storm?**

During the 2017 hurricane response, HHS deployed more than 210 mental health officers and behavioral health staff to the impacted areas. The mental health teams conducted more than 7,000 force protection contacts, acute interventions, and assessments in shelters and operation centers for survivors and field staff. The officers focused on conducting broad assessments and addressing acute behavioral health needs, as well as working with community providers to facilitate identifying recovery needs and determining how to address them moving forward. HHS formed a Recovery Task Force that has a behavioral health-specific working group to determine ongoing and anticipated mental and behavioral health needs, in addition to implementation strategies to consider.

HHS also engaged in numerous support activities through the Substance Abuse and Mental Health Services Administration's (SAMHSA) disaster-related initiatives. SAMHSA, in coordination with partners such as CDC, the Health Resources Services Administration (HRSA), and ASPR, provided behavioral health technical assistance, consultation, coordination, and disseminated resources to state, territory, local, tribal, and non-governmental organizations responding to the disasters. CDC, working in collaboration with SAMHSA, created materials for children to be distributed at schools on coping with stress. The SAMHSA-funded Disaster Distress Helpline has responded and addressed 10,061 calls and texts from the impacted areas. SAMHSA also provided grant flexibilities for the impacted regions to meet needs caused by the storms.

Efforts have been underway to ensure that clients on medication-assisted treatment for substance use could continue treatment by granting permission for service providers to issue take-home medications and to allow guest dosing in impacted areas. SAMHSA provided staff to the Secretary's Operation Center, Joint Field Offices and Emergency Operation Centers in impacted regions to assure behavioral health continuity, connection to SAMHSA programs, and workforce protection services. FEMA, in partnership with SAMHSA, administers the federally funded supplemental program Crisis Counseling Assistance and Training Program grants to areas impacted by the storms. This program hires and trains local crisis counselors to conduct outreach, brief interventions, and provide referral for survivors. This program hires and trains local crisis counselors to conduct outreach, brief interventions, and referral to survivors. Programs are up and running in all areas.

b. What have these assessments concluded?

Behavioral health continues to be a priority as hurricane affected areas begin recovery efforts. Behavioral Health Liaison Officers worked as part of the Incident Response Coordination Team and worked with deployed Mental Health Teams throughout the response to determine current and emerging behavioral health needs. CDC also included mental health questions in community surveillance tools.

Overall, assessments have concluded that high levels of anxiety and grief resulted from the storms, including anger and frustration. People with pre-existing conditions struggled without access to care. The establishment of crisis counseling outreach programs has allowed states, territories, and localities to access data about the evolving behavioral health needs of their communities as the recovery continues.

c. What mental health services is HHS currently providing in affected areas, and how long will these services be available?

In collaboration with ASPR, FEMA and SAMHSA administer the Federal award for the Crisis Counseling Assistance and Training Program which hires and trains local crisis counselors to conduct outreach, brief interventions, and make referrals for the

survivors. These programs are up and running in all hurricane affected areas and will operate for nine months from the date of award.

d. What current actions is HHS taking to address long-term mental health issues stemming from this storm?

Working through the ASPR-led HHS Recovery Task Force, SAMHSA has convened an interagency workgroup of HHS entities with interest in behavioral health, the Behavioral Health Recovery Workgroup, to find ways to incorporate state programing and meet ongoing recovery needs. ASPR is including mental and behavioral health as a priority area for Recovery Support Function efforts and will be including field staff with behavioral health expertise as part of ongoing technical assistance and guidance being provided to the affected states and territories. An emphasis on assisting affected localities in ensuring access to support and treatment will be part of these efforts.

Rep. Jan Schakowsky**1. Following up**

- a. What is HHS, CDC, and other federal agencies doing to ensure local Puerto Rico government employees have the necessary health and safety equipment to protect themselves during their ongoing relief and recovery work?**

Federal Medical Station (FMS) sets include PPE as part of the equipment and supplies necessary to establish and operate each station, and the FMS sets deployed for the 2017 hurricane responses were fully stocked and included PPE. The Department of Health and Human Services (HHS) is coordinating with the Occupational Safety and Health Administration (OSHA) to support occupational safety and health issues that arise during a response. HHS is aware that OSHA's National Alliances agreed to donate personnel protective equipment (PPE), including gloves, hard hats, and reflective vests, to help protect volunteers and workers performing hurricane recovery and clean-up efforts in Puerto Rico and the U.S. Virgin Islands (USVI). The Centers for Disease Control and Prevention (CDC) has developed public health communication materials that describe how employers, workers, and volunteers responding to Hurricane Maria can stay protected from a variety of response and recovery hazards.

- b. Have these issues been addressed in Puerto Rico?**

Shortages and low supplies of respirators in USVI have been reported. HHS has engaged commercial supply chain partners to better understand current PPE shortages and inform commercial decision makers and guide activities for improving access in Puerto Rico and USVI.

- c. Which federal government agencies are responsible for providing needed PPEs to recovery workers?**

There is no single agency responsible for providing PPE during an emergency. The employers of the workers are responsible (and accountable by OSHA regulations and state and local laws) to ensure that their employees have PPE. To support the needs of relief and recovery workers, HHS has provided training to worker camps and larger work sites to ensure the workforce understand the requirements and what they can do to protect themselves. In addition, the local health departments and OSHA conduct periodic site assessments about the use and availability of PPE for relief and recovery workers.

Rep. Kathy Castor

1. **I also heard from these health professionals that water sanitation is one of the biggest issues in Puerto Rico right now, which is leading to gastrointestinal issues as well as systemic infections. How is the Administration helping get clean water to Puerto Rico, especially to remote areas? Additionally, how is HHS working with health professionals on the ground to treat illnesses stemming from the lack of clean water?**

CDC/ATSDR field staff in Puerto Rico have facilitated contacts between EPA and the Puerto Rican authorities. We also currently have a representative on a workgroup dealing with water quality.

CDC is working with EPA and public health officials to identify health risks and prevent illnesses from unsafe water and to restore public health capacity. CDC conducted basic water testing immediately following the hurricane and EPA followed up with additional testing for fecal contamination.

Both CDC and EPA have worked with Puerto Rico and the U.S. Virgin Islands (USVI) to educate home- and business owners of methods of treating their household water to reduce their risk of waterborne disease.

2. **Physicians have told me they are seeing other health issues such as asthma, COPD, conjunctivitis, scabies, diabetes, and hypertension being exacerbated due to lack of medications, power, transportation and supplies, increased air pollution from generators and unsanitary living conditions. Is HHS monitoring this situation, and what steps are being taken to address these additional health issues?**

ASPR led health care facility assessments in Puerto Rico. These assessments focused on predominantly structural integrity issues.

CDC headquarter staff recommended additional island wide active surveillance to track disease outbreaks. CDC was able to partner with Department of Veterans Affairs health care facilities in Puerto Rico to establish a sentinel surveillance system in three of the largest facilities on the island. This system provided situational awareness for Federal and territorial partners on infectious disease syndromes and exacerbation of chronic diseases. This system provided information in places where power and internet connectivity did not allow for routine surveillance information to be transmitted. The CDC team abstracted over 13,800 medical charts, provided weekly reports to all partners, and briefed leadership on findings. It provided concrete information about syndromic influenza illnesses and leptospirosis, both high priority pathogens of concern to the community and our partners. Additionally, the system identified exacerbation of mental health issues attributable to the hurricanes and individuals with symptoms and exposure suggestive of carbon monoxide poisoning, prompting further engagement of clinical and

public health partners. This system was in place from the end of October 2017 to the end of January 2018.

CDC also published a Health Alert Network (HAN) Health Advisory: Advice for Health Care Providers Treating Patients in or Recently Returned from Hurricane-Affected Areas, including Puerto Rico and the U.S. Virgin Islands. This advisory reminded clinicians assessing patients in or recently returned from hurricane-affected areas to be vigilant for certain infectious diseases, including leptospirosis.

In addition, CDC worked with PRDH and CDC Foundation to create a laboratory transport system, for key diseases of concern (flu, TB, leptospirosis). Since October 20, 2017, CDC received samples from over 1,100 patients with suspected leptospirosis, TB, and influenza in Puerto Rico. Testing is ongoing, and results continue to be reported to the Puerto Rico Department of Health.

CDC communicated generator-use safety messages in multiple languages through print, broadcast, internet and social media and other channels such as Clinician Outreach Communication Activity call (COCA) and a Health Alert Notice. Thousands of safe generator-use and Carbon Monoxide (CO) poisoning awareness door hangers and flyers have been distributed in hurricane-affected areas. CDC has provided technical assistance to Texas and Florida for CO poisoning surveillance. CDC has also provided technical assistance to Puerto Rico, USVI, and the American Academy of Pediatrics on public messaging to prevent CO poisoning.

CDC staff have deployed to Texas, Puerto Rico, and USVI to support state and territorial health departments in monitoring and addressing health issues related to air pollution from improper generator use and mold in flood-damaged buildings. CDC has several guidance documents for homeowners, workers, and clinicians about mold remediation, personal protective equipment, and cleanup, and mold safety for medically vulnerable populations and patients with asthma. These have been developed, updated, translated to multiple languages, and distributed online and in print to all affected areas.

HHS's Strategic National Stockpile (SNS) deployed six Federal Medical Stations (FMS) into Puerto Rico. FMSs are non-emergency medical centers that can provide care for displaced persons with special health needs. These needs include chronic health conditions, limited mobility, or mental health issues that cannot be met in a shelter for the general population. As of November 17, 2017 all FMS in Puerto Rico had officially been signed over to the Puerto Rico Department of Health.

CDC also continues to provide technical assistance to PRDOH regarding immunization program activities and supports vaccine needs. As part of this effort, SNS has procured \$2.3 million worth of vaccines and ancillaries to support PRDOH vaccination programs targeted to protect people from vaccine preventable disease. CDC is also coordinating with HHS to procure vaccines to support immunization program efforts in USVI.

To date, CDC has not received requests from Puerto Rico to support disease surveillance. CDC stands ready to support epidemiological and surveillance activities for infectious and non-infectious diseases, as needed for Puerto Rico.

On November 12, 2017, CDC personnel deployed to assist in investigations of disease on as requested by USVI. The CDC team will assist USVI Department of Health with patient screening guidance and rapid diagnostic tests for both diseases, leptospirosis and melioidosis, that will supplement pre-existing arbovirus disease syndromic surveillance activities. The team will also assist in the coordination of shipping diagnostic samples to CDC for confirmatory testing, investigating confirmed and probable cases of leptospirosis and melioidosis in an attempt to discover the exposures that led to infection, and conducting public and clinician outreach and education regarding leptospirosis and melioidosis. In addition, CDC has placed posters about leptospirosis within clinics and hospitals around the island. Over a million fact sheets were distributed to residents of Puerto Rico and USVI letting them know about the risk for infectious diseases following a natural disaster and what precautions to take. Once power began to be restored these public health messages were further distributed via radio and social media messaging.

Rep. Pete Olson

- 1. After tackling 3 Hurricanes in a short period of time, what strain s have you seen on your current resources. Also, what additional resources do you need to provide these communities the help that they need?**

In responding to the three hurricanes, the Office of the Assistant Secretary for Preparedness and Response (ASPR) deployed approximately 2,500 National Disaster Medical System (NDMS) personnel, deployed 944 tons of equipment and logistics, and treated 36,370 patients. However, responding to three near simultaneous hurricanes has resulted in ASPR significantly drawing resources from its medical caches, logistics equipment, and NDMS teams. ASPR is currently understaffed for day-to-day logistical requirements supporting hurricane response and recovery efforts. Direct hiring authority would allow ASPR to fill current vacancies and ensure that an adequate number of personnel can continue to support impacted communities and provide effective real time response.

Deploying multiple teams of U.S. Public Health Service (USPHS) staff as mental health officers, some for two or three deployment periods, created a strain on available assets. This resulted in assets in the field being stretched to the limits of existing capacity.

Rep. Gus Bilirakis

1. **Does the Hospital Preparedness Program currently allow States to use grant funds to help defray costs associated with procurement and maintenance of generators for assisted living facilities and skilled nursing facilities to support the development and sustainment of regional healthcare coalitions?**

Hospital Preparedness Program (HPP) funds may not be used for this purpose. HPP awardees and their sub-recipients may provide funding to individual hospitals or other health care entities, as long as the funding is used for activities to advance regional, health care coalitions (HCC), or health care system-wide priorities, and are in line with the Office of the Assistant Secretary for Preparedness and Response's (ASPR) four health care preparedness and response capabilities.

HPP funding to individual health care entities shall not be used to meet Centers for Medicare & Medicaid Services (CMS) conditions of participation, including CMS-3178-F *Medicare and Medicaid Programs, Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers*. CMS-3178-F requires providers and suppliers to meet the following conditions of participation:

- **Development of an emergency plan.** Develop an emergency plan based on a risk assessment using an all-hazards approach focusing on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters specific to the location of a provider or supplier. HPP funding may not be provided to individual health care entities to meet this requirement; however, ASPR encourages HCCs to provide technical assistance to their individual members to assist them with the development of their emergency plans. HCCs are permitted to use HPP funding to develop the staffing capacity and technical expertise to help their members meet this requirement.
- **Develop policies and procedures.** Develop and implement policies and procedures based on the plan and risk assessment. HPP funding may not be provided to individual health care entities to meet this requirement; however, ASPR encourages HCCs to provide technical assistance to their individual members to assist them with the development of policies and procedures. HCCs are permitted to use HPP funding to develop the staffing capacity and technical expertise to help their members meet this requirement.
- **Develop and maintain a communication plan.** Develop and maintain a communication plan that complies with both Federal and state law. Patient care must be well-coordinated within the facility, across health care providers, and with state and local public health departments and emergency systems. HPP funding may not be provided to individual health care entities to meet this requirement; however, ASPR encourages HCCs to provide technical assistance to their individual members to assist them with the development of a communication plan that integrates with the HCC's communications policies and procedures.

HCCs are permitted to use HPP funding for costs associated with adding new providers and suppliers to their HCC who are seeking to join coalitions to coordinate patient care across providers, public health departments, and emergency systems (e.g., hiring additional staff to coordinate with new HCC members, providing communications equipment and platforms to new members, conducting communications exercises, securing meeting spaces, etc.).

- **Develop and maintain training and testing program.** Develop and maintain training and testing programs, including trainings, and conduct drills and exercises or participate in an actual incident that tests the plan. HPP funding may not be provided to individual health care entities for individual health care organizations' trainings and exercises. HPP funding may be used to plan and conduct trainings and exercises at the regional or HCC level.

Medicare skilled nursing facilities and Medicaid nursing facilities are required to have back up power. This requirement was established before the CMS Emergency Preparedness Final Rule, and is set out at 42 C.F.R. 483.90(b).

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

November 9, 2017

The Honorable Scott Gottlieb, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Gottlieb:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, October 24, 2017, to testify at the hearing entitled "Examining HHS's Public Health Preparedness for and Response to the 2017 Hurricane Season."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Tuesday, November 28, 2017. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Ali.Fulling@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Greg Walden
Chairman

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations
Attachment



U.S. FOOD & DRUG
ADMINISTRATION

APR 27 2018

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Walden:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the October 24, 2017 hearing before the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, entitled "Examining HHS' Public Health Preparedness for and Response to the 2017 Hurricane Season." This letter is a response for the record to questions posed by the committee.

If you have further questions, please let us know.

Sincerely,

John Martin
Principal Associate Commissioner
for Legislative Affairs

Page 2 – The Honorable Greg Walden

Your questions have been restated in bold below, followed by our responses.

The Honorable Greg Walden

1. Approximately how many of the pharmaceutical and medical device manufacturing facilities in Puerto Rico are still operating on generator power?

a. How much longer can the facilities using generator power continue to rely on generator power?

As of October 24, 2017, we believe most, if not all, facilities are operating on generator power. While generators allowed many facilities to restart production, they are not a long-term solution.

Updates on this status can be found on FDA's website.

b. Has the Food and Drug Administration (FDA) identified any preservation concerns or access issues associated with temperature-controlled pharmaceuticals, and if so what is it doing to address them?

FDA has undertaken swift and extensive efforts to prevent or limit the loss or shortage of multiple drugs critical to American patients due to challenges related to refrigeration, storage, and transportation. We have also been working closely with manufacturers to relocate products, and have been following critical infrastructure work done by our federal partners including: clearing roads to reach facilities; helping manufacturers procure fuel to keep generators running; and securing permissions to allow planes to land in Puerto Rico and fly critical products to the continental United States.

c. How many pharmaceutical and medical-device manufacturing facilities in Puerto Rico are fully functional?

As of October 24, 2017, we do not believe that many of the medical product facilities are fully functional. For pharmaceuticals, most are producing at anywhere from 20 percent to 70 percent of their normal capacity based on our own informal survey. One firm is producing at 100 percent of pre-hurricane output but they have dialed back certain other portions of the facility.

Updates on this status can be found on FDA's website.

d. As the crisis in Puerto Rico has evolved have any new challenges arisen for pharmaceutical and medical device manufacturing facilities in Puerto Rico? If so, what steps is FDA taking to address those issues?

FDA is prioritizing its work with facilities that make critically important medical products to prevent or limit the impact of nationwide shortages. FDA is actively working with several companies who have requested assistance from FDA because their

manufacturing facilities in Puerto Rico were impacted by the hurricanes. And, we are working closely with the Federal Emergency Management Agency (FEMA) and other government partners as well. Our interventions have evolved as the nature of the risk has changed and our response progresses. Early on, we helped individual firms secure landing rights for planes to fly out finished products that were in some cases at risk of being destroyed by flooding warehouses. We are also working – with other government partners – to help facilities obtain fuel to keep generators running and, in certain cases, medical-grade gases that are used by some manufacturers.

A key challenge for the medical products facilities is obtaining access to the power grid. Many generators are old and not meant to function for months on end, and many facilities cannot return to full production on generator power alone.

As of October 24, 2017, we continue to be in contact with all firms that manufacture medical products we consider critical, where a falloff in production and an ensuing shortage could have public health implications. FDA is working to prevent and mitigate shortages of critically important medical products. We believe we have a good understanding of the potential risks and are taking steps to mitigate them. We are working with some companies to import medically necessary drugs from alternate manufacturing sites approved by a designated regulatory body, expediting review related to the import of medically necessary drugs from manufacturing sites that are not FDA approved, expediting review and approval of other dosage forms and generic versions, and approving production test methods to allow faster release of drug products to the market.

The Honorable Gus Bilirakis

1. What challenges still exist for Florida and what are your post-storm recommendations?

FDA recognizes that Hurricane Irma has led to hardships for many, and impacted drug and device manufacturers, as well as food and agriculture operations in Florida. FDA has been working closely with drug and device manufacturers in all the affected areas to help prevent or mitigate a shortage, both before and after Hurricane Irma. Crops and agriculture that were impacted by Hurricane Irma include citrus, avocados, tomatoes, sweet corn, bell peppers, sugarcane, cotton, and dairy from Florida. FDA has provided guidance to the industry regarding the safety evaluation of flood affected crops for human and animal consumption, as well as guidance for food manufacturers, warehouses, and transporters of food affected by floods or power outages.

Additionally, local intermittent blood shortages occurred in areas of Florida impacted by the storms. However, the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism, of which FDA is an active member, ensured areas impacted by the storms had sufficient levels of safe blood products on hand to meet local medical support requirements, primarily through coordination networks comprised of non-profit independent national and regional blood centers.

2. What resources are available to communities like mine impacted by Irma?

FDA recognizes that these hurricanes have presented unique challenges for those in the affected areas, and the Agency is committed to working with those who were impacted, as well as with our Federal and state partners, to help prevent or mitigate issues.

FDA has conducted assessments of the impact of Hurricane Irma on FDA-regulated firms and industries. For Hurricane Irma, FDA's Florida District Incident Management Team (IMT) conducted more than 2,380 post-storm assessments, and FDA staff remains available to answer any questions and provide assistance when appropriate.

The Honorable Frank Pallone, Jr.

1. The widespread devastation in Puerto Rico caused by Hurricane Maria had a direct effect on pharmaceutical and medical device manufacturing facilities located on the island. Has FDA partnered with the suppliers of life-saving medicines to treat Puerto Rico's residents? What has the agency done to ensure facilities are well-equipped to ensure consistent production for residents in Puerto Rico and the rest of the nation?

As an agency dedicated to promoting public health, and as fellow Americans, the staff at FDA are doing all they can to support the immediate needs of those affected by the destruction of these devastating storms. We are also working closely with our HHS colleagues and Federal partners to address the unique challenges facing Puerto Rico. FDA continues to work closely with medical product manufacturers to ensure availability of products that meet rigorous FDA standards for safety and efficacy. FDA is focusing on facilities that make critically important medical products to prevent or limit the impact of nationwide shortages.

Our interventions have evolved as the nature of the risk has changed and our response progresses. We are working closely with FEMA and other government partners. Early on we helped individual firms secure landing rights for planes to fly out finished products that were in some cases at risk of being destroyed by flooding warehouses, we have also worked to help facilities obtain fuel to keep generators running and, in certain cases, medical-grade gases that are used by some manufacturers, and to help local manufacturers who provide sterilization services to hospitals to get back online.

2. During your testimony before this Committee on October 24 you stated that Puerto Rican pharmaceutical plants manufacturer 30 products that are considered "critical medicines" and that of those 30, 14 are sole-source products meaning that there are no alternative drug products available.

a. Are all plants which manufacture the 30 critically-important products operating at full capacity today?

As of October 24, 2017, we do not believe any of the medical product facilities are fully functional. Most are producing at anywhere from 20 percent to 70 percent of their normal capacity based on our own informal survey. One firm is producing at 100 percent of pre-hurricane output but they have dialed back certain other portions of the facility. We continue to monitor the situation and provide assistance as appropriate.

Updates on this status can be found on FDA's website.

b. Has the FDA evaluated how long each such plant can continue to operate under current conditions?

Our focus continues to be on plants that make critically important products and we are taking steps to try to mitigate the shortages that have occurred but are also looking at situations where we see the potential for a product to tip into shortage. We are typically looking out one-to-two months for what we think could potentially happen if full production does not resume.

c. What contingency plans has the FDA considered in the event that power and other capabilities are not restored by the first quarter of next year?

As of October 24, 2017, we continue to be in contact with all the firms that manufacture medical products we consider critical, where a falloff in production and an ensuing shortage could have public health implications. The FDA is working to prevent and mitigate shortages of critically important medical products. We believe we have a good understanding of the potential risks and are taking steps to mitigate them. We are working with some companies to import medically necessary drugs from alternate manufacturing sites approved by a designated regulatory body, expediting review related to the import of medically necessary drugs from manufacturing sites that are not FDA approved, expediting review and approval of other dosage forms and generic versions, and approving production test methods to allow faster release of drug products to the market.

3. On October 20 you released a statement that Puerto Rican manufacturers produce 50 types of medical devices that are critically important to patient care because they are life-sustaining and/or because they are produced by the only manufacturer of that device type. According to your statement, blood-related medical devices are of particular concern.

a. Are all plants which manufacture the 50 types of medical devices operating at full capacity today?

As of October 24, 2017, we do not believe that many of the medical product facilities are fully functional. We continue to monitor the situation and provide assistance as appropriate.

Updates on this status can be found on FDA's website.

b. Has FDA evaluated how long each plant can continue to operate under current conditions?

Our focus is on plants that make critically important products and we are taking steps to try to mitigate the shortages that have occurred but are also looking at situations where we see the potential for a product to tip into shortage. We are typically looking out one-to-two months for what we think could potentially happen if full production does not resume.

c. What contingency plans has the FDA considered in the event that power and other capabilities are not restored by the first quarter of next year?

As we continue to monitor at-risk devices, FDA will take other steps as appropriate to mitigate the potential for shortages, including considering, when necessary, importing a device from outside of the U.S. or allowing manufacturers to shift production to alternative sites.

4. What is the status of delivery of essential medical products to geographically remote areas such as Vieques, Culebra, St. Croix and St. Thomas?

FDA works with manufacturers to assess and address the overall, national supply of medical products. Regarding localized transportation and distribution of essential medical products, FDA defers to the HHS Assistant Secretary for Preparedness and Response.

The Honorable Jan Schakowsky

1. Following up, in the aftermath of disasters like these devastating hurricanes, government should provide relief and recovery workers with required health and safety protections and Personal Protective Equipment (PPEs) to ensure workers' health is not compromised during current and on-going clean-up and future rebuilding. Unfortunately we have heard that this is causing problems in Puerto Rico. We know that Puerto Ricans in both the private and public sector want to do the work needed to help rebuild their lives, homes, communities and their Commonwealth. Government workers are willing and eager to help address short-term needs – even when working as assigned by the Puerto Rico government is outside their long-standing responsibilities and expertise. Nonetheless workers simultaneously want to protect their own health and safety and avoid unnecessary health problems. The long-term medical problems flowing from the tragic events on September 11, 2001 and the resulting cleanup efforts at Ground Zero and on the Pile taught us the vital importance of providing appropriate health and safety equipment and training to workers in conditions that are dangerous or uncertain.

a. What is HHS, CDC, and other federal agencies going to ensure local Puerto Rico government employees have the necessary health and safety equipment to protect themselves during their ongoing relief and recovery work?

Page 7 – The Honorable Greg Walden

- b. Have these issues been addressed in Puerto Rico?**
- c. Which federal agencies are responsible for providing needed PPEs to recovery workers?**

FDA defers to the Centers for Disease Control and Prevention to answer these questions.

The Honorable Pete Olson

- 1. After tackling 3 Hurricanes in the short period of time, what strains have you seen on your current resources? Also what additional resources to you need to help provide these communities that help that they need?**

FDA has spent about \$3 million as of mid-October for hurricane response activities. We continue to use funding from our current budget to pay for staff time, travel, and supplies. We are working with the Administration to determine additional funding needs to help pay for repair of FDA facilities and equipment damaged by Hurricanes Harvey, Irma, and Maria.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2827
Minority (202) 225-3641

November 9, 2017

Ms. Kimberly Brandt
Principal Deputy Administrator for Operations
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Brandt:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, October 24, 2017, to testify at the hearing entitled "Examining HHS's Public Health Preparedness for and Response to the 2017 Hurricane Season."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Tuesday, November 28, 2017. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Ali.Fulling@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Greg Walden
Chairman

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

**Kim Brandt's Hearing on
 "Examining HHS's Public Health Preparedness for and Response to
 The 2017 Hurricane Season"
 E&C O&I
 October 24, 2017**

The Honorable Gus Bilirakis

- 1. The "alternate/backup power" provision of the Emergency Preparedness Rule is final next month, what is the size of the pool of providers that are currently 'out of compliance' with this rule?**
 - a. Why despite having a year to comply, are these providers still out of compliance with this rule?**

Answer: Patient safety is a top priority at CMS, and we expect it to be the top priority in every single facility that participates in the Medicare and/or Medicaid program, including nursing homes. In order to become certified by CMS, a nursing home must meet basic health and safety requirements included in the Social Security Act and the Medicaid Requirements for Long Term Care Facilities. We expect facilities to meet these requirements at all times, even in emergencies. For long-term care facilities, including nursing homes, these requirements¹ incorporate requirements for infection control, quality of care, nursing services, and many others, including numerous emergency power² and preparedness³ standards. For example, they are required to have emergency power systems adequate enough to supply power for lighting all entrances and exits; equipment to maintain the fire detection, alarm and extinguishing systems; and life support systems, such as ventilators, in the event that normal electrical supply is interrupted. When life support systems are used, the facility must provide emergency electrical power with an emergency generator that is located on the premises. In addition, the long-term care facility must have an emergency plan, and must implement emergency and standby power systems based on that emergency plan.

Our requirements also outline resident rights. Every resident has a right to a safe, clean, comfortable and homelike environment, including receiving treatment and supports for daily living safely. For example, all CMS-certified long-term care facilities must provide comfortable and safe temperature levels; for those initially certified after October 1990, this is specifically defined as 71 to 81 degrees Fahrenheit. Facilities are expected to meet these requirements at all times, even during emergencies.

Using lessons learned from previous natural disasters, CMS updated and improved existing emergency preparedness requirements in our Requirements for nursing homes and other providers participating in Medicare and Medicaid by issuing an Emergency Preparedness Final

¹ 42 CFR Part 483

² 42 CFR §483.73(e)

³ 42 CFR §483.73

Rule.⁴ In our updates, we clarified that long-term care facilities, including nursing homes, must store emergency fuel and associated equipment and systems, and introduced additional testing requirements for their emergency and stand-by-power systems.⁵ The new standards became effective on November 15, 2016. Surveys to evaluate compliance with the new requirements will begin November 15, 2017, at which time we will assess whether additional resources are needed by facilities.

Transparency is an important part of CMS's patient safety work and CMS is committed to making sure that patients, their families and policymakers have the information they need about the health care facilities we oversee. CMS's Nursing Home Compare Website⁶ contains resident quality of care and staffing information for more than 15,000 Medicare and Medicaid nursing homes around the country. The website includes detailed reports on health inspections, life safety code inspections and any identified noncompliance deficiencies.

b. How are inspections prioritized: By provider size? By season? (testing northern providers during winter; southern providers during summer) By non-compliance history?

Answer: Certain Medicare participating facility types have statutorily-mandated survey frequencies: each individual nursing home must be surveyed at least every fifteen months; each home health agency must be surveyed at least every three years; and hospice facilities must be surveyed at least once every three years. Hospitals are also surveyed at least once every three years. In addition, surveys are conducted in response to complaints received from patients, providers, facility staff, or others who have concerns about a facility within our oversight. Complaint surveys can be performed at any time of the year, with the actual timing dependent on the severity of the allegation.

The Honorable Frank Pallone, Jr.

1. The Centers for Medicare and Medicaid Services (CMS) have established a special open enrollment period for hurricane victims. Since Puerto Rico receives medical coverage and benefits differently from U.S. states, what efforts are being made to ensure affected people in Puerto Rico are receiving aid?

Answer: CMS established a Federal Health Insurance Exchange special enrollment period, allowing certain individuals impacted by these hurricanes who experienced a qualifying life event to select a new 2017 Exchange plan or make changes to their existing plan at any time through December 31, 2017. In addition, individuals who reside in, or move from, areas affected by a hurricane in 2017 will be eligible for a special enrollment period that extends the 2018 Annual Open Enrollment Period through December 31, 2017. CMS also established a Medicare Part C and D special enrollment period, allowing individuals affected by the hurricanes to enroll in, dis-enroll from, or switch, Medicare health or prescription drug plans. It is available from the

⁴ <https://www.gpo.gov/fdsys/pkg/FR-2016-09-16/pdf/2016-21404.pdf>

⁵ 42 CFR §483.73(c)

⁶ <https://www.medicare.gov/nursinghomecompare/search.html>

start of the incident period and runs through the end of the calendar year.

In addition, we are dedicated to making sure all of our program beneficiaries impacted by the hurricanes are able to access their needed treatments and supplies. This is why we are using our waiver authority to give beneficiaries, providers, suppliers, and states the flexibility they need to meet emergency health situations. For example, CMS established a hotline to assist healthcare providers in Puerto Rico, the U.S. Virgin Islands, and several affected states in receiving temporary Medicare billing privileges, making sure providers will be appropriately reimbursed for their critical services. CMS also gave Medicare providers in locations impacted by the hurricanes the flexibility to move patients between facilities, administer care in almost any location, and approve out-of-state or out-of-network providers as needed, in order to ensure continuity of care.

2. There has been outward migration from the Island to mainland states. Those affected are still eligible for benefits. What efforts are being made to ensure that Puerto Ricans displaced by Hurricane Maria know about the enrollment period in the mainland and how to apply? Are any outreach efforts and materials being provided in Spanish?

Answer: CMS is committed to making sure our beneficiaries have access to necessary treatment, even when they have been evacuated. CMS has released materials in Spanish⁷ in order to make sure those who are still eligible for enrollment in Medicare through a Special Enrollment Period are informed. In addition, Medicare Beneficiaries and Exchange consumers can receive information about Special Enrollment Periods in English or Spanish by contacting the 1-800- MEDICARE or the Exchange Call Center. We are also working with our partners on the ground to see how we can better meet the needs of those in affected areas, including outreach efforts in Puerto Rico.

Addendum: On December 22, 2017, CMS released an FAQ addressing coverage issues for displaced Puerto Rican Medicaid, traditional Medicare, and Medicare Advantage beneficiaries in Florida.⁸ In addition, a Spanish translation of the FAQ will soon be available on the CMS website.

3. CMS extended open enrollment until December 31, 2017, for all Medicare beneficiaries and for those enrolled in plans through the Federal Health Insurance Exchange. It appears, however, that power and communications systems may continue to be severely restricted through that time period, and possibly into the first quarter of next year and beyond. What steps is CMS taking to ensure that affected individuals in Puerto Rico and the U.S. Virgin Islands will be able to obtain coverage even if electricity and/or Internet services are not restored by the end of the year?

⁷ Examples at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-10-30-3.html#>, <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-09-12.html>, <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-09-11.html>, <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-09-08-2.html>, <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-09-08-3.html>

⁸ <https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Questions-and-Answers-for-displaced-Puerto-Ricans-in-Florida-Englishpdf.pdf>

Answer: CMS is committed to making sure our beneficiaries have access to necessary treatment. Working with our partners on the ground in Puerto Rico and the U.S. Virgin Islands, we will continue to assess how we can best accommodate their needs.

Addendum: On December 19, 2017, CMS announced an extension until March 31, 2018 for the Medicare Part C and Part D special enrollment period allowing individuals affected by the hurricanes to enroll in, disenroll from, or switch plans in the event they were unable to make an election during another qualifying election period.

- 4. CMS has taken a number of actions to improve open enrollment in the Marketplaces and in Medicare, but to date, Medicaid has been largely absent from Administration activity. This is concerning given that, in Puerto Rico for example, more than half of the population receive their health coverage through Medicaid. Similarly, in both Florida and Texas, more than half of all births are financed by the Medicaid program, and more than 1 in every 3 children is covered through Medicaid. Given the volume and special needs for those with Medicaid coverage in Hurricane affected areas, what steps does CMS plan to take to provide clear guidance on disaster-related Medicaid coverage that addresses administrative burdens? For example, similar to the Administration's response during Hurricane Katrina, will this Administration take actions such as permitting a simplified Medicaid application or allowing for self-attestation for a temporary period of time for Hurricane victims in the absence of documentation?**

Answer: CMS is dedicated to making sure all of our program beneficiaries impacted by the hurricanes are able to access their needed treatments and supplies. This is why we are using our waiver authority to give beneficiaries, providers, suppliers, and states the flexibility they need to meet emergency health situations. There is considerable flexibility for states and territories to streamline and simplify enrollment in both Medicaid and CHIP in emergency situations. For example, for a limited time period:

- States and Territories have flexibility to permit enrollment of new applicants based on self-attestation of necessary information if regular verification sources and processes are not available, allowing eligibility criteria to be verified post-enrollment.
- Use of hospitals, providers and other qualified entities identified by the state to make presumptive eligibility determinations is also available to facilitate enrollment and ensure immediate coverage.
- States and territories also can extend deadlines for renewals when emergency circumstances prevent them from meeting ordinary deadlines.

States generally have flexibility to suspend premiums, enrollment fees and other cost sharing charges for beneficiaries impacted by a hurricane. CMS is available to provide states with technical assistance to ensure that needed state plan amendments or other authorities are in place.

The Honorable Jan Schakowsky

- 1. Following up, in the aftermath of disasters like these devastating Hurricanes, government should provide relief and recovery workers with required health and safety protections**

and Personal Protective Equipment (PPEs) to ensure workers' health is not compromised during current and ongoing clean-up and future rebuilding. Unfortunately, we have heard that this is causing problems in Puerto Rico.

We know Puerto Ricans in both the private and public sector want to do the work needed to help rebuild their lives, homes, communities, and their Commonwealth. Government workers are willing and eager to help address short-term needs - even when working as assigned by the Puerto Rico government is outside their long-standing employee responsibilities and expertise. Nonetheless, workers simultaneously want to protect their own health and safety and avoid unnecessary health problems. The long-term medical problems flowing from the tragic events on September 11, 2001 and the resulting cleanup efforts at Ground Zero and on the Pile taught us the vital importance of providing appropriate health and safety equipment and training to workers in conditions that are dangerous or uncertain.

- a. What is HHS, CDC, and other federal agencies doing to ensure local Puerto Rico government employees have the necessary health and safety equipment to protect themselves during their ongoing relief and recovery work?
- b. Have these issues been addressed in Puerto Rico?
- c. Which federal government agencies are responsible for providing needed PPEs to recovery workers?

Answer: CMS defers to the Centers for Disease Control and Prevention (CDC) and other HHS offices and components to respond to this question.

The Honorable Kathy Castor

1. A number of health professionals from the University of South Florida in my Congressional District traveled to Puerto Rico recently to see how they could support the health care needs of our fellow citizens there and a few will be going back in early November. One main concern of the physicians who went to Puerto Rico was how long it took to get the Emergency Medical Assistance Compact (EMAC) into place, which would allow medical professionals from the State of Florida to go to Puerto Rico and be able to practice under their Florida license.
 - a. Did you hear similar concerns from health professionals in other states?
 - b. What role does the federal government play in these compacts?
 - c. How can the federal government facilitate quick approval of these compacts to allow health professionals from other states to assist states or territories that have been impacted by a natural disaster?

Answer: The Emergency Medical Assistance Compact (EMAC) is a state-to-state mutual aid system under which states contract with other states or territories to send personnel, equipment

and commodities to assist with response and recovery efforts in other states/territories. Although CMS does not have a role in EMAC, there are many things CMS can do to help providers continue to take care of patients following disasters. For example, the Section 1135 waiver authority enables CMS to waive or modify certain Medicare, Medicaid, CHIP, Stark Law, and EMTALA requirements, including certain deadlines, quality reporting requirements, conditions of participation, and certification requirements. Providers can now submit waiver requests to the state survey agency or the CMS regional office,⁹ and they will be evaluated to ensure that they meet the requirements set out under the law. CMS has made all approved waivers and hurricane related information, such as Frequently Asked Questions and Presidential declarations, available on its website.¹⁰

In each of these emergency events, CMS is using our waiver authority to maintain access to care for Medicare and Medicaid beneficiaries by supporting the ability of providers, suppliers, hospitals, and other healthcare facilities that participate in those programs to provide timely care to as many people impacted by the storm as possible. For example, using our waiver authority, CMS:

- Gave Medicare providers in locations impacted by the hurricanes the flexibility to move patients between facilities, administer care in alternative locations, and approve out-of-network providers as needed to ensure continuity of care.
- Expedited Medicaid enrollment for out-of-state providers. This means providers can be reimbursed for services provided to beneficiaries who have been evacuated from locations impacted by the hurricanes, and allows reimbursement to providers who go into impacted areas to provide relief.

Though not a part of EMAC, CMS staff in Region II coordinated with the Puerto Rico Department of Health to develop and facilitate a process for credentialing of nurses and technicians from the mainland to provide relief for island healthcare personnel who were either working extended hours or were unable to get to work, especially in dialysis facilities on the island.

Addendum: On November 28, 2017, CMS approved a Medicaid waiver for the Puerto Rico Disaster Relief demonstration, which authorizes Puerto Rico to provide off-island medical coverage to Medicaid beneficiaries who are eligible for the Federal Emergency Management Agency (FEMA) Transitional Shelter Assistance Program who are temporarily relocated to New York and Florida. The effective date of the demonstration is November 13, 2017, and the waiver expires January 18, 2018.¹¹

The Honorable Pete Olson

1. **After tackling 3 Hurricanes in a short period of time, what strains have you seen on your current resources? Also, what additional resources do you need to provide these communities the help that they need?**

⁹ <https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Requesting-an-1135-Waiver-Updated-11-16-2016.pdf>

¹⁰ <https://www.cms.gov/About-CMS/Agency-Information/Emergency/Hurricanes.html>

¹¹ <https://www.medicare.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/?entry=44731>

Answer: Our approach to disaster preparedness and response has been informed by CMS's experience responding to Hurricane Katrina and other recent significant disasters. For example, the devastation of Hurricane Harvey taught us valuable lessons that allowed us to respond even more quickly for Hurricanes Irma and Maria.

HHS is working with the Administration to identify needs as they arise. To date, OMB has sent two emergency supplemental requests to Congress. The initial request included funding for organizations providing rapid emergency response, like FEMA's Disaster Relief Fund and the federal flood insurance program. We know that there are significant health care needs in the areas impacted by these hurricanes, including in Puerto Rico, and we look forward to working with Congress on how you can help us address these needs.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-3927
Minority (202) 225-3641

November 9, 2017

Rear Admiral Stephen C. Redd, MD
Director
Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dear Admiral Redd:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, October 24, 2017, to testify at the hearing entitled "Examining HHS's Public Health Preparedness for and Response to the 2017 Hurricane Season."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Tuesday, November 28, 2017. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Ali.Fulling@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Greg Walden
Chairman

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations
Attachment

Questions for the Record

Rear Admiral Upper Half Stephen C. Redd, M.D.
Director of the Office of Public Health Preparedness and Response, Centers for Disease Control
and Prevention
U.S. Department of Health and Human Services

House Energy and Commerce Subcommittee on Oversight and Investigations
Examining HHS's Public Health Preparedness for and Response to the 2017 Hurricane Season

Tuesday, October 24, 2017

The responses are current as of November 2017

The Honorable Greg Walden

- 1. According to the Centers for Disease Control and Prevention's (CDC) testimony on October 24, 2017, laboratories in Puerto Rico are not able to conduct any public health tests because of damage sustained during Hurricane Maria. As a result, the CDC is lending support and arranging clinical specimens for suspected priority infectious diseases-such as tuberculosis, leptospirosis, rabies, influenza, and salmonella-to be sent to the U.S. mainland for testing. To date, how many specimens has CDC sent to the U.S. mainland for testing?**

Since October 20, 2017, CDC has received specimens for testing various priority pathogens from Puerto Rico. CDC reports these results to the Puerto Rico Department of Health (PRDOH) for official confirmatory test results reporting. The PRDH is then responsible for publically reporting the results. As of November 25, 2017, CDC has assisted PRDOH with:

- Leptospirosis testing from 324 suspect cases, of which 42 have been identified as either a confirmed or probable case of leptospirosis.
- Tuberculosis (TB) testing from 59 suspect cases, of which 21 have been confirmed.
- Influenza testing from 65 suspect cases, of which 48 have been confirmed.

- a. Approximately how long does it take for CDC to receive a diagnostic result for the samples it sends to be tested on the U.S. mainland?**

CDC receives shipments of specimens three times a week from Puerto Rico for confirmatory disease testing. Actual testing times vary depending on the sample type and test being performed. Average testing times range from two to five days. For TB testing, tests are performed at multiple public health labs and some samples require repeat testing.

- b. What, if any, infectious diseases have been detected through the testing of these specimens?**

Please see the response to Question 1 above.

- c. Do the laboratories in Puerto Rico have generator power yet? If not, when does CDC expect the laboratories in Puerto Rico to be at least partially functional?**

As of November 27th, Puerto Rico Department of Health's (PRDOH) San Juan main facility which includes eight individual laboratories, is currently all powered by generators. PRDOH's satellite laboratories in Mayaguez and Ponce have power through the electrical grid. As of November 6th, PRDOH's satellite laboratory in Arecibo had power through a generator.

PRDOH's laboratories sustained significant damage during Hurricane Maria. It is important to note that there may be other reasons besides a lack of power, such as damaged testing supplies or equipment, which prevent the laboratories from operating as they did prior to the hurricane.

CDC will continue to work with PRDOH and other Federal agencies to re-establish important public health infrastructure such as disease surveillance and laboratory diagnostics.

d. Has CDC assessed what, if any, equipment from the laboratories can be salvaged?

As part of the work to get the public health laboratory back in operation, CDC experts deployed to Puerto Rico to assess immediate laboratory needs, including equipment and supplies that have been damaged and need to be fixed or replaced. CDC has also partnered with the Association of Public Health Laboratories to conduct a laboratory assessment to understand the current status of laboratory activities, prioritize activities to restore essential testing services, and determine long-term needs. This assessment identified a need for critical lab supplies and equipment to replace what was damaged during the hurricane. CDC is working with the CDC Foundation, in accordance with agency statutory authority, to fulfill these needs.

2. What disease risks have been detected by CDC's National Syndromic Surveillance Program in the affected regions?

CDC's National Syndromic Surveillance Program receives diagnosis codes reported by deployed Disaster Medical Assistance Teams during this hurricane response. The majority of patient encounters in Puerto Rico and U.S. Virgin Islands (USVI) by the Disaster Medical Assistance Teams have been related to injuries or existing chronic disease.

Additionally, CDC's hurricane response is working with PRDOH to help provide leptospirosis, tuberculosis, and influenza diagnostic testing. CDC reports these results to PRDOH for official confirmatory test results reporting. These results are then officially and publically reported by PRDOH. As of November 25, 2017, CDC has assisted PRDOH with:

- Leptospirosis testing from 324 suspect cases, of which 42 have been identified as either a confirmed or probable cases of leptospirosis.
- TB testing from 59 suspect cases, of which 21 have been confirmed.
- Influenza testing from 65 suspect cases, of which 48 have been confirmed.

In addition to the National Syndromic Surveillance Program, CDC has provided diagnostic testing to confirm the presence of leptospirosis, tuberculosis, and influenza cases in Puerto Rico. Moreover, CDC has numerous other disease surveillance programs that capture conditions of

public health importance. Of note, there may be lags in any identified conditions being confirmed and reported by PRDOH.

3. During the Agency's hurricane response efforts, has CDC identified any scarcities of medical supplies, such as vaccines, that could hinder the public health response efforts? If so, could you please elaborate?

As part of this response effort, CDC's Strategic National Stockpile has procured \$143,000 worth of vaccines to support Puerto Rican vaccination programs targeted to protect adults from vaccine preventable disease. CDC is also coordinating with HHS to procure vaccines to support immunization program efforts in USVI.

CDC defers questions related to pharmaceutical shortages due to the hurricanes to the FDA.

The Honorable Gus Bilirakis

1. Can you discuss public health surveillance post-storm?

To understand the burden of diseases in hurricane-affected areas, public health authorities rely on surveillance systems and the ability to conduct laboratory tests for specific diseases. In Puerto Rico and the U.S. Virgin Islands (USVI), surveillance and lab capacity have been greatly diminished due to Hurricane Maria. Identifying and controlling diseases of public health importance in hurricane-affected areas is a top priority for CDC and HHS. Through the Epidemiology and Laboratory Capacity cooperative agreement, CDC supports 64 jurisdictions (including all 50 states and U.S. territories) to help with prevention and surveillance efforts and build laboratory capacity for addressing infectious diseases. Puerto Rico Department of Health's (PRDOH) infrastructure sustained significant damage during Hurricane Maria, including to their laboratories. To date, the laboratories have only been able to conduct limited public health testing.

CDC provided in-the-field technical assistance and leadership to USVI, including two Community Assessments for Public Health Emergency Response (CASPERs). The CASPERs assessed immediate community needs, behavioral and physical health status, and vector control concerns to inform ongoing response and recovery efforts. On November 12, 2017, a CDC team deployed to USVI to assist in investigations of disease as requested. The CDC team is assisting the USVI Department of Health with patient screening guidance and rapid diagnostic tests for leptospirosis and melioidosis to supplement pre-existing surveillance activities. The team is also assisting in the coordination of shipping diagnostic samples to CDC for confirmatory testing, investigating confirmed and probable cases of leptospirosis and melioidosis in an attempt to discover the exposures that led to infection, and conducting public and clinician outreach and education regarding leptospirosis and melioidosis. CDC has also provided on-the-ground technical consultation to USVI regarding vector control.

In Puerto Rico, CDC's Dengue Branch resumed testing for arboviruses like Zika, dengue, and chikungunya in early October. This arbovirus disease surveillance supports preventing the spread of vector borne diseases in Puerto Rico by initiating mosquito surveillance in forests, open fields, swamps, and high- and low-density urban areas to determine mosquito densities and advise local and federal authorities on control measures. CDC has also developed and implemented a system

for transporting leptospirosis, influenza, and tuberculosis specimens from Puerto Rico laboratories to the continental United States for testing.

As part of the work to get the public health laboratory back in operation, CDC experts have deployed to Puerto Rico to assess immediate laboratory needs and have provided essential laboratory supplies. CDC has also partnered with the Association of Public Health Laboratories (APHL) to conduct a comprehensive assessment of laboratory needs. This assessment is critical to help ensure long-term laboratory capacity and positive health and public health outcomes of residents in Puerto Rico.

Syndromic surveillance is used to monitor health-related data that precede diagnosis and signal a probable disease case or outbreak. This surveillance system uses existing data as an early warning system of disease outbreaks, and water or food contamination. As part of response activities, CDC's National Syndromic Surveillance Program (www.cdc.gov/nssp) has partnered with Disaster Medical Assistance Teams (DMAT) in affected areas to collect all data on DMAT patient encounters. CDC has also partnered with the Department of Veterans Affairs (VA) to develop an enhanced surveillance system for Puerto Rico's main VA medical center and the island's two largest VA community-based outpatient clinics to monitor priority diseases of epidemic potential.

As part of the response to Hurricanes Irma and Maria, since September 2017 the Epidemiology Surveillance Task Force has been tracking infectious and non-infectious diseases in the affected states and territories using the methods below:

- Syndromic surveillance using Disaster Medical Assistance Teams and Department of Defense data,
- Department of Veterans Affairs Medical Center data for selected illnesses and injuries,
- Hurricane-related deaths through online media reports,
- Shelter surveillance, and
- Poison control center reports.

a. What public health and health care delivery challenges still exist?

This has been a challenging hurricane response and recovery effort. Especially in the territories, significant damage from the hurricanes has caused problems with water supplies, sanitation, food supply, electricity, transportation, shelter, communications, security, medical care, and mosquito control. Additionally, each of the affected areas—Texas, Louisiana, Georgia, Florida, Puerto Rico, and USVI—have distinct characteristics and challenges based on both their situation before the storms and the severity and characteristics of the three different hurricanes. The 2017 hurricanes that have hit the U.S. have been unusually frequent and intense compared to previous hurricane seasons. Hurricane Harvey took a serious toll on Texas, resulting among other things, in major mold issues from the extensive flooding. Florida was heavily impacted by Hurricane Irma, which took out more than 60 percent of the state's power after the storm, prompting many residents to use generators, and leading to many cases of potential carbon monoxide (CO) poisoning/death. For example, CO poisoning during Irma was attributed to 17 deaths (15 in Puerto Rico, one in South Carolina and one in North Carolina); and of the total poison exposure calls to National Poison Data System (NPDS), 16 were during Harvey, 165 during Irma, and six during Maria.

Infrastructure challenges in Puerto Rico and USVI before the storms compounded the devastating impact of Hurricanes Irma and Maria. For example, prior to the storms, power outages in Puerto Rico were common, as a result of aging energy infrastructure.

Communicable disease outbreaks of diarrhea and respiratory illness can occur when water and sewage systems are not working, and personal hygiene is hard to maintain as a result of a disaster. Crowded living conditions in shelters can also create conditions for infectious disease outbreaks. It is critical for the public health system to quickly set up tracking systems that monitor illnesses in hurricane-affected areas. CDC is working closely with Puerto Rico and USVI, and other Federal agencies to re-establish important public health infrastructure such as disease surveillance and laboratory diagnostics.

b. Have previous public health hazards (like Zika) been heightened? If so, how do we proactively address during our recovery process?

Significant damage from the hurricanes has caused problems with water supplies, sanitation, food supply, electricity, transportation, shelter, communications, security, medical care, and mosquito control. Post-hurricane environmental conditions may pose an increased risk for the spread of infectious diseases among persons in or recently returned from hurricane-affected areas. Contaminated drinking water and reduced access to safe water, food, and shelter in some areas may create conditions for outbreaks of infectious diseases such as leptospirosis, hepatitis A, typhoid, vibriosis, Zika, dengue, chikungunya, and influenza.

Post-hurricane transmission of mosquito-borne diseases such as Zika remains a threat. CDC's Dengue Branch, located in Puerto Rico, and the PRDOH Laboratory have resumed testing since the hurricanes. CDC resumed testing on October 9th, and PRDOH resumed testing in early November.

The Dengue Branch has tested almost 3,000 blood and urine samples from its enhanced surveillance site in southern Puerto Rico from cases with onset dates between September and November.

CDC is also working with PRDOH to prevent the spread of vector borne diseases in Puerto Rico. Mosquito surveillance in forests, open fields, swamps, and high- and low-density urban areas will determine mosquito densities and form the basis for control measures.

Moreover, CDC is providing technical assistance to the CDC-funded Puerto Rico Vector Control Unit. Through this assistance, CDC is informing messaging strategies to encourage community participation in cleaning up trash where mosquitoes, like *Aedes aegypti*—the mosquito species that transmits Zika, dengue, and chikungunya can lay eggs. For safe water storage, CDC has recommended that containers be covered with lids or screens to prevent mosquitoes from laying eggs. The Vector Control Unit has procured and begun disseminating insect repellent to communities.

To assist the USVI, CDC's Atlanta lab has provided surge testing of arboviruses (viruses spread by insects). To date, one post-hurricane case of Zika has been reported in the USVI to CDC, although there can be significant storm-related reporting lags of testing results. CDC has also provided on-the-ground technical consultation to the USVI regarding vector control. The USVI is currently conducting mosquito surveillance.

CDC will continue to work with the Puerto Rico and USVI departments of health on requests for support of vector-borne disease prevention, as requested.

The Honorable Frank Pallone, Jr.

- 1. There have been 51 deaths officially associated by Hurricane Maria, as reported by the Puerto Rico government. The Center for Disease Control has confirmed three deaths due to leptospirosis. To date, the island has reported 76 possible cases of the disease. What is the Department of Health and Human Services (HHS) doing to prepare for the potential onslaught of disease caused by contaminated drinking water and the spread of leptospirosis?**

CDC is working with the Environmental Protection Agency (EPA) and public health officials to identify health risks and prevent illness from unsafe water and to restore public health capacity. CDC conducted basic water testing immediately following the hurricane and EPA followed up with additional testing for fecal contamination. Both CDC and EPA have worked with Puerto Rico and the U.S. Virgin Islands (USVI) to educate home and business owners on methods of treating their household water to reduce the risk of waterborne disease.

On October 24, 2017, CDC released a CDC Health Advisory to advise health care providers treating patients in or recently returned from hurricane-affected areas, including Puerto Rico and USVI, to be vigilant in looking for certain waterborne and vector-borne infectious diseases that hurricane affected populations may be at particular risk for, such as leptospirosis, Zika, dengue, and chikungunya.

CDC also coordinated with the Puerto Rico Department of Health (PRDOH) to provide updated guidance on preventing the spread of infectious diseases targeted for medical care providers and healthcare facilities. CDC developed 17 fact sheets, adapted and translated for general audiences in Puerto Rico, to include safe food and water, leptospirosis, coping after a disaster, safe use of generators, handwashing, conjunctivitis, mosquito control, mold clean up, cleaning cisterns, scabies, and diarrhea. To improve overall disease and prevention communication, CDC has issued key messages for the public about preventing leptospirosis and other diseases. CDC has developed and is frequently updating hurricane key messages. The key messages can be found on CDC's website at <https://www.cdc.gov/disasters/hurricanes/index.html>.

In addition to the health communication materials disseminated to the public and clinicians, on November 12, 2017, CDC personnel deployed to assist in investigations of disease as requested by USVI. The CDC team is assisting the USVI Department of Health with patient screening guidance and rapid diagnostic tests for leptospirosis and melioidosis. The team is also assisting in the coordination of shipping diagnostic samples to CDC for confirmatory testing, investigating confirmed and probable cases of leptospirosis and melioidosis in an attempt to discover the exposures that led to infection, and conducting public and clinician outreach and education regarding leptospirosis and melioidosis.

To assist PRDOH with laboratory testing, CDC developed and implemented a system for transporting specimens from Puerto Rico laboratories to the continental United States for

confirmatory testing of select diseases, including leptospirosis. As recovery continues, CDC expects to gain more clarity on the status of infectious diseases in Puerto Rico and USVI and stands ready to assist with the surveillance and infrastructure needs of the Puerto Rico and USVI health departments, as needed.

2. What are HHS, CDC, and other involved federal agencies doing to ensure local Puerto Rico government employees have the necessary health and safety equipment to protect themselves during their ongoing relief and recovery workers?

CDC is working with the Occupational Safety and Health Administration (OSHA) to support occupational safety and health issues that arise during the response. CDC is aware that OSHA's National Alliance partners agreed to donate Personal Protective Equipment (PPE), including gloves, hard hats, and reflective vests, to help protect volunteers and workers performing hurricane recovery and clean-up efforts in Puerto Rico and USVI. CDC has developed a key messages document that provides information on how employers, workers, and volunteers responding to Hurricane Maria can protect themselves from a variety of response and recovery hazards. CDC is aware of reports of shortages and reduced inventories of respirators in the U.S. Virgin Islands; we are working to determine the causes for the shortages, and we spoke with the organizations representing PPE manufacturers and distributors to understand if any shortages existed in the supply chain.

a. Which federal government agencies are responsible for providing needed Personal Protective Equipment (PPEs) to relief and recovery workers?

There is no single agency officially responsible for providing personal protective equipment during an emergency. If existing stockpiles and government procurement of commercially available supplies are insufficient to meet relief and recovery demands, CDC maintains supplies of PPE in the Strategic National Stockpile that may be deployed to support such requirements.

3. What precautionary measures and/or infrastructure is currently in place to treat potential disease outbreaks in geographically remote areas?

CDC's Dengue Branch, located in Puerto Rico, has been helping prevent the spread of vector-borne diseases in Puerto Rico through mosquito surveillance in forests, open fields, swamps, and high- and low-density urban areas. CDC has not otherwise received requests from Puerto Rico to support disease surveillance in Puerto Rico. CDC has also provided on-the-ground technical consultation to USVI regarding vector control, and USVI is currently conducting mosquito surveillance.

Public health surveillance provides the information necessary to determine that a disease outbreak is occurring. CDC is working with the Department of Veterans Affairs, the Disaster Medical Assistance Teams, and Department of Defense to establish public health surveillance in Puerto Rico. To date, CDC has not received requests from Puerto Rico to support disease

surveillance or epidemiology support. CDC stands ready to support epidemiological and surveillance activities for infectious diseases as needed for Puerto Rico.

Although overall challenges still exist, progress is being made, as evidenced by CDC's Dengue Branch, located in Puerto Rico, and the PRDOH laboratory being able to resume mosquito-borne disease testing of specimens since the hurricanes. CDC's Atlanta laboratory has also provided surge arbovirus testing support to USVI. To date, CDC has not received requests from Puerto Rico to support disease surveillance outside of the CDC's Dengue Branch's surveillance activities. To further support the Puerto Rico Department of Health, CDC continues to transport specimens from Puerto Rico laboratories to the continental United States for confirmatory testing of select diseases, including leptospirosis, influenza, and tuberculosis. As recovery continues, CDC expects to gain more clarity on the status of infectious diseases in Puerto Rico and USVI, and stands ready to assist with surveillance and infrastructure needs of the Puerto Rico and USVI health departments as needed.

4. **What percentage of the population of Puerto Rico and the U.S. Virgin Islands currently has access to potable water through their tap? Is the CDC certain that, where water service has been restored, that the water is safe to drink?**

According to FEMA's November 17, 2017 Hurricane Maria report, 83 percent of water treatment plants in Puerto Rico are operational, and 85 percent of clients of the Puerto Rico Aqueducts and Sewers Authority (PRASA) have access to drinking water. However, due to inconsistencies in the power-grid, treatment plant pumps have had difficulty maintaining pressure throughout the distribution lines. Combined with unknown line breaks and potential for contamination entry, Puerto Rico and St. Croix are still under a boil water advisory. According to the U.S. Virgin Islands Water and Power Authority (WAPA), the boil water notice was lifted for St. Thomas and St. John on November 7, 2017. CDC continues to work with EPA and Puerto Rico and USVI health authorities to monitor municipal water quality. Based on the water meeting safe standards, WAPA and EPA will make the decision when to lift the boil water notice in St. Croix.

The Honorable Jan Schakowsky

1. **Following up, in the aftermath of disasters like these devastating Hurricanes, government should provide relief and recovery workers with required health and safety protections and Personal Protective Equipment (PPEs) to ensure workers' health is not compromised during current and ongoing clean-up and future rebuilding. Unfortunately, we have heard that this is causing problems in Puerto Rico.**

We know Puerto Ricans in both the private and public sector want to do the work needed to help rebuild their lives, homes, communities, and their Commonwealth. Government workers are willing and eager to help address short-term needs -even when working as assigned by the Puerto Rico government is outside their long-standing employee responsibilities and expertise. Nonetheless, workers simultaneously want to protect their own health and safety and avoid unnecessary health problems. The long-term medical

problems flowing from the tragic events on September 11, 2001 and the resulting cleanup efforts at Ground Zero and on the Pile taught us the vital importance of providing appropriate health and safety equipment and training to workers in conditions that are dangerous or uncertain.

- a. **What is HHS, CDC, and other federal agencies doing to ensure local Puerto Rico government employees have the necessary health and safety equipment to protect themselves during their ongoing relief and recovery work?**

CDC is coordinating with the Occupational Safety and Health Administration (OSHA) to support occupational safety and health issues that arise during the response. CDC is aware that OSHA's National Alliance partners agreed to donate PPE, including gloves, hard hats, and reflective vests, to help protect volunteers and workers performing hurricane recovery and clean-up efforts in Puerto Rico and the U.S. Virgin Islands. CDC has developed a key messages document that describes messages for how employers, workers, and volunteers responding to Hurricane Maria can protect themselves from a variety of response and recovery hazards.

- b. **Have these issues been addressed in Puerto Rico?**

Shortages and low supplies of respirators in Puerto Rico and USVI have been reported. CDC spoke to the professional associations representing PPE manufacturers and distributors to learn if there were true PPE shortages. They reported no shortages at the time.

- c. **Which federal government agencies are responsible for providing needed PPEs to recovery workers?**

There is no single agency responsible for providing personal protective equipment during an emergency. If existing stockpiles and government procurement of commercially available supplies are insufficient to meet relief and recovery demands, CDC maintains supplies of PPE in the Strategic National Stockpile that may be deployed to support such requirements.

The Honorable Kathy Castor

1. **I also heard from these health professionals that water sanitation is one of the biggest issues in Puerto Rico right now, which is leading to gastrointestinal issues as well as systemic infections. How is the Administration helping get clean water to Puerto Rico, especially to remote areas? Additionally, how is HHS working with health professionals on the ground to treat illnesses stemming from the lack of clean water?**

CDC's /Agency for Toxic Substances and Disease Registry field staff in Puerto Rico have facilitated contacts between the Environmental Protection Agency (EPA) and the Puerto Rican authorities. We also currently have a representative on a workgroup dealing with water quality.

CDC is working with EPA and public health officials to identify health risks and prevent illnesses from unsafe water and to restore public health capacity. CDC conducted basic water testing immediately following the hurricane and EPA followed up with additional testing for fecal contamination.

Both CDC and EPA have worked with Puerto Rico and the U.S. Virgin Islands (USVI) to educate home- and business owners of methods of treating their household water to reduce their risk of waterborne disease.

2. **Physicians have told me they are seeing other health issues such as asthma, COPD, conjunctivitis, scabies, diabetes, and hypertension being exacerbated due to lack of medications, power, transportation and supplies, increased air pollution from generators and unsanitary living conditions. Is HHS monitoring this situation, and what steps are being taken to address these additional health issues?**

Identifying and controlling diseases of public health importance in Puerto Rico and USVI is a top CDC and HHS priority. Of concern, the Puerto Rico Department of Health sustained significant damage during Hurricane Maria, including to their laboratories. CDC is working with the Puerto Rico Department of Health and the Federal Emergency Management Agency (FEMA) to get the public health laboratory back in operation. Additionally, given the extensive hurricane damage and limited power and communications, regular timely and comprehensive disease surveillance is not yet possible. CDC's National Syndromic Surveillance Program, in coordination with the HHS Assistant Secretary for Preparedness and Response (ASPR), and Disaster Medical Assistance Teams, are routinely monitoring approximately 115 syndromic surveillance data groupings. These medical data come from on-the-ground patient-provider contacts that provide awareness of disease trends to help guide response actions.

CDC has been communicating generator-use safety messages in multiple languages through print, broadcast, internet, social media and other channels. Thousands of safe generator-use and Carbon Monoxide poisoning awareness door hangers and flyers have been distributed in hurricane-affected areas. CDC has provided technical assistance to Texas and Florida for Carbon Monoxide poisoning surveillance. CDC has also provided technical assistance to Puerto Rico, USVI, and the American Academy of Pediatrics on public messaging to prevent Carbon Monoxide poisoning.

CDC staff have deployed to Texas, Puerto Rico and USVI to support state and territorial health departments in monitoring and addressing health issues related to air pollution from improper generator use and mold in flood-damaged buildings. CDC has several guidance documents for homeowners, workers, and clinicians about mold remediation, personal protective equipment, and cleanup, and about mold safety for medically vulnerable populations and patients with asthma. These have been developed, updated, translated to multiple languages, and distributed online and in print to all affected areas. Tens of thousands of copies of *Eight Tips For Mold Clean Up* have been distributed in multiple languages. Also available is the *Homeowner's and Renter's Guide for Mold Cleanup After Disasters*; a tool developed jointly by CDC, EPA, FEMA, the Department of Housing and Urban Development, and the National Institutes of Health based on experience with Hurricane Sandy and earlier storms. CDC has provided over 100,000 copies of an activity book for children on flooding and mold safety in a recovery environment.

CDC's Strategic National Stockpile deployed six Federal Medical Stations into Puerto Rico. Federal Medical Stations are non-emergency medical centers that could provide care for displaced persons with special health needs. These needs included chronic health conditions, limited mobility, or mental health issues that cannot be met in a shelter for the general

population. As of November 17, 2017 all Federal Medical Stations in Puerto Rico had officially been signed over to the Puerto Rico Department of Health. As of November 14, 2017, the Strategic National Stockpile had provided more than \$2.5 million in supplies, totaling more than 339 tons of cargo, to support public health needs resulting from Hurricane Maria. These supplies included 81 tons of supplies for Disaster Medical Assistance Teams; \$475,000 in additional medical supplies purchased for Puerto Rico; 177,000 bottles of water; and 42,000 meals ready to eat. In addition, a total of 115 CDC Strategic National Stockpile staff have supported procurement, shipping logistics, inventory management, warehouse operations in Puerto Rico, and site surveys for the Federal Medical Stations.

CDC also continues to provide technical assistance to the Puerto Rico Department of Health regarding immunizations program activities and support for vaccine needs. As part of this effort, the Strategic National Stockpile, has procured vaccines worth more than \$143,000 along with \$37,000 in purchased ancillary supplies, to support Puerto Rican vaccination programs. As of November 15, 2015, CDC committed an additional \$2.24 million to meet additional vaccine requirements.

On November 12, 2017, a CDC team deployed to USVI to assist with patient screening guidance and rapid diagnostic tests for leptospirosis and melioidosis. The team will also assist in the coordination of shipping diagnostic samples to CDC for confirmatory testing to discover the exposures that led to leptospirosis and melioidosis infection, and will conduct public and clinician outreach and education.

The Honorable Pete Olson

- 1. After tackling 3 Hurricanes in a short period of time, what strains have you seen on your current resources. Also, what additional resources do you need to provide these communities the help that they need?**

Since August 31, over 580 CDC staff members have supported the hurricane response. CDC is also providing technical assistance to federal, state, local, territorial, and tribal partners to save lives, minimize adverse health and medical effects, and stabilize public health and medical infrastructure. Communicable disease outbreaks of diarrhea and respiratory illness can occur when water and sewage systems are not working and personal hygiene is hard to maintain as a result of a disaster. Crowded living conditions in shelters can also create conditions for infectious disease outbreaks. It is critical for the public health system to quickly set up tracking systems that monitor illnesses in hurricane-affected areas. These systems provide an early warning that enables prompt public health response, including vaccinations and interventions to remove threats from water and food. While CDC cannot engage in the full range of comprehensive hurricane recovery activities without the supplemental appropriations request, CDC is providing the following support to areas affected by these hurricanes:

- Environmental health surveillance and laboratory testing to identify environmental hazards such as chemical spills and mold
- Crisis communications (including translating critical messages into multiple languages), media support, webinars, Clinician Outreach and Communication Activity (CoCA) calls, and other partner outreach
- Vaccination supplies

- Laboratory capacity assessments and diagnostic testing
- Subject matter expertise as requested.

