TESTIMONY

OF

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

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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 30 products that are critical and either manufactured solely or primarily in Puerto Rico. Of those 30 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.