



FDA Statement

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Statement by FDA Commissioner Scott Gottlieb, M.D., on efforts to address impact of IV fluid shortages following hurricane destruction and resolve manufacturing shortfalls

Summary: Update on the efforts by the FDA to address IV fluid shortages exacerbated by Hurricane Maria and advice for hospitals in managing the shortage

STATEMENT: It's been nine weeks since Hurricane Maria made landfall on Puerto Rico and the island continues to struggle to recover from the devastation brought by this storm, as well as Hurricane Irma.

As I've commented on previously, the medical products industry has a significant presence in Puerto Rico, and the disruption to this industry has had ramifications for patients both on the island and throughout the U.S. The FDA has been working closely with federal and Puerto Rican authorities to help stabilize the medical products manufacturing sector. We're taking steps to mitigate or avert product shortages but we've still seen shortages of certain medically important products, some of which are sourced primarily or only in Puerto Rico.

Most significantly to date, hospitals across the country are reporting shortages of IV fluids, particularly sodium chloride 0.9% injection bags – a type of saline bag. Saline IV fluids, which are used to inject drugs intravenously in hospital and outpatient settings, have been intermittently in shortage dating back to 2014. However, despite our best efforts, the situation in Puerto Rico has greatly exacerbated this supply issue. The FDA understands the concerns and impact of the ongoing shortages of IV solutions. These products have been on the list of approximately 90 medical products (which includes biologics, devices and drugs) that the FDA has been monitoring since the storm hit, and the FDA is actively working to address the shortage. Among the steps the FDA is taking, in conjunction with manufacturers of these products:

- temporarily allowing the importation of IV saline products from facilities outside of the U.S.;
- encouraging the expansion of production at existing facilities to meet shortfalls; and
- expediting our review of new product applications that will help address this shortage.

For instance, [we're working with one supplier, Baxter](#), to help them restore operations in their Puerto Rico facilities and move critical ingredients and products onto and off the island. Additionally, the FDA recently approved IV solution products from Fresenius Kabi and Laboratorios Grifols. Both companies are expected to increase production of saline products in the coming weeks. We believe steps like these will help to improve the shortage situation over time.

Beyond these regulatory measures, given the extraordinary situation in Puerto Rico, we have also been working closely with local and federal authorities, and manufacturers of saline and other products, to help address the needs caused by challenges to the basic infrastructure on Puerto Rico. This includes steps to help a subset of critical production facilities gain access to fuel or generators. We're also connecting companies to other parts of the federal and local government to help clear roads or secure transport priority to import critical raw ingredients.

Going forward, access to reliable power is integral to ensuring Puerto Rico-based medical product manufacturers return to full production capacity quickly. This is the focus of a lot of effort. Unfortunately, most manufacturers are still relying on generator power, and even those that have returned to the electrical grid continue to face interruptions as the grid is rebuilt.

As part of our efforts to reduce the risk of further shortages, the FDA has been working with federal and local government partners to prioritize a small number of critical facilities based on public health needs, including those plants that manufacture IV saline bags, for consideration or prioritization to gain earlier access to the electrical grid. Federal and local authorities have been very responsive to these requests. We're hopeful that these companies manufacturing medically important products will see their power needs addressed on an accelerated basis. The FDA continues to encourage the companies with FDA-approved saline products to add capacity to meet U.S. demand. We're also working to identify additional potential manufacturers.

That said, this shortage will require a sustained effort by industry, the agency and other partners to return to production levels that adequately meet the needs of patients. For our part, the FDA will continue to do all we can to address this shortage. We also want to discourage hoarding of products by some healthcare providers. We're concerned that shortages of some products may be exacerbated in part because of hoarding behavior.

In the meantime, the FDA encourages hospitals to consider clinical recommendations for managing the shortage of these IV fluids, including recommendations by the American Society of Health-System Pharmacists (ASHP) and the University of Utah. The recently released guidance [Small-Volume Parenteral Solutions Shortages](#)² provides an outline for potential actions for organizations and healthcare professionals to consider in managing the shortage.

The FDA remains committed to fully supporting Puerto Rico's medical products industry, both as a key aspect of the island's recovery and in ensuring that Americans continue to have access to the products they need.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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