

## FDA Statement

# FDA Commissioner Scott Gottlieb, M.D., updates on some ongoing shortages related to IV fluids

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## For Immediate Release

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## Statement

Earlier this month, we [updated \(/NewsEvents/Newsroom/PressAnnouncements/ucm591391.htm\)](#) on the FDA's efforts to mitigate ongoing IV saline shortages that resulted from, or were worsened by, the devastating impact of Hurricane Maria in Puerto Rico. We also provided some additional updates related to our continued efforts to help the island fully recover from this disaster.

As we continue to hear concerns about shortages in our discussions with hospitals and health care providers, as well as in media reports, I wanted to provide more information on this evolving challenge.

Based on the information we're receiving from companies and the actions we've taken at FDA, we continue to expect that the shortage of IV fluids will improve in the coming weeks and months. In addition to working with manufacturers to ensure that their Puerto Rico facilities can operate at full capacity, we've worked with manufacturers such as Baxter and B. Braun to import product into the U.S. from their foreign facilities including most recently from a Baxter facility in Brazil.

We are also looking at additional potential import sites for both small and larger volume IV saline bags. Further, our approval of IV saline products from additional companies, specifically Fresenius Kabi and Laboratorios Grifols, is expected to result in increasing product supply in U.S. market in the next several weeks. Small volume IV saline bags, or those in 50 and 100 ml sizes, are often used to deliver other medicines like antibiotics to patients while larger volume sizes are typically used to hydrate patients. The tight supply of saline products has been exacerbated by an increased demand for saline we're seeing as a result of the worse-than-typical flu season.

In addition to these steps, we're asking companies to submit data to extend expiration dates for these products. If expiration dates can be safely extended, it would allow some near-expiry product that remains at the hospital level to be used. Updates, including new supply sources and extensions of expiration dating, will be posted on the FDA's drug shortage website as soon as they're available.

Despite these steps, it may still take more time for new product supply to diffuse across the marketplace and have a noticeable impact on product availability. Because of the generally tight product supply, even when certain volumes of IV saline are not technically in shortage, there could be individual institutions that have a hard time obtaining adequate stock. We've heard from institutions that only have a few days' worth of supply on hand; as well as institutions that have to ration diminished stores of these products. We believe that as more supply enters the market these challenges will start to diminish.

In the meantime, we're closely monitoring the impact of the mitigation strategies being employed by health care providers as a result of the shortage of IV saline fluids. One area that we're paying particularly close attention to is the demand for empty IV containers as an alternative to filled bags.

These empty containers are regulated by the FDA as class II medical devices. They are manufactured by some of the same companies as the filled bags as well as other medical supply manufacturers. We understand that, with the shortage of filled bags, hospitals and other health care providers are turning to the repackaging or compounding of IV saline fluids and utilizing empty IV containers. This is resulting in diminished supplies of these containers and concerns that supplies of empty bags could tighten further.

We've been in direct communication with manufacturers, distributors, hospitals and other health care providers, including the Department of Veterans Affairs, about this issue. We're assessing existing product supply, demand trends, and the capacity of manufacturers of these bags to ramp up their production. We believe the demand for empty containers will recalibrate as the supply of filled bags increases. However, in the meantime, we want to see what steps we can take to ensure that shortages of these empty containers do not occur, given their clinical importance and their utility as an alternative to filled bags. We are identifying what steps the FDA can take to help mitigate the issue, if necessary.

As I noted, we also are aware of the impact that this year's severe flu season may continue to have on further impacting the IV saline shortage and any possible shortages of empty IV bags. As such, we encourage health care organizations and hospitals to **[contact FDA \(/AboutFDA/ContactFDA/default.htm\)](#)** directly if they aren't receiving the products they need. We also continue to encourage hospitals to consider clinical recommendations for managing the shortage of these IV fluids, including recommendations issued by the American Society of Health-System Pharmacists (ASHP) and the University of Utah. The recently released guidance **[Small-Volume Parenteral Solutions Shortages \(https://www.ashp.org/Drug-Shortages/Shortage-Resources/Publications/Small-Volume-Parenteral-Solutions-Shortages\)](https://www.ashp.org/Drug-Shortages/Shortage-Resources/Publications/Small-Volume-Parenteral-Solutions-Shortages)** (**<http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>**) provides an outline for potential actions for organizations and health care professionals to consider in managing the shortage.

As I've noted in my prior communications, our drug shortage **[website \(https://www.accessdata.fda.gov/scripts/drugshortages/dsp\\_ActiveIngredientDetails.cfm?AI=Sodium%20Chloride%20.9per%20Injection%20Bags&st=c\)](https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Sodium%20Chloride%20.9per%20Injection%20Bags&st=c)** remains the best source of information the FDA has regarding product availability for IV saline fluids. The website includes a list of manufacturers with products in shortage, the current availability, and the estimated duration of shortages.

In most cases, manufacturers, based on historical need, are allocating IV saline products to health care providers until supply is improved. That means that individual providers may find that they're not able to order excess supply, above the volumes they've purchased in the past, until there is

more product in the supply chain. We'll continue to pursue efforts to increase supplies of IV saline while product availability concerns remain, as well as monitor the impact of mitigation strategies on the supply chain.

The dynamics of all shortages are challenging. This situation is no different. We recognize that these challenges have created hardships and, in some cases, have had an impact on patients. We're deeply concerned by this situation. Resolving it remains one of my highest priorities. We're actively monitoring the situation and taking actions to address this shortage. We also will continue to communicate with the public about any possible new shortages that could occur as a consequence of the IV saline solution shortage as the agency receives additional information from manufacturers and distributors.

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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#### Related Information

- [FDA's drug shortages website \(https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm\)](https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm)
- [Statement by FDA Commissioner Scott Gottlieb, M.D., update on recovery efforts in Puerto Rico, and continued efforts to mitigate IV saline and amino acid drug shortages \(/NewsEvents/Newsroom/PressAnnouncements/ucm591391.htm\)](/NewsEvents/Newsroom/PressAnnouncements/ucm591391.htm)

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