

United States Senate

October 25, 2024

The Honorable Xavier Becerra
Secretary
Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Becerra:

I write regarding the urgent shortage of IV saline products and peritoneal dialysis products and action needed from the Department of Health and Human Services (HHS), the Assistant Secretary of Preparedness and Response (ASPR) and the Food and Drug Administration (FDA) to ensure Americans have reliable access to these medical necessities.

Hurricane Helene caused significant damage to the Baxter facility in North Carolina, which is responsible for 60% of the IV solutions used by hospitals in the U.S.¹ Right now, the facility is installing temporary bridges for transportation, and the company has recently restored power, but not water, to the facility. An October 7 letter by the American Hospital Association notes that the U.S. hospitals use 1.5 million bags of IV solutions every day and that because of the facility's closure orders are being reduced.² Even with Baxter increasing allocations up to 60% of what is ordered, this still creates a potential shortage of products in the U.S.³

The Baxter facility provides peritoneal dialysis supplies and is the largest provider of IV solutions. While Baxter believes its facility can start limited operations by the end of this month with full operations being restored by the end of this year, this is a large gamble to wait as its limited production may not meet the needs of all patients across America.

- What are HHS and FDA doing to help get the North Carolina facility operational again?
- When does HHS think the facility will be fully operational again and supplies will not be in shortage?
- How much additional capacity does HHS think will be available from competing companies for IV solutions and peritoneal dialysis supplies? Will this be able to fill this gap in supplies?

¹ <https://thehill.com/policy/healthcare/4922978-hurricane-helene-iv-solution-shortage/>

² <https://www.aha.org/2024-10-07-aha-president-urging-administration-take-immediate-action-address-iv-solution-supply-shortage-result-helene>

³ <https://www.baxter.com/baxter-newsroom/hurricane-helene-updates>. Accessed Oct 9 2024.

The Honorable Xavier Becerra

October 25, 2024

Page Two

- Baxter and other companies may have additional facilities overseas but they are not currently an FDA-approved facility. What barriers exist in importing IV solutions from the European Union or other countries?
 - Is FDA looking to approve those facilities quickly under an Emergency Use Authorization, special importation license or other designation? Why is FDA using one method over using the other available designation?
 - Will this increase capacity to reduce the full loss of production at the NC facility?
- How much new product will come from China? Has FDA inspected the Chinese facility before allowing importation?
- Has HHS looked at using the Defense Production Act to require manufacturers to prioritize certain contracts for materials and services to produce IV solutions?
- The FDA has allowed certain entities to compound IV during the shortage. Does FDA, HHS or ASPR have any plans to ensure these facilities have an adequate supply of bags for the saline?
- Please explain why HHS has not stockpiled a supply of IV solutions in the Strategic National Stockpile (SNS)? Does HHS have any plans to add products to the SNS that could go into shortage in the event of a natural disaster?
- Does HHS or ASPR have any plans to ensure a more robust domestic supply chain in case something like this happens again whether it be an IV supplier or another health product supplier?

I look forward to your prompt response. HHS, ASPR and FDA must take swift and decisive actions to solve this growing supply shortage.

Sincerely,



Rick Scott
United States Senator