

United States Senate
WASHINGTON, DC 20510

October 10, 2024

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services

The Honorable Robert Califf, MD, MACC
Commissioner of Food and Drugs
U.S. Food & Drug Administration

Dear Secretary Becerra and Commissioner Califf :

I urge the Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) to take immediate action to address the intravenous (IV) fluids supply challenges – specifically, sterile water, irrigation, dextrose, normal saline, lactated ringer’s (sodium lactate), and peritoneal dialysis solutions. HHS and FDA must urgently respond to this crisis and ensure measures are in place to prevent future shortages.

Georgia is reeling from one of the deadliest hurricanes to ever make landfall in the United States.¹ In the midst of the destruction left in Hurricane Helene’s path, hospitals and other health facilities in my state have stepped up to serve Georgians. Additionally, South Georgia hospitals are now providing care to Florida evacuees due to Hurricane Milton, increasing the patient population on an already-strained system. I am grateful for the incredible work of health care workers who have gone above and beyond in their response to this crisis.

However, our frontline workers are encountering a critical shortage of IV fluids. This shortage stems from the closure of Baxter International, which was forced to shut down its North Carolina facility due to catastrophic flooding following Hurricane Helene. Baxter manufactures sixty percent---over half---of the entire country’s IV solution supply, and they have not produced any IV solution at its largest facility in the world since before September 29, 2024.² The second-most prominent IV fluid manufacturer in the U.S., B. Braun Medical, has a plant in Daytona, Florida, which will be closed for at least several days due to Hurricane Milton.³ B. Braun supplies one-fourth of the country’s IV fluids.⁴

¹ Dan Stillman, *Helene has become one of the deadliest hurricanes of the modern era*, Washington Post, (Oct. 4, 2024), <https://www.washingtonpost.com/weather/2024/10/03/hurricane-helene-deadliest-mainland-since-katrina-storm/>.

² Berkely Lovelace Jr. and Mustafa Fattah, *Hospitals take steps to conserve IV fluid supply after Helene strikes critical factory*, NBC News, (Oct. 3, 2024), <https://www.nbcnews.com/health/health-news/hospitals-take-steps-conserve-iv-fluid-supply-helene-strikes-critical-rcna173861>.

³ *IV Fluids and Irrigation Solutions*, B. Braun Medical Inc., <https://www.bbraunusa.com/en/products-and-partnerships/smart-infusion/iv-fluids-and-irrigation-solutions.html>.

⁴ Christina Jewett, *U.S. Races to Replenish Storm-Battered Supplies of IV Fluids at Hospitals*, The New York Times, (Oct. 9, 2024), <https://www.nytimes.com/2024/10/09/health/hurricane-helene-iv-shortages.html>.

In response to IV solution shortages, hospitals across Georgia are already having to conserve IV solution and cancel non-emergent surgeries.⁵ While I appreciate the work of HHS and FDA to help Baxter resume operations, HHS and FDA must take urgent action to respond to this crisis and, in the long-term, take steps to secure supply chains of essential health care supplies.

Specifically, I request that HHS and FDA take the following actions immediately:

1. FDA should declare a shortage of IV solution to open up additional flexibility in responding to the crisis. By declaring a shortage under the authority of Section 506C and 506E of the Food and Drug Cosmetics Act, 503A and 503B compounders can step up to provide products during this shortage.⁶ Additionally, products can be imported from global suppliers with expedited approval from the FDA.
 - FDA should provide explicit guidance for 503A and 503B compounding pharmacies on current flexibilities for compounding products related to the shortage.⁷
2. FDA should monitor the shortage of IV bags, which are regulated as Class II medical devices.⁸ In addition to IV solution, hospitals are experiencing shortages of bags, which are necessary to deliver fluids through an IV.⁹ FDA has the authority to declare shortages of a medical device under 506J of the Food and Drug Cosmetics Act.¹⁰
3. FDA must evaluate the safety of imported IV fluids and provide guidance to manufacturers on extension of shelf-life. Hospitals and other health care facilities rely on the safety of these products to ensure quality patient outcomes.
4. HHS should recommend that President Biden invoke the Defense Production Act (DPA) of 1950.¹¹ This will incentivize U.S.-based manufacturers to ramp up production of IV fluids during the current crisis.
5. HHS must continue to work with suppliers and health facilities to ensure that patients who use peritoneal dialysis have access to the required solution. While Baxter is currently allocating peritoneal dialysis solution at 100 percent of standard supply, patients depend on consistent access.
 - HHS should also work with local health officials to connect patients who were set to newly start on peritoneal dialysis before the supply chain issues to alternative care.
6. HHS should evaluate adding IV fluids, or raw materials for compounding, and empty bags to the Strategic National Stockpile to establish access in the event of another crisis. There have been IV solution shortages over the last six years, including after Hurricane

⁵ Tom Murphy, *Helene damaged a factory that makes IV fluids*, The Atlanta Journal-Constitution, (Oct. 4, 2024), <https://www.ajc.com/news/nation-world/helene-damaged-a-factory-that-makes-iv-fluids/DB7YV477WJFCJLIS5L4J2KMCJU/>.

⁶ 21 U.S.C. §356e.

⁷ *Hurricane Helene: Baxter's manufacturing recovery in North Carolina*, FDA, (Oct. 8, 2024), <https://www.fda.gov/drugs/updates-2024-hurricane-season/hurricane-helene-baxters-manufacturing-recovery-north-carolina#:~:text=below%20national%20demand.,Information%20on%20Compounding,-Compounded%20drugs%20might>.

⁸ FDA General Hospital and Personal Use Therapeutic Devices, 21 C.F.R. § 880.5025.

⁹ Ken Alltucker, *Hospitals urge emergency steps on IV fluid shortage after Hurricane Helene*, USA Today, (Oct. 7, 2024), <https://www.usatoday.com/story/news/health/2024/10/07/iv-bag-shortage-hurricane-helene/7555628700/>.

¹⁰ 21 U.S.C. §356j.

¹¹ 50 U.S.C. §§4501 et seq.

Maria.¹² To be prepared for the next crisis, HHS must consider creating a stockpile of these essential products.

7. Both FDA and HHS should coordinate with state Attorneys General to prevent bad actors from price gouging health supplies while responding to this crisis. Hospitals have reported facing skyrocketing price of alternative sources of IV fluids during prior shortages.¹³

I am committed to working with HHS and FDA to build a more resilient supply chain for our health care system so that patients in Georgia and around the country can access the care they need. In the meantime, I appreciate your commitment to addressing this issue.

Sincerely,



Raphael Warnock
United States Senator

CC: Dawn O'Connell, Assistant Secretary at Administration for Strategic Preparedness and Response

¹² Anne Saker and Shari Rudavsky, *Hospitals find other ways to deliver medicine amid IV bag shortage*, USA Today, (Jan. 14, 2018), <https://www.usatoday.com/story/money/nation-now/2018/01/14/iv-bag-shortage-puerto-rico/1032369001/>.

¹³ Robert Glatter, MD, *Hurricane Helene Damages Could Result in IV Bag Shortage*, Forbes, (Oct. 6, 2024), <https://www.forbes.com/sites/robertglatter/2024/10/06/hurricane-helenes-unexpected-impact-on-us-healthcare-delivery/>.