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## How Will Pfizer Plant's Tornado Damage Impact Congress's Drug Shortages Debate?

by Bowman Cox

The stakes on Capitol Hill rose another notch as tornado hit supplies of sterile injectable drugs at North Carolina plant. Workers escaped serious injury by gathering in designated shelters; patients may need effective legislation to escape serious injury from drug shortages.

A tornado put an exclamation point on the debate in Washington over how to stop shortages of sterile injectable drugs when it touched down 4:43 pm Wednesday near Battleboro, NC, and tore through a warehouse at *Pfizer Inc.*'s Rocky Mount, NC, plant, scattering an estimated 50,000 pallets of finished sterile injectable drug products.

Workers scurried into designated shelters like the old gamma irradiation chamber next to the warehouse shortly before it was hit by the EF3 tornado, which the National Weather Service's Storm Prediction Center said brought winds as high as 150 mph.

Pfizer confirmed that workers followed the plant's established safety protocol and were all safe and accounted for.

Beset already by constituents suffering from shortages of treatments for their attention deficit disorders, bacterial infections and spreading cancers, members of Congress could soon hear from yet more whose medical care is delayed by new shortages of analgesics, neuromuscular blockers and other sterile injectable staples of hospital care that are likely to result from the tornado strike.

Pfizer's website describes the Rocky Mount plant as "one of the largest sterile injectable facilities in the world," saying it produces nearly 8% of all sterile injectables used in US hospitals. [Editor's note: this article was revised 21 July after Pfizer changed the figure from 25% to 8%, explaining that 25% is the plant's share of sterile injectables Pfizer manufactures for US hospitals.]



"At this facility, a wide range of products are produced, including anesthesia, analgesia, therapeutics, anti-infectives and neuromuscular blockers," the Pfzer website says. "These products are available in small volume presentations, such as ampules, vials and syringes, and large volume presentations, such as IV bags and semi-rigid bottles."

The plant produces more than 400 million units per year, Pfizer says. That's nearly 1.1 million every day that it's operating.

## **Collateral Damage On Capitol Hill?**

The tornado damage arrived as the House Energy and Commerce Committee spun on party lines, with Republicans promising a standalone drug shortages bill while Democrats offered up for discussion a version of the must-pass pandemic response reauthorization bill that includes their favored drug shortages response provisions. (Also see "House Republicans: Drug Shortage Solutions Must Move Beyond FDA" - Pink Sheet, 13 Jul, 2023.)

The Senate Health, Education, Labor and Pensions Committee on 20 July marked up its version of the Pandemic and All-Hazards Preparedness Act that would include some drug shortage response measures. The day before, the House Energy and Commerce Committee had passed more narrowly focused pandemic legislation. (Also see "*US FDA Gets Wanted Pathogen Program, Manufacturers Get Longer BARDA Contracts In Competing Pandemic Prep Bills*" - Pink Sheet, 20 Jul, 2023.)

## What Health System Pharmacists Would Like To See

The American Society of Health-System Pharmacists on 20 July shared its short-term and long-term recommendations on drug shortages even as its members braced for the Rocky Mount tornado's impact on their drug supplies.

One of those recommendations, to diversify the manufacturing base, is something that came up after Hurricane Maria triggered sterile injectables shortages when it hit Puerto Rico. (Also see "<u>As Saline Shortages Persist, Providers Pin Hopes On Feds Demanding Backup Manufacturing Capacity</u>" - Pink Sheet, 28 Mar, 2018.). It's a recommendation the tornado strike is sure to underscore.

Another ASHP recommendation that the tornado damage is likely to amplify: health care providers and distributors should work together to maintain a buffer inventory of critical medicines.

## More Infrastructure Seen As Key

"There were some changes made after Hurricane Maria, but we're clearly still running into problems where acts of God can wipe out a manufacturer and then you don't really have necessarily the backstops there you'd want to see to ensure a consistent supply chain," Jillanne



Schulte Wall of ASHP's government relations team told the *Pink Sheet*.

While there has been an effort to help the FDA know where products are manufactured so it can "nip shortages in the bud," Wall said.

"Unfortunately, there just hasn't been as much investment in some of the infrastructure that is really needed to create redundancies in the system to protect against something like this."