

# United States Senate

WASHINGTON, DC 20510

February 16, 2012

Dr. Margaret Hamburg  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Building 32, Room 2346  
Silver Spring, MD 20993

Dear Dr. Hamburg:

I am writing regarding the impending shortage of Methotrexate – an invaluable drug used in the fight against acute lymphoblastic leukemia (A.L.L), a virulent form of childhood cancer. I have heard from parents, doctors, and hospitals expressing grave concerns that without this drug they will not be able to properly treat pediatric cancer patients.

Ben Venue Laboratories, Inc., one of the country's largest suppliers of Methotrexate, voluntarily suspended production at its Bedford, Ohio facility in November 2011. Since then, the supply of Methotrexate has shrunk so significantly that many oncologists believe only a two-week supply remains. While Ben Venue is releasing an additional supply of Methotrexate produced before the voluntary shutdown, I remain concerned that a shortage of this life-saving drug will soon be upon.

As the Food and Drug Administration (FDA) is tasked with regulating pharmaceuticals, it is imperative that your agency do everything necessary to alleviate this shortage in a timely manner. First, I urge the FDA to work closely with Ben Venue to identify and correct the manufacturing issues that led the company to suspend Methotrexate production. Second, it is imperative that the FDA collaborate with other Methotrexate manufacturers and encourage them to increase production of the drug. Third, given that restoring production at Ben Venue and ramping up production among competing manufacturers will likely take longer than two weeks, I encourage the FDA to seek and approve a foreign Methotrexate supplier or suppliers to ensure this life-saving medication remains available to American families. Finally, I also encourage the FDA to provide physicians and patients with updated information regarding the extent and duration of the shortage.

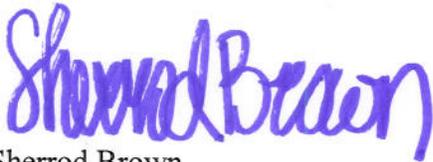
Unfortunately, Methotrexate is only one of the many drugs in short supply. I believe we can learn from the FDA's reaction to the potential shortage of Methotrexate and in order to mitigate – or prevent – other shortages. To that end, please provide the following information:

- When did Ben Venue inform the FDA that its Bedford, Ohio facility would cease production?

- Did Ben Venue or the FDA reach out to other Methotrexate manufactures to ask them to increase production?
- How long will Ben Venue's limited supply last?
- What is the average lead time necessary for a manufacturer ramp up production?
- Have any of these suppliers agreed to increase production? If so, when are their products expected to enter the market and will this increase be enough to meet demand?
- Besides Methotrexate, what other drugs are in shortage or in danger of falling into shortage due to Ben Venue's closure of its Bedford, Ohio facility?
- What efforts have you taken to assist Ben Venue in correcting their manufacturing problems? When is Ben Venue expected to resume production at their Bedford, Ohio facility?

With proper treatment – including Methotrexate – 90 percent of patients with A.L.L. go into remission. Without proper treatment, these young cancer patients face an uncertain – and harrowing – future. I urge the FDA to work diligently to ensure that children with cancer do not go without this life-saving drug.

Sincerely,



Sherrod Brown  
United States Senator