

# CHILD SAFETY BLOG

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## Cancer Drug's Short Supply Moves to Critical Stage

February 19, 2012 by *Patrick A. Malone*

After it failed an inspection in November by the FDA, Ben Venue Laboratories in Ohio was shut down. No one in his or her right mind would want to take drugs manufactured in a place where mold was growing on the walls and machinery rust was falling into vials.

Now, the toll of the lab's decrepit state might have to be paid by children with acute lymphoblastic leukemia (ALL) and a type of bone cancer, osteogenic sarcoma. They rely on a longtime cancer drug, methotrexate, that, as [NPR reported](#), can mean the difference between death and cure.

Ben Venue was a principal supplier of injectable methotrexate. Now, its shortage is acute, the latest in long line of [critical drug shortages](#). We've written often on the topic, and [what is being done to address it](#).

According to NPR, hospitals throughout the country are "perilously close" to exhausting their supplies of the kind of methotrexate that treats ALL and osteogenic sarcoma. In a few weeks, substituting or delaying therapy might be forced on some patients. Their doctors aren't certain how that will affect their chances of a cure, which are 9 in 10 with the right treatment.

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One expert on drug shortages told NPR that most people don't realize how many U.S. drug plants are in extreme disrepair, especially those that manufacture generic drugs. Ben Venue claims to have invested \$250 million recently to upgrade its facilities, but it's unclear when it will reopen. That lab also was the sole manufacturer of Doxil, an ovarian and breast cancer drug that's now unavailable.

But there's cause for hope. The FDA said the methotrexate and Doxil crises soon may be over. Three other manufacturers are increasing production of the specific kind of methotrexate at issue, and they told the feds that additional supplies should be available within weeks.

The FDA is considering licensing a foreign company to make Doxil, a measure it has taken eight times in the last year to address other drugs in critical shortage.

And last week Ben Venue [posted a message on its website](#) that it was working with the FDA to expedite the availability of methotrexate and immediately would begin releasing a limited supply to oncology clinics, hospitals and pediatric facilities. "We hope this supply will help address near-term patient needs while other companies licensed to manufacture methotrexate increase production," the statement read.

Doctors were optimistic about restocking hospital supplies of methotrexate, but, as one told NPR, "[T]his is not the last shortage we'll have to cope with."

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