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Supply of a Cancer Drug May Run Out Within Weeks

By GARDINER HARRIS FEB. 10, 2012

A crucial medicine to treat childhood leukemia is in such short supply that hospitals across the country may exhaust their stores within the next two weeks, leaving hundreds and perhaps thousands of children at risk of dying from a largely curable disease, federal officials and cancer doctors say.

“This is dire,” said Valerie Jensen, associate director of the Food and Drug Administration’s drug shortages program. “Supplies are just not meeting demand.”

The drug is methotrexate, and the cancer it treats is known as acute lymphoblastic leukemia, or A.L.L., which most often strikes children ages 2 to 5. It is an unusually virulent cancer of white blood cells that are overproduced in bone marrow and invade other parts of the body.

The cancer commonly spreads to the lining of the spine and brain, and oncologists prevent this by injecting large quantities of preservative-free methotrexate directly into the spinal fluid. The preservative can cause paralysis when injected into the spinal column, so cannot be used for this disease. Methotrexate is also used to treat rheumatoid arthritis.

Ben Venue Laboratories was one of the nation’s largest suppliers of

injectable preservative-free methotrexate, but the company voluntarily suspended operations at its plant in Bedford, Ohio, in November because of “significant manufacturing and quality concerns,” the company announced.

Since then, supplies of methotrexate have gradually dwindled to the point where oncologists now say they are fearful that shortfalls may occur at many hospitals within two weeks.

“This is a crisis that I hope the F.D.A.’s hard work can help to avert,” said Dr. Michael P. Link, president of the American Society of Clinical Oncology. “We have worked very hard to take what was an incurable disease and make it curable for 90 percent of the cases. But if we can’t get this drug anymore, that sets us back decades.”

Jackson Schwartz, 6, of Langhorne, Pa., received a diagnosis of A.L.L. in August after he complained of terrible stomach pains and spent much of his family’s vacation sleeping on the beach, said his father, Jon Schwartz. A doctor initially gave Jackson a diagnosis of constipation, but when the constipation medicine did not ease his symptoms, Jackson’s parents took him to Children’s Hospital of Philadelphia.

Within a day, doctors started Jackson on methotrexate, and the drug has been an essential part of his treatment ever since. Jackson is scheduled to have methotrexate injected into his spine weekly for the next eight weeks to ensure that his cancer does not return. If the hospital is unable to get more supplies, however, Jackson’s treatment and life may be in serious jeopardy, Mr. Schwartz said.

“It would be devastating if we can’t get this drug,” he said.

There are four other manufacturers of methotrexate in the United States, and they are trying to increase production, Ms. Jensen said. The F.D.A. is also seeking a foreign supplier to provide emergency imports until the approved domestic ones can meet demand, she said.

“We’re working on many fronts, and will keep this a priority,” Ms. Jensen said.

So far this year, at least 180 drugs that are crucial for treating childhood leukemia, breast and colon cancer, infections and other diseases have been declared in short supply — a record number. Prices for some have risen as much as eightyfold. President Obama issued an executive order in October to help ease the problems.

“People are panicking” about the methotrexate shortage, said Erin Fox, manager of the drug information service at the University of Utah. “There isn’t a lot of hope that supplies will improve drastically over the next few weeks, which is why people are so worried.”

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