Doctors Urge More Production Of Scarce Cancer Drug

TRENTON, N.J. (AP) — Four pharmaceutical companies that make a crucial cancer drug for children that's suddenly in short supply are being urged to try to quickly step up production to prevent unnecessary deaths.

A senator and three doctor groups late Monday sent the pleas to the companies, saying that hospitals will run out of the drug in days to weeks, increasing chances that young patients who might otherwise survive will die.

The critical shortage of methotrexate has doctors and hospitals around the country panicking because it's the key treatment for a common childhood cancer called acute lymphoblastic leukemia, or ALL.

With the drug, doctors say they can cure nearly 90 percent of the roughly 3,500 American children and teens diagnosed with this cancer each year.

Last year, there were a record 267 new drug shortages reported, and most remain unresolved. The inability to get crucial medicines has disrupted chemotherapy, surgery and care for patients with infections and pain. At least 15 deaths since 2010 have been blamed on the shortages.

Specialty groups representing researchers and doctors who care for children with cancer say the methotrexate shortage began in December when production declined. That drop resulted primarily from Ben Venue Laboratories Inc. temporarily closing its factory in Bedford, Ohio, in November after federal inspectors said the company had not been properly maintaining equipment or promptly addressing defective product batches and sterility problems.

Besides making methotrexate, the factory was the sole source for Johnson & Johnson's Doxil, a drug widely used for breast and ovarian cancer that's not been available for new patients for months.

Each of the remaining four manufacturers of methotrexate has had some type of production problem, and it's been unclear when the next batches of the drug will be sent to wholesalers and hospitals, according to Erin R. Fox, manager of the University of Utah Drug Information Service, which tracks national drug shortages.

Late Monday, the heads of the American Society of Clinical Oncology, American Cancer Society of Pediatric Hematology/Oncology and Children's Oncology Group, a nationwide network of researchers, wrote to top executives at four U.S. makers of the drug pleading for help.

The cancer groups urged the drugmakers to "take all necessary steps to rapidly increase access" to the preservative-free version of methotrexate, which is needed for children because the preservatives can be dangerous for them.

"Doctors and pharmacists are scrounging for supply with very little luck and are beginning to ration the remaining supply. It is not an understatement to say that this is creating a panic in the childhood cancer community," the letters state.

Sen. Amy Klobuchar, D-Minn., sent a similar plea to the companies Monday evening.

"Families fighting childhood cancer should not have to worry about where they're going to get the next dose of the drug they need to save their child's life," Klobuchar wrote.

The letters went to APP Pharmaceuticals LLC, Hospira Inc., Sandoz Inc. and Mylan Inc. An APP spokeswoman wrote that the company doesn't have FDA approval for a preservative-free product, but "over the next two weeks we will be shipping additional methotrexate" with preservative to customers across the U.S.

Spokespeople at the other three companies did not have responses Monday evening.

Klobuchar is the sponsor of a bill that would require manufacturers to notify the Food and Drug Administration immediately of impending shortages of key drugs — to give the FDA enough advance notice that it can take steps to prevent a shortage by working with other manufacturers. The agency increasingly has been doing that and already is working to increase the supply of methotrexate, also used to treat rheumatoid arthritis.

Most of the medicines that have become scarce are sterile injected drugs that are the workhorses of hospitals and are normally inexpensive because they've long been available as generics.

The FDA says the main reason for the shortages is manufacturing deficiencies leading to production shutdowns. Shortages also are resulting from companies halting production of drugs with low profit margins, companies consolidating in the generic drug industry and supplies of some ingredients shrinking.

Source URL (retrieved on *11/24/2014 - 5:04pm*):
http://www.surgicalproductsmag.com/news/2012/02/doctors-urge-more-production-scarce-cancer-drug