

American Society of Clinical Oncology Calls on Congress to Solve the Growing Crisis of Cancer Drug Shortages

ASCO's President Lays out Three Legislative Priorities to Ensure Life-Saving Cancer Treatments Remain Available to Patients

SILVER SPRING, Md. - The American Society of Clinical Oncology today called for specific actions by Congress to avert shortages of essential treatments for children and adults with cancer. Speaking at a Food and Drug Administration press conference, ASCO President Michael P. Link, MD, called for Congress to appoint a joint House-Senate working group to develop permanent legislative solutions within 60 days. He outlined three priorities that ASCO believes are essential to address the economic and regulatory drivers of recent shortages.

Dr. Link's remarks come just days after FDA and manufacturers worked to narrowly avert a critical shortage of methotrexate, a drug that is essential to the cure of thousands of children with acute lymphoblastic leukemia. Methotrexate is among a growing number of drugs - most of them generic, injectable medications - that have recently been subject to shortages.

"While the crisis among children with cancer has captured national attention, thousands of adult patients have also had their cancer treatment threatened by shortages of highly effective, affordable medicines," said Dr. Link. "Congress needs to take action to solve this growing problem. Without a permanent solution, we can be sure that more patients will have the terrible experience of hearing that an inexpensive, potentially life-saving treatment is no longer available."

ASCO is calling on Congressional leadership to immediately appoint a bipartisan, bicameral working group to consider all possible solutions and develop comprehensive legislation. In his remarks, Dr. Link described three essential elements that must be included:

- **Require advance notification of potential shortages** - FDA should receive confidential notification from manufacturers of market withdrawals or manufacturing interruptions six months in advance, or as soon as such problems become known. This information is essential to FDA's ability to help address manufacturing issues or to identify alternative drug sources before shortages occur.
- **Provide economic incentives to ensure continued availability** - To address economic factors that have driven shortages of low-cost, generic medicines, Congress should provide incentives for companies to develop contingency plans - for example, involving alternate suppliers of raw materials and redundancies in manufacturing. Additional incentives should be considered to encourage manufacturers to enter and remain in the market for essential medications that are susceptible to shortage.
- **Establish FDA user fees for generic drugs** - Expand FDA's authority to collect user fees from generic drug manufacturers as part of the regulatory approval process, similar to fees paid by branded drug makers. These fees should be used to ensure that FDA has the resources to quickly review generic drug applications and speed the availability of these medicines to patients. The fees would also provide flexibility for FDA to incentivize production of key drugs, for example, by charging reduced fees for companies that demonstrate adequate contingency plans for manufacturing disruptions.

On behalf of ASCO, Dr. Link also acknowledged the recent efforts by FDA, manufacturers, and key legislators to address the shortages of methotrexate and other cancer drugs. "These are truly tragic and frustrating circumstances, and many people have been working tirelessly to address them. But we cannot continue to practice medicine from crisis to crisis - our patients' lives depend on achieving a permanent solution."

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About ASCO

The American Society of Clinical Oncology (ASCO) is the world's leading professional organization representing physicians who care for people with cancer. With more than 30,000 members, ASCO is committed to improving cancer care through scientific meetings, educational programs and peer-reviewed journals. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation, which funds ground-breaking research and programs that make a tangible difference in the lives of people with cancer. For ASCO information and resources, visit www.asco.org/presscenter. Patient-oriented cancer information is available at www.cancer.net.