America's Drug Shortage and what YOU can do to have your Voice Heard

The American Childhood Cancer Organization is a member organization of the National Coalition for Cancer Research (NCCR). A recent meeting of this umbrella group was focused on the increasing crisis to cancer care and clinical trial research as a result of **critical drug shortages** in the U.S.

As the largest grassroots organization representing children with cancer and their families, it is important that our voice be heard on this issue. Our children must not be robbed of a cure as they battle cancer, because of an inability to access essential life-saving drugs. We ask that you contact your Members of Congress in the House and Senate and ask them to support the bi-partisan Bills described below. Be sure to tell them your story of how a drug shortage could impact your child's fight against cancer.

Click here for contact info for your House Representatives: and **here for your Senate contact info.**

In the last five years, the number of new drug shortages has more than tripled. In 2010, there were 211 medications including essential chemotherapy drugs in short supply. That number had almost been reached by August 2011 with the estimation that the 2011 drug shortage will surpass 300 drugs and be the greatest drug shortage ever recorded. A survey of over 800 hospitals indicated that forty-four percent reported a shortage of 21 or more drugs in the last six months alone.

Cancer care and cancer clinical trials are being impacted for both adult cancer patients and child/ adolescent cancer patients. Patients are having treatments delayed, are being treated with substitute drugs which could result in less probability for cure, clinical trials are being suspended, patient accrual is being halted, and drug substitutions are resulting in potential problems with the data analysis of the clinical trials. Many of the drugs on the shortage list are regarded as standard of care, with no effective drug alternative. For example, two drugs effectively shown to treat AML are Danuorubicin and cytarabine (ara-C). Both of these drugs are on the drug shortage list with limited emergency quantities of Danuorubicin available in many institutions. In addition to these drug shortages, the American Society of Hematology has also reported severe shortages of BiCNU (Carmustine), Bleomycin injection, Cytarabine (ARA-C), Daunorubicin, Leucovorin, and Thiotepa. http://www.hematology.org/News/2011/6943.aspx. A total of 23 chemotherapy drugs were in short supply in 2010, and 22 reported by August 2011.

There are two opposing opinions on why this is happening in a country rich with pharmaceutical industry. The FDA sites industry manufacturing and compliance issues (product quality), shortage of raw material to produce the drugs, merging of companies leading to economic decisions to discontinue the production of drugs with poor economic returns, time required between different drug production runs leading to delays in availability and others.

Companies site increasing demand due to multiple-drug regimens, aging population leading to more cancer treatment and subsequently more drug demand, more stringent FDA oversight as a result of increased pressure for the FDA to place a higher priority on drug safety, more complex manufacturing processes and more. Steps need to be taken to remove all barriers leading to drug shortages to ensure that lives aren't lost because of an inability to access essential chemotherapy drugs.

Senator Amy Klobuchar (D-MN) has taken Congressional Action on this issue through the sponsorship of: **Preserving Access to Life-Saving Medications Act (S.296)**. Introduced February 7, 2011- Preserving Access to Life-Saving Medications Act amends the Federal Food, Drug, and Cosmetic Act to require a prescription drug manufacturer to notify the Secretary of Health and Human Services (HHS) of a

discontinuance, interruption, or other adjustment of the manufacture of the drug that would likely result in a shortage of such drug. Specifically the Bill requires:

- Manufacturers to notify the FDA of any drug discontinuation, interruption in production, or adjustment (supply of raw materials, production capabilities and/or business decisions resulting in the discontinuation of the drug) at least 6 months in advance or ASAP.
- FDA to develop an effective enforcement compliance process.
- FDA would work with manufacturers to devise continuity plans for medically necessary drugs.

On June 21, 2011, House Representative Diana DeGette (D-CO) introduced **H.R. 2245 – Preserving Access to Life-Saving Medications Act of 2011**.

In addition to the above two legislative activities, the Energy and Commerce Committee will be holding a Hearing to address this issue on September 23, 2011. This will be followed by an FDA Public Meeting scheduled for September 26, 2011.

As Michael Link, Pediatric Oncologist and President of ASCO said: "These shortages are just killing us. These drugs save lives, and it's unconscionable that medicines that cost a couple of bucks a vial are unavailable." (New York Times, Aug. 19, 2011)

ACCO will continue to keep you updated on this issue. Additional Information is available at the following sites:

- FDA U.S Food and Drug Administration Drug Shortages Program, including a current list of drug shortages
- American Society of Health-System Pharmacists (ASHP) Drug Shortage Resource Center
- American Society of Clinical Oncology (ASCO) Connection
- H.R. 2245: Preserving Access to Life-Saving Medications Act of 2011
- S.296: Preserving Access to Life-Savings Medication Act