

NORTH CAROLINA ONCOLOGY ASSOCIATION

President:

Birgit A. Arb, M.D.
(Wilmington)

March 14, 2011

President-Elect:

Linda Sutton, M.D.
(Durham)

The Honorable G. K. Butterfield
2305 Rayburn House Office Building
Washington, DC 20515-3301

Secretary/Treasurer:

Theodore Flint Gray III, M.D.
(Boone)

**RE: S. 296 and Shortages of Chemotherapeutics and Related
Drugs for Cancer Treatment**

Dear Representative Butterfield:

Immediate Past-President/

Jennie R. Crews, M.D.
(Washington)

As a non-profit organization promoting the practice of excellence in cancer care in North Carolina, the North Carolina Oncology Association (NCOA) would like to bring your attention to a major threat to patient access for needed medications: Certain chemotherapeutics and other related drugs are in scarce supply in North Carolina and across the country. These therapies are necessary for providing quality care and without them, patients may be forced to change – or potentially stop – recommended regimens for treatment of their disease.

Members At Large:

Alan D. Kritz, M.D.
(Raleigh)

Glen Lesser, M.D.
(Winston-Salem)

Michael J. Messino, M.D.
(Asheville)

Matthew E. Nielsen, M.D.
(Chapel Hill)

Some of the oncology therapies undergoing a supply shortage are: **Leucovorin, Doxorubicin, Vincristine, Etoposide, Cisplatin, and Cytarabine.** While the shortage of these drugs is the most problematic, this list is not exhaustive. Manufacturers have different reasons for not making the drugs, and some will resume production later this year. However, this is not the case in all situations, and some drugs have no timeline for future availability. Additional shortages can be viewed at <http://www.fda.gov/drugs/drugsafety/drugshortages/ucm050792.htm>.

Oncology CAC Representative

David Eagle, M.D.
(Moorestville)

In most cases providers are not warned of impending shortages, which increases frustration and prohibits them from anticipating adjustments to treatment regimens. Currently, it is the responsibility of providers to report shortages to the U.S. Food and Drug Administration (FDA), creating an additional burden on these doctors on top of the clinical implications. This is of considerable concern to NCOA, and we have communicated these concerns to the manufacturers.

Hematology CAC Representative

James Boyd, M.D.
(Charlotte)

CPC Representative

Stephen Bernard, M.D.
(Chapel Hill)

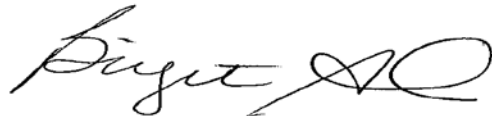
However, there is something Congress can do to hold manufacturers more accountable for these shortages. S. 296, *Preserving Access to Life-Saving Medications Act*, recently introduced by Senator Klobuchar, requires manufacturers to report impending manufacturing stoppages to the FDA. It is hoped that this legislation will discourage unnecessary shortages in the future. While this bill does not solve all of the problems associated with drug scarcity, it is a step in the right direction. Therefore, NCOA requests your support of this important legislation.

Additionally, we are interested in any other assistance your office can provide, including letters on behalf of your constituents to manufacturers, distributors, and the FDA.

The shortage of chemotherapeutic drugs is a growing problem that continues to affect

more patients. Any assistance you can provide is greatly appreciated. Please feel free to contact me for more information.

Sincerely,



Birgit A. Arb, MD

cc: Teva Pharmaceuticals; Attn: Leucovorin/Doxorubicin/Vincristine/
Etoposide/Cisplatin Department; Jeffrey Herzfield, Senior VP and General
Manager, Teva Health Systems; 1090 Horsham Road; PO #1090; North Wales, PA
19454

Hospira Pharmaceuticals; Christopher B. Begley, Chairman and Chief Executive
Officer; 275 North Field Drive; Lake Forest, Illinois 60045

APP Pharmaceuticals; John Ducker, Chief Executive Officer and President; 1501
East Woodfield Road, Suite 300 East; Schaumburg, IL 60173-5837

David Gaugh, VP and General Manager of Bedford Labs; 300 Northfield Road;
Bedford, OH 44146

LCDR Valerie Jensen; Drug Shortage Project Manager; Center for Drug Evaluation
and Research; Food and Drug Administration; 5600 Fishers Lane; Rockville, MD
20857

Mark J. Goldberger, MD, MPH; Drug Shortage Coordinator; Center for Drug
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