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February 21, 2012 (202) 225-7772

Burgess Presses FDA on Drug Shortages, FDA Responds By Allowing Importation of Replacement Drug

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Washington, D.C. – Last week, Congressman Michael C. Burgess, M.D. (TX-26), Vice Chair of the House Energy and Commerce Committee's Subcommittee on Health and Chairman of the Congressional Health Care Caucus, pressed the Food and Drug Administration (FDA) about drug shortages, specifically Doxil a chemotherapy drug, during the Energy and Commerce Subcommittee on Health hearing, "Review of the Proposed Generic Drug and Biosimilars User Fees and Further Examination of Drug Shortages." Today the FDA announced that they will allow a temporary importation of Lipodox, a replacement for Doxil. Upon the announcement, Dr. Burgess issued the following statement:

"This action is a step in the right direction, but it is only temporary and the FDA will need to continue to work on a long-term solution for this and other drug shortages. Simply importing drugs from other countries is not a solution, but was unfortunately a necessary step in a drastic situation. Importing drugs should not become the norm, and it could be avoided by improving communication on the front end to avoid shortages.

"Drug shortages happen for many reasons, and there is no silver bullet. However, when they occur, each case must be approached, dissected, and dealt with. Chemotherapy drugs are different than other drugs and you can't just switch a patient from one chemotherapy drug to another.

"I have raised this issue many times during Energy and Commerce Committee hearings. As I said in the hearing last week, when doctors don't have essential tools they may be restricted in what they can do for patients, and that can result in a life being saved or lost. A physician never wants to tell a patient they can't receive the care they need simply because a product is not available."

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