

Language Included in FDA Reform Act

WASHINGTON – Today, bipartisan legislation to combat drug shortages sponsored by U.S. Reps. Diana DeGette (CO-1) and Tom Rooney (FL-16) passed the House of Representatives, as part of the Food and Drug Administration (FDA) Reform Act. The drug shortage provision language will improve patient safety by creating a communication framework to reduce shortages of life-saving drugs and give patients and physicians early warning of impending shortages so that they may adjust treatments accordingly. The FDA Reform Act, including the drug shortage legislation, overwhelmingly passed the House by a 387-5 vote.

“I started working on drug shortage legislation more than a year ago after meeting with doctors and hospital administrators at Charlotte County Regional Medical Center, who told me they were facing shortages of critical, life-saving drugs, and we needed to act. I’m very proud today to tell them that with the support of patients, doctors and pharmacists across the country, the House has passed this important, bipartisan bill,” **said Rooney**. “By giving doctors, suppliers and FDA get an early notice about a potential shortage, we can help them respond and even prevent disruptions from occurring.”

“Throughout this crisis I’ve talked to patients battling devastating diseases like cancer, who show up for treatment one day, only to find out their life-saving drugs are not available. Just last week I met with Denver EMS and ER doctors who told me that the medicines they need to treat us in life-threatening emergencies are now also in shortage,” **said DeGette**. “That is why I am so proud we passed a bipartisan bill to create an early warning system so the FDA, drug companies and doctors can better respond to shortages, quickly and efficiently. Today, the U.S. House came together across party lines to take a significant step towards getting drug shortages under control and protecting the health of America’s families.”

Rep. Fred Upton (MI-06), Chairman of the House Energy and Commerce Committee, said, “Representatives DeGette and Rooney have been real leaders in the effort to call attention to and address the issue of drug shortages. They’ve worked tirelessly to find bipartisan solutions to a crisis that is threatening patients across the country, and I’m pleased we were able to include those ideas in the FDA Reform Act passed overwhelmingly by the House.”

Recent data from the University of Utah Drug Information Service showed that 2011 had 56 more incidents of drug shortages than 2010, with a total of 211 life-saving medications suddenly unavailable. Many of these shortages impact cancer patients – and particularly pediatric cancer patients – leaving them, literally, without lifesaving treatment. In emergency medicine, EMS workers and ER doctors are coping with shortages of medications that treat everything from cardiac arrests, to seizures, to life-threatening allergic reactions, to severe pain, among others. These shortages often force medical providers to delay or alter patient care plans. In many instances, no safe alternatives to these drugs exist, leaving patients with an increased risk of side effects and adverse drug interactions.

Early reporting to the Food and Drug Administration (FDA) has recently proven to go a long way

towards addressing these shortages and protecting patients. In fact, since last November, because of mostly voluntary reporting from manufacturers, the FDA has prevented 128 shortages. This February, because of early notification, the FDA stepped in to allow for temporary, emergency importation of the cancer drug Doxil when it went into shortage. At the same time, they prioritized the review of a new manufacturer of methotrexate when this critical cancer drug went into shortage.

The DeGette-Rooney language creates an early warning system between the FDA, drug companies, and providers so that the community can respond to a drug shortage quickly and efficiently. Specifically it would:

- Require manufacturers of prescription drugs, including biologics, to notify the FDA of any discontinuance or interruption in the production of a drug at least six months in advance or as soon as practicable;
- Instruct the Secretary to distribute this information to appropriate health care providers and patient organizations; and
- Authorize the GAO to conduct a study to examine the causes of drug shortages and issue recommendations on how to prevent or alleviate a drug shortage.

The American Hospital Association, the American Medical Association, American Society of Clinical Oncology, American Society of Health-System Pharmacists, and the American Cancer Society, Ovarian Cancer National Alliance, the Leukemia and Lymphoma Society, the National Association of Children's Hospitals, and many other medical associations and health care groups have endorsed the DeGette-Rooney bill, as has the generic drug manufacturer Hospira, Inc.

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DeGette, Rooney Drug Shortage Legislation Passes U.S. House

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