

Language Included in Unanimously Supported PDUFA Reauthorization

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 Energy and Commerce Committee, as part of the Prescription Drug User Fee Act (PDUFA). The drug shortage provision language should 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. PDUFA, including the drug shortage legislation, passed the Committee unanimously.

“Today we take a significant step in protecting the health of American families, and particularly those patients who have faced the frightening situation of being unable to access the medication they desperately need,” said DeGette. “Our bipartisan legislation will create an early warning system so the FDA, drug companies, and doctors can better respond to any shortage, quickly and efficiently, and make sure patients’ health is protected. The bipartisan support for this bill is a reminder of the seriousness of this crisis, and a sign that when the health of the American people is on the line, it is still possible for Congress to come together to do the right thing.”

“Across the country, patients and their doctors are facing shortages of critical, life-saving drugs,” said Rooney. “When doctors, suppliers and FDA get an early notice about a potential shortage, they’re better able to respond and even prevent disruptions from occurring. By including our legislation in the bill approved today, the Energy and Commerce Committee has taken an important step toward reducing drug shortages and saving lives.”

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. These shortages often force doctors 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.

But 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.

The drug shortage language, as passed in PDUFA, is expected to come to the House Floor for a full vote in the coming weeks.

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DeGette, Rooney Legislation to Combat Drug Shortages Clears Committee

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