

Bill Responds to Concerns of Local Doctors, Hospitals

WASHINGTON – Bipartisan legislation to combat drug shortages sponsored by U.S. Rep. Tom Rooney (FL-16) after meeting with doctors and administrators at Charlotte County Regional Medical Center is now headed to the President for his signature. The Senate approved the bill, which Rooney cosponsored with Rep. Diana DeGette (CO-1), as part of the Food and Drug Administration (FDA) Reform Act.

“I started working on drug shortage legislation more than a year ago after meeting with doctors and hospital administrators at Charlotte Regional, who told me they were facing shortages of critical, life-saving drugs, and we needed to act,” Rooney said. “I’m proud to tell our local patients, doctors and pharmacists that with their support, this bipartisan bill is finally headed to the President for his signature.”

“Today is a great day for thousands of American families, and particularly those patients who have recently faced the frightening situation of being unable to access the medication they desperately need,” said DeGette. “This bipartisan legislation heading to President Obama’s desk 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.”

In 2011, 211 life-saving medications suddenly became unavailable for doctors and patients, forcing medical providers to delay or alter patient care plans. These shortages include medications to treat cancer, seizures, life-threatening allergic reactions, and severe pain, among others. There are no safe alternatives to many of these drugs, leaving patients with an increased risk of side effects and adverse drug interactions.

The DeGette-Rooney language creates an early warning system between the FDA, drug companies, and providers so they 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, 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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