

Washington, D.C. – U.S. Reps. Tom Rooney (FL-16) and Diana DeGette (CO-01) today announced President Obama’s support for the [“Preserving Access to Life-Saving Medications Act,”](#) a bipartisan bill Rooney and DeGette introduced in June to improve patient safety by reducing shortages of life-saving drugs.

“I’ve heard from patients and doctors in my district and nationwide who are experiencing limited, and sometimes zero, access to life-saving drugs, from commonly used anesthetics to cancer therapies,” Rooney said. “I’m very pleased that President Obama is addressing this critical issue and supporting our bipartisan bill. The earlier doctors, suppliers and the FDA are able to communicate a potential drug shortage, the better equipped they will be to respond and prevent a disruption in supply from occurring.”

“While I am excited that the President will take the steps that are available to him to address the growing drug shortage problem,” said DeGette, “today’s announcement does not diminish the necessity of passing our bipartisan legislation. Not only does our bill go beyond what the President outlined today, but it will encase in law a common-sense approach to dealing with drugs that are heading towards shortage. As the number of potentially life-threatening drug shortages continues to grow, it’s time for Congress to come together and pass our critical legislation.”

According to the Food and Drug Administration (FDA), drug shortages have nearly tripled since 2005 and hit a record high of 178 last year, forcing 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.

Currently, only sole-source manufacturers of medically necessary drugs are required to report discontinuances to the FDA, so the agency can help mitigate the disruption and notify doctors. In fact, the FDA says 38 shortages were prevented in 2010 from companies who provided early notification of a possible disruption. The DeGette-Rooney bill would expand that law to combat drug shortages by:

- Requiring manufacturers of all 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;
- In the event of an unplanned discontinuance or interruption, requiring manufacturers to

notify the FDA as soon as possible;

- Instructing the Secretary to publish these notifications and any actual drug shortage on its website, and work to distribute this information to appropriate health care providers and patient organizations; and,
- Directing a GAO study to examine the possible causes of drug shortages, including manufacturing problems, breakdown in supply chains and delivery systems, and restrictive regulatory requirements.

**The American Hospital Association, Premier, the American Medical Association, the American Cancer Society, the Leukemia and Lymphoma Society, the National Association of Children’s Hospitals, the American Society of Clinical Oncologists, the Institute for Safe Medication Practices, the American Society of Health-System Pharmacists, the American College of Emergency Physicians, the Pharmaceutical Care Management Association, the Association of Community Cancer Centers, Hematology/Oncology Pharmacy Association, and generic manufacturer Hospira, Inc. have endorsed the bill.**

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