

## **The Preserving Access to Life-Saving Medication Act of 2011 (HR 2245)**

### **About Us**

Registered dietitians work to improve the health of all Americans through access to healthy food and nutrition services. The American Dietetic Association is a non partisan group that represents more than 70,000 members; and is the world's largest organization of food and nutrition professionals.

### **We Ask For Your Support for the Preserving Access to Life-Saving Medication Act**

HR 2245 will amend the Federal Food, Drug, and Cosmetic Act to require a prescription drug manufacturer to notify the Secretary of HHS of a discontinuance, interruption or other adjustment of the manufacturer of a drug that would likely result in a shortage of such drug. The bill requires a six month notice of any discontinuance or planned interruption or adjustment and provides for a penalty of \$10,000 for each day of violation but not to exceed \$1.8 million. There is a senate companion bill (S 296) introduced by Senator Klobuchar (D-MN), the bill has 11 cosponsors and is currently in the Senate HELP committee.

- The Institute for Safe Medication Practices released a study in July where they surveyed 1,800 health care practitioners showing a clear frustration with the shortage of injectable drug such as anesthetics, painkillers and drugs used for chemotherapy. (1)
- A record 211 medication became scarce in 2010; three times the amount when compared to 2006. (2)
- Lack of advance notice to pharmacists is a primary concern. Currently a company can simply stop manufacturing a drug. A health care provider has awareness that the drug or IV solution is unavailable until an order is placed.
- In early 2011 at Miami Children's Hospital, doctors had to postpone, for a month, the last round of chemotherapy for a 14 year old girl because of a months-long nationwide shortage of cytarabine – a drug considered key to curing a type of leukemia. (3)
- The FDA doing what they can within their jurisdiction to investigate the shortages but needs expanded authority to develop a process and solution.
- When a patient's recovery is sidetracked by a drug shortage that inhibits his/hers ability to get healthy. As a result that negatively affects the registered dietitian's ability to do their job by aiding in that recovery through food and nutrition therapy.

### **By Supporting HR 2245 you will help to:**

- Give doctors, pharmacists, RDs and nurses time to find a potential substitute and explore other options so that dispensing errors can be minimized.
- Allow the FDA to work with other manufacturers, both domestic and international, to find new sources and ensure that the supply chain is not interrupted.

In the event of drug shortages this bill will give registered dietitians the time needed to address the problem, while maintaining the quality of care for their patients.

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- (1) <http://www.ismp.org/Newsletters/acutecare/articles/20100923.asp>
  - (2) [http://www.washingtonpost.com/national/shortages-of-key-drugs-endanger-patients/2011/04/26/AF1aJJVF\\_story.html](http://www.washingtonpost.com/national/shortages-of-key-drugs-endanger-patients/2011/04/26/AF1aJJVF_story.html)
  - (3) [http://www.huffingtonpost.com/2011/05/30/drug-shortages-rise\\_n\\_868778.html](http://www.huffingtonpost.com/2011/05/30/drug-shortages-rise_n_868778.html)