

## **The Preserving Access to Life-Saving Medication Act of 2011 (S 296/HR 2245)**

### **Situation**

Nutrition Support Therapy (NST) is a vital procedure to patient recovery, managed by registered dietitians. As you know, NST provides a way to supply nutrients via a feeding tube or IV to supply nutrition. A registered dietitian working in critical care needs to have assurances that he/she will be available to provide nutrients to treat and prevent malnutrition. Components of TPN such as calcium, gluconate, sodium and potassium phosphate as well as various drugs (pain killers) needed to administer TPN are in shortage. The Preserving Access to Live-Saving Medication Act (S 296) was introduced in the Senate by Amy Klobuchar (D-MN) on February 7, 2011. The bill was referred to the Senate Committee on Health, Education Labor and Pensions (HELP) and has legislation has 11 cosponsors, including: Blumenthal (CT), Brown (OH), Cardin (MD), Casey (PA), Coons (DE), Feinstein (CA), Franken (MN), Mikulski (MD), Reed (RI), Schumer (NY), Tester (MT).

The companion bill introduced by Congresswoman DeGette (HR 2245) is a bipartisan bill that was introduced on June 21, 2011 and is originally cosponsored by Congressman Tom Rooney (F-FL). On June 21 the bill was referred to the House Committee on Energy and Commerce. There have not been scheduled hearings or votes.

### **Differences between Senate and House bills**

Both bills create an early warning detection system; however Congresswoman DeGette's measure would include biologics (*a medical product such as a vaccine, allergenic, stem cell that is created by a biologic process and not chemically synthesized*). Including these drugs ensures that certain types of cancer treatments be covered, as some of these treatments are included within the bills mandate.

### **Overview of the Act**

The bills 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 manufacture of a drug that would likely result in a shortage of such drug. It requires:

- A six month notice of any discontinuance or planned interruption or adjustment.
- The bill would be applied to any approved prescription drug. The bill sets forth the types of adjustment for which a manufacturer must submit notice, including:
  - Adjustments related to the supply of raw materials.
  - Adjustments to production capabilities.
  - Business decisions that may affect the manufacturer of the drug and,
  - Other adjustments as determined appropriate by the Secretary of HHS.
- The bill determines the appropriate penalty to be \$10,000 for each day of violation, but not to exceed \$1.8 million.
- The bill directs to Government Accountability Office (GAO) to examine the causes behind the drug shortages.

**Bottom Line:**

The problem of drug shortages including for parenteral solutions continues to grow nationwide. The purpose of TPN is to provide total nutrition to a patient and with shortages of vitamins and minerals this is not always possible. HR 2245 will provide a process to predict shortages and ways to resolve them.

**Talking Points for Hill Visits****Introduction: Who You Are**

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

**What:**

Our purpose today is to ask for support through co-sponsorship and/or passage of the Preserving Access to Live-Saving Medication Act of 2011 (HR 2245)

**The Problem**

- 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.

**The Solution:**

This bill would provide the following solutions to this life threatening problem:

- Give physicians, registered dietitians, pharmacists 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.
- Prevent interruption in care and help to ensure that the recovery of a patient is not negatively interrupted.

**Setting the Stage for the Ask:**

- Proper and total nutrition is imperative for critically ill patients.
- A registered dietitian working in critical care needs to have assurances that he/she will be available to provide nutrients to treat and prevent malnutrition. Components of TPN such as

calcium, gluconate, sodium and potassium phosphate as well as various drugs (pain killers) needed to administer TPN are in shortage. Children and infants especially are in need of TPN, mostly because they are vulnerable to malnutrition.

**For more information on the language of the bill visit:**

Senate bill → <http://thomas.loc.gov/cgi-bin/thomas>

House bill → <http://thomas.loc.gov/cgi-bin/thomas>

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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)