Drug Shortages Effecting Patient Care

March 2012

Overview
The drug shortage issue has been a concern since 2000 and is much broader than just TPN solutions. Unfortunately the problem is increasing. The shortages are attributed to many complex factors including consolidation and mergers of drug companies that leaves fewer production options for a particular drug, mineral or solution, or quality issues that surface and become problematic for certain drugs.

In addition, the approval process for domestic drugs versus foreign drugs is vastly different, sometimes making it difficult to quickly end a shortage. There is also a backlog in drug approvals and many common generic drugs are caught in this process.

Components of Total Parenteral Nutrition (TPN) such as calcium, gluconate, sodium and potassium phosphate as well as various drugs (painkillers) needed to administer TPN are in shortage. This legislation takes steps to identify and resolve the drug shortage problem which includes vital drugs administered by dietitians in the workplace.

Executive Order
In 2011 the President issued an executive order that directed the Food and Drug Administration (FDA) and the Department of Justice to take action to help further reduce and prevent drug shortages. The executive order took steps in the right direction to address the problem. However, the President’s authority does not have the binding effect of law, and so these bills were drafted to codify many of the President’s initiatives into law. To read the President’s entire Executive Order click here: [http://www.whitehouse.gov/the-press-office/2011/10/31/fact-sheet-obama-administration-takes-action-reduce-prescription-drug-shm](http://www.whitehouse.gov/the-press-office/2011/10/31/fact-sheet-obama-administration-takes-action-reduce-prescription-drug-shm)

THE SENATE FINANCE COMMITTEE HAS HELD HEARINGS TO EXAMINE EXISTING AND FUTURE DRUG SHORTAGES AND THEIR EFFECT ON OUR NATION’S HEALTH AND ACCESS TO LIFE-SAVING TREATMENTS.

SENATOR MAX BAUCUS’ OF MONTANA COMMENTS HIGHLIGHT THE IMPACT OF SHORTAGES AFFECTING PATIENTS’ NUTRITIONAL STATUS.

CLICK HERE TO SEE HIS COMMENTS-http://www.youtube.com/watch?v=1e-axsx_zkQ

KEY POINTS TO COVER IN HILL VISITS

1. WITH INCREASING SHORTAGES, WE NEED TO TAKE STEPS NOW TO HELP ADDRESS THIS PUBLIC HEALTH CRISIS.

2. SHORTAGES OF NUTRIENT SOLUTIONS HAVE NEGATIVELY IMPACTED OUR MEMBERS’ (RDs) ABILITY TO SERVE THEIR PATIENTS.

3. THESE SHORTAGES SIGNIFICANTLY IMPAIR THE HEALING AND RECOVERY OF THESE SICKEST AND MOST VULNERABLE PATIENTS WHILE DRIVING UP HEALTH CARE COSTS.

WANT STORIES TO SHARE WITH YOUR MEMBERS OF CONGRESS?

CONTACT MEMBERS OF KEY DIETETIC PRACTICE GROUPS WORKING IN THE AREA-

- CLINICAL NUTRITION MANAGEMENT
- DIETITIANS IN NUTRITION SUPPORT
- MEDICAL NUTRITION PRACTICE GROUP
- PEDIATRIC NUTRITION
- PUBLIC HEALTH/COMMUNITY

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Bills in Congress

Congress has taken on this issue and has introduced three bills, two in the House and one in the Senate. The Academy supports all three bills and would like to see passage.

   
   Congressman Diana DeGette (D-CO) introduced this bill in June 2011 and was referred to the House Committee on Energy & Commerce, Subcommittee on Health. The bill currently has 74 co-sponsors. This legislation will amend the Federal Food, Drug and Cosmetic Act to require drug manufacturers to notify FDA of a discontinuance, interruption, or other adjustment that would likely result in a shortage of a drug.
   
   Key components of the bill:
   - Require a six month notice of any discontinuance/ planned interruption or adjustment.
   - Require the manufacturer to submit a notice to FDA regarding:
     - Adjustments related to the supply of raw materials
     - Adjustments to production capabilities
     - Business decisions that may affect the manufacturer of the drug
   - Determine the appropriate penalty to be $10,000 for each day of violation, but not to exceed $1.8 million.
   - Direct the Government Accountability Office to examine the causes of the shortages.

2. **U.S Senate Preserving Access to Life-Saving Medications Act-S.296**
   
   A companion bill was introduced by Senator Klobuchar (D-MN) on February 7, 2011 and was referred to the Senate Health, Education, Labor and Pensions (HELP) Committee. The bill currently has 27 co-sponsors. The major difference between the two bills is that the House version includes biologics in the list of drugs that must be monitored. A biologic is a medical product such as a vaccine, allergenic or stem cell that is created by a biologic process and therefore not chemically made. Biologics can be included in certain types of cancer treatments.


   Introduced by Congressmen John Carney (D-DE) and Larry Bucshon (R-IN) with 9 co-sponsors, this bill complements the others by providing ways to address the drug shortage problem. Key components of the bill:
   - Create a national “critical drug” list.
   - Develop a proactive notification system to alert the public.
   - Allow the FDA to speed up the review process for drugs seeking approval, so that companies can produce faster if certain drugs are in shortage.
   - Streamline the regulatory and approval process.