The Impact of the Withdrawal of Propoxyphene from the U.S. Market

Michele Hedba, PharmD candidate and Mark V Siracuse, PharmD, PhD

Background

- Timeline and Clinical Profile
- Propoxyphene - originally developed by Eli Lilly & Co.1,2
- Approved on August 16, 19573
- Indicated for the relief of mild to moderate pain1,3
- Brand names: Darvon® and Darvocet®1,2
- Most dispensed outpatient prescription from 1967 – 19694
- Assigned to schedule IV drug status on March 14, 1977

Background

- In 2005, the United Kingdom announced its phased withdrawal of propoxyphene based on the well known risk of overdose and the poorly established efficacy.5
- In 2006, Public Citizen petitions the FDA for the second time to remove propoxyphene from the market citing:1
  - Poor efficacy
  - Potential addiction profile
  - Placement on Beers list
  - Cardiotoxic metabolite implicated in over 2000 accidental propoxyphene-related deaths from 1981-1999 according to DAWN (Drug Abuse Warning Network)

- FDA advisory committee recommended withdrawal of propoxyphene on January 30, 2009.5,10
- FDA rejected the advisory committee recommendation on July 6, 2009
- Xanodyne agreed to withdraw propoxyphene from the U.S. market on August 6, 2009

Objectives

- To determine the clinical and economic impact of the withdrawal of propoxyphene from the U.S. market. Using a proprietary data set we:
  - Determined the prescription products that patients were switched to following withdrawal of propoxyphene.
  - Determined the cost of the prescription products that patients were switched to.

Study Design

- Using a pharmacy claims database, investigators will analyze the impact of the withdrawal of propoxyphene products
- The procedure will be to first determine baseline propoxyphene usage and economic parameters via a query of databases to determine all pharmacy claims for these products between November 19, 2009 and November 19, 2010
- The next step will be to determine alternative drugs used for pain management in place of propoxyphene from November 20, 2010 through November 19, 2011 with identification numbers only.
- The information gathered from database queries will include the number of prescriptions for each drug, number of patients taking each product, number of doses dispensed per prescription, and economic data for each product.

Predicted Outcomes

- In regards to pain relief, the potency of propoxyphene is the same as aspirin or acetaminophen.
- Taking into account all of the alternatives to propoxyphene, literature would suggest that acetaminophen would be the safest, most economic and most prevalent option for the majority of patients. While this may be true, there is the possibility and speculation that contrary will be apparent in our results from our database study.

Funding Source

School of Pharmacy and Health Professions Student Research Program