

## Drugs in the News 6/19/09 – Positive Public Health Effect of Withdrawing Propoxyphene Containing Analgesics in the UK

In January 2005 the Medicines and Healthcare Products Regulatory Agency (MHRA), the UK's equivalent of the US FDA, announced that all propoxyphene containing products would be withdrawn from the market by December 31, 2007. The basis for this regulatory action was lack of analgesic efficacy and the unacceptable safety of the drug. The risk and minimal, if any, benefit of propoxyphene have long been documented in the medical literature.

Academics publishing in this morning's *British Medical Journal* analyzed the effect of withdrawing propoxyphene on prescribing and deaths from drug poisoning in England and Wales. The authors reported that after the announcement of the propoxyphene withdrawal in January 2005 there was an immediate large reduction in prescriptions of 59% compared to prescription data from 1998 to 2004. This was associated with a 62% reduction in deaths from suicide with an estimated absolute reduction in the number of deaths of 349 over a three year period.

The authors concluded that these results are an example of an action by the UK's drug regulatory authority, based on a risk assessment of propoxyphene that had an important positive public health impact.

In the US, propoxyphene products have long been included on the Beers List of inappropriate drugs for use in older adults because of safety and effectiveness issues. See the May 2006 publication of the *Drug Information Letter* available on the Center for Drug Information and Research's Web site, [cdi.lecom.edu](http://cdi.lecom.edu) at [http://cdi.lecom.edu/newsletters/2006/2006\\_vol\\_2\\_no\\_5.pdf](http://cdi.lecom.edu/newsletters/2006/2006_vol_2_no_5.pdf) for additional information on propoxyphene products and the elderly.

Despite serious safety concerns with propoxyphene there were more than 20 million prescriptions dispensed for the drug in 2008 in US pharmacies according to the *Drug Topics* list of the top 200 generic drugs for that year.

Public Citizen a Washington DC based public interest group sued the FDA on June 19, 2008, for failing to act on its petition to withdraw all drugs containing propoxyphene gradually from the market as has now been required in the UK ([http://www.worstpills.org/public/page.cfm?op\\_id=415](http://www.worstpills.org/public/page.cfm?op_id=415)).

The FDA's Anesthetic and Life Support Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee held a joint meeting January 30, 2009 to discuss the safety and efficacy of propoxyphene combination products. The Committee voted 14 to 12 to recommend that the FDA discontinue marketing authorization for these products.

Propoxyphene products should no longer be prescribed and patients on propoxyphene containing products should be switched to more effective safer analgesics.

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