FDA Requests Endo Pharmaceuticals Remove Opana ER from the Market

In a historic announcement on June 8, 2017, the U.S. Foods and Drug Administration (FDA) requested that Endo Pharmaceuticals voluntarily remove reformulated Opana ER (oxymorphone hydrochloride) from the market due to reports of abuse. This is the first time the FDA has requested removal of an opioid analgesic from the market due to abuse concerns. The FDA approved the original ER oral tablets in June 2006 with a black box warning for abuse. They are now concerned that the risks of abuse with use of the drug are greater than the benefit it may provide patients.

Opana is a schedule II, potent, semi-synthetic, opiate-agonist analgesic that can be used to relieve pain for a variety of different conditions. It is commonly used for relief of moderate to severe pain, pain relief during labor, and as an adjunct to anesthesia during surgery. Post-marketing studies have shown that despite reformulating Opana ER in 2012 and adding polyethylene oxide in an attempt to make it abuse deterrent, it is increasingly abused intravenously. This abuse has been associated with serious health consequences, including an outbreak of HIV and hepatitis C. It has also been associated with a serious blood disorder (thrombotic microangiopathy) and acute kidney injury. In response to the announcement, Endo Pharmaceuticals has said they will review the request and determine potential options to resolve the issue. However, they are confident that the benefits of reformulated Opana ER, if used as directed in the appropriate patient population, still outweigh the risks. If Endo Pharmaceuticals does not voluntarily remove Opana ER from the market, then the FDA has said it will take steps to withdraw its approval to prevent further public health consequences of abuse.

References:

- FDA News Release. FDA requests removal of Opana ER for risks related to abuse. FDA. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm
- Opana. Clinical Pharmacology [Internet database]. Gold Standard, Inc., 2017. Available at: http://www.clinicalpharmacology.com. Accessed: June 12, 2017.
- RTT News. FDA asks Endo Pharmaceuticals to remove Opana ER for risks related to abuse. Nasdaq. Available at: http://www.nasdaq.com/article/fda-asks-endo-pharma-to-remove-opana-er-for-risks-related-to-abuse-20170608-01346
- Ellen Fields. Regulatory history of Opana ER. FDA. Available at: https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM547235.pdf
- Ambruzs, J. M., Serrell, P. B., Rahim, N., & Larsen, C. P. (2014). Thrombotic Microangiopathy and Acute Kidney Injury Associated With Intravenous Abuse of an Oral Extended-Release Formulation of Oxymorphone Hydrochloride: Kidney Biopsy Findings and Report of 3 Cases. *American Journal of Kidney Diseases, 63*(6), 1022-1026. doi:10.1053/j.ajkd.2014.01.015

Chelsea Yeager, PharmD Candidate