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DUR Matters

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Warnings for Use of Opioids with Benzodiazepines

On August 31, 2016, the Food and Drug Administration (FDA) issued a press release regarding the class-wide changes for the labeling of products to inform health care providers and patients about the risks of combining opioids and benzodiazepines. These changes require the FDA's strongest warning for drug product labeling and Medication Guides for patients to be added to nearly 400 products which include opioid analgesics, opioid-containing cough products and benzodiazepines. The boxed warnings will provide information about the serious risks of concomitant use of the medications including extreme sleepiness, respiratory depression, coma and death.[1]

"It is nothing short of a public health crisis when you see a substantial increase of avoidable overdose and death related to two widely used drug classes being taken together," said FDA Commissioner Robert Califf, M.D. "We implore health care professionals to heed these new warnings and more carefully and thoroughly evaluate, on a patient-by-patient basis, whether the benefits of using opioids and benzodiazepines – or CNS depressants more generally – together outweigh these serious risks."[1]

The FDA reviewed data about the co-administration of opiates and benzodiazepines. This review found an increase in prescribing them together, and an association with adverse outcomes. "The FDA concluded that from 2004 to 2011, the rate of emergency department visits involving non-medical use of both drug classes increased significantly, with overdose deaths (from taking prescribed or greater than prescribed doses) involving both drug classes nearly tripling during that period. Additionally, the number of patients who were prescribed both an opioid analgesic and benzodiazepine increased by 41 percent between 2002 and 2014, which translates to an increase of more than 2.5 million opioid analgesic patients receiving benzodiazepines."[1]

The labeling changes are consistent with the March 2016 recommendations from the Centers for Disease Control and Prevention (CDC) for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The CDC noted that studies suggest patients are at greater risk for potentially fatal overdose when benzodiazepines and opioids are used concomitantly. Concomitant use of benzodiazepines and opioids was reported in 31% to 61% of patients who suffered a fatal overdose. More importantly, the death rate was higher among patients who received opioids from multiple prescribers and pharmacies.[2]

In Nebraska, the DUR Board has discussed the risks for patients taking an opioid and benzodiazepine concomitantly. In January of 2016, there were 1,811 prescribers of 2,143 patients who were identified by claims data as taking both a benzodiazepine and an opioid medication. Letters were sent to 400 of the prescribers with the highest number of patients to inform them of this important safety concern. In August of 2016, there were 1,687 prescribers of 1,909 patients identified as taking this dangerous combination. Prescribers and pharmacists should talk to patients about the risk of serious adverse effects and possibly death when these drugs are used together. Prescribers need to avoid initiating the combination of these drugs and should work with patients to taper and eliminate the combination of these medications when possible.

References:

1. FDA News Release August 31, 2016 (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm)

2. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016 Recommendations and Reports / March 18, 2016 / 65(1);1–49

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