Title: Reduction In Extended Release (ER) Oxycodone Diversion Rates Following the Introduction of a Reformulated ER Oxycodone Product

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Abstract:

**Aim of Investigation:** In August 2010, Purdue Pharma introduced a reformulated extended release (ER) oxycodone product that is intended to deter crushing and that forms a gel when dissolved. The new formulation is intended to deter abuse through routes that require tampering. This study examines whether there was a decline in rates of diversion of ER oxycodone manufactured by Purdue following the introduction of the reformulation using data collected from drug diversion agents participating in the RADARS® System, an established surveillance system for prescription drug abuse. The RADARS® Drug Diversion Program surveys approximately 300 reporters in 50 states. Drug diversion agents participating in the program covered 61% of the US population in the 3rd quarter of 2011.

**Methods:** Diversion cases were obtained on a quarterly basis using reports from law enforcement agencies participating in the RADARS® System. To adjust for changes in program coverage, diversion rates per 100,000 population were calculated for each year/quarter using the 2000 US Census population data adjusted for population growth. To adjust for changes in drug availability, diversion rates per 1,000 unique recipients of dispensed drug (URDD) were calculated for each year/quarter. Rates from October 1, 2008 through September 30, 2010 were considered the period before introduction of the new formulation. Rates from October 1, 2010 to September 30, 2011 were considered the period after introduction of the new formulation. The mean rate before the introduction of the new formulation was compared to the mean rate after the introduction of the new formulation. This difference was compared to the difference observed for other prescription opioids tracked by the RADARS System during the same time period. Rates were compared using negative binomial regression.

**Results:** There was an estimated 47% decline (95% CI: 34-57%) in the average ER oxycodone diversion population rate from 0.35 per 100,000 before to 0.18 per 100,000 after the introduction of the new formulation. There was an estimated 45% decline (95% CI: 32-57%) in the average ER oxycodone diversion URDD rate from 1.45 per 1,000 URDD before to 0.79 per 1,000 URDD after introduction of the new formulation. The differences in the mean rates for other opioids excluding ER oxycodone were not significant.
**Conclusions:** These findings indicate that the introduction of the new formulation was followed by a decline in diversion of ER oxycodone manufactured by Purdue independent of changes in the survey coverage area and in the number of individuals filling prescriptions for ER oxycodone. The observed decline did not reflect an overall change in diversion of prescription opioids. The decreased diversion of ER oxycodone to illegal channels suggests a decline in demand for the new formulation versus the original formulation.