Title: The Role of Tapentadol ER in the Illicit Market for Opioid Analgesics in the United States

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Abstract: US law enforcement officers routinely investigate diversion of prescription opioids to the illicit market. Tapentadol (Nucynta®) is an USDEA Schedule II analgesic with dual actions: modest mu agonist activity and norepinephrine reuptake inhibition. We compared rates of diversion events from the Drug Diversion Program of the RADARS® System for tapentadol ER (Nucynta® ER) to tapentadol IR, and to other Schedule II opioid oral tablets (oxycodone, hydromorphone, morphine, oxymorphone, and methadone). The program has 250 investigators in 49 states. Rates were determined by dividing the number of diversion cases in a jurisdiction by the population of the same jurisdiction (population rate) and dividing by drug availability as represented by the number of people filling a prescription in the jurisdiction (termed URDD). Poisson regression with a Bonferroni multiple comparisons adjustment was used to compare the average rate over the study period (July 2011 through June 2013). There were 28 diversion cases for tapentadol IR, 3 for tapentadol ER and 14,604 for other Schedule II opioid tablets. The population based rates were 0.0029 (tapentadol IR), 0.0003 (tapentadol ER), and 1.515 (other Schedule II opioids) reports per 100,000 population. The tapentadol ER population rate was lower than the other Schedule II opioids (p<0.0001) and tapentadol IR (p=0.0015). Rates based on drug availability were 0.0629 (tapentadol IR), 0.0279 (tapentadol ER), and 0.4609 (other Schedule II opioids) per 1,000 URDD. The tapentadol ER URDD rate was less than the other Schedule II opioid URDD rate (p=0.0430) but not significantly different from tapentadol IR. Due to the extremely low rate for tapentadol ER, we interviewed randomly-selected drug diversion investigators regarding their experiences, which supported the observation that tapentadol ER is rarely diverted to the illicit market. In conclusion, we found that the diversion rate of tapentadol ER is very low compared to other Schedule II opioid tablets.

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