

Title:

Abuse, misuse, and diversion of hydromorphone before and after the

introduction of the extended-release formulation (EXALGO®)

Authors: Dart R, Severtson S, Patrick J, Webster J

Meeting: American Pain Society (APS) Annual Meeting

Date: May 2013

Location New Orleans, LA

Abstract:

In March 2010, the US Food and Drug Administration approved EXALGO® (Mallinckrodt Inc., Hazelwood, MO, USA), an extended-release (ER) tablet formulation of hydromorphone. Although ER opioids may be attractive for abuse and diversion due to their high drug load, putative tamperresistant formulations, like the OROS technology in EXALGO, may decrease abuse. Data from the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System's Poison Center, Opioid Treatment, Survey of Key Informants' Patients, College Survey, and Drug Diversion programs were examined for changes in rates of hydromorphone abuse, misuse, and diversion. The quarterly exponentiated values of the slopes per 100,000 population (POP) and per 1000 unique recipients of dispensed drug (URDD) from Q3 2006 or program inception through Q2 2012 were compared before and after the release of EXALGO using negative binomial regression. Before the release of EXALGO, the mean rate of change in hydromorphone abuse rates among individuals in the Opioid Treatment program significantly increased by 11.9% (POP) and 7.6% (URDD) per quarter (P<.001 for both); after the release of EXALGO, these rates showed a nonsignificant decline of 1.4% (POP) and 4.4% (URDD). The positive slopes of the rates of change before release of EXALGO were significantly different from the negative slopes after release of EXALGO for both POP and URDD (P<.01). Similar patterns occurred in rates measured by each of the other 4 programs. Although hydromorphone abuse, misuse, and diversion rates have been increasing over time, release of EXALGO corresponded with slowing or decreasing rates across all 5 programs. The release of EXALGO did not increase overall rates of nonmedical hydromorphone use; whether it may have mitigated the increasing rate or reflects changes in overall patterns of nonmedical prescription opioid use awaits further research. Development of this abstract funded by Mallinckrodt Inc.