RADARS® SYSTEM

Title:	Non-medical use surveillance and signal identification of lisdexamfetamine dimesylate, a pro-drug stimulant to treat ADHD
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Abstract:

Background: To identify signals of non-medical use (misuse, abuse, diversion and intentional overdose) of the pro-drug stimulant lisdexamfetamine dimesylate (LDX), during the first 3 years post-approval.

Methods: Data relevant to LDX nonmedical use were collected from DAWN Live!, Internet and media monitoring, supply chain monitoring, and postmarketing adverse event reports (all through February 2010), and Drug Diversion and Poison Centers studies from the RADARS® (Researched Abuse, Diversion and Addiction-Related Surveillance) System (Q3 2007-Q4 2009).

Results: Internet postings about LDX discussed potential methods of tampering, liking/disliking, and polydrug use. To date, there is little indication of successful extraction recipes. No exceptional orders were identified in supply chain monitoring nor did investigations of product complaints indicate any diversion. From market launch to February 2010, approximately 10.4 million prescriptions were filled for LDX. During the respective analysis periods there were 78 postmarketing adverse event reports of non-medical use and 99 DAWN Live! mentions. As of Q4 2009, the RADARS® System Poison Center call rates for LDX were 0.199/1,000 Unique Recipients of Dispensed Drug (URDD) (to account for product availability), compared to total extended-release amphetamines at 0.153/1,000 and total extended-release oral methylphenidate at 0.207/1,000. Likewise, the RADARS® System Drug Diversion rates were 0.026/1,000 URDD, versus 0.034/1,000 and 0.018/1,000, respectively.

Conclusions: There was little evidence of non-medical use of LDX during its first 3 years post approval, based on data from DAWN Live!, Internet and media monitoring, supply chain monitoring, post-marketing adverse event reports, and RADARS®.

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