RADARS® SYSTEM

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

Objective: To identify signals of misuse, abuse, diversion and intentional overdose (non-medical use) of the prodrug stimulant lisdexamfetamine dimesylate (LDX), during its first 30 months of approval in the US.

Methods: Data relevant to LDX non-medical use were collected from DAWN Live!, Internet and media monitoring, supply chain monitoring, and postmarketing adverse event reports (all ending August 2009), and Drug Diversion and Poison Centers studies from the RADARS® (Research Abuse, Diversion and Addiction-Related Surveillance) System (Q3 2007-Q2 2009).

Results: Internet postings about LDX discussed potential methods of tampering, liking/disliking, and polydrug use. No exceptional orders were identified in supply chain monitoring nor did product quality complaints suggest diversion. From market launch to August 2009, 7,385,712 prescriptions were filled for LDX. During the respective analysis periods there were 54 postmarketing adverse event reports of nonmedical use and 73 DAWN Live! mentions. As of Q2 2009, RADARS System Drug Diversion rates for LDX were 0.027/1,000 Unique Recipients of Dispensed Drug (URDD, to account for product availability), compared to total extended-release amphetamines at 0.037/1,000 and total extended-release methylphenidate at 0.037/1,000. Likewise, RADARS System Poison Center call rates were 0.207/1,000 URDD, versus 0.170/1,000 and 0.228/1,000, respectively. RADARS trend data will be presented for Q3 2007-Q2 2009. We anticipate having an additional 6 months of data to present.

Conclusions: Non-medical use of LDX was minimal during its first 30 months of marketing, based on data from DAWN Live!, Internet and media monitoring, supply chain monitoring, postmarketing adverse event reports, and RADARS.