



<b>Title:</b>	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) in the first 36 months post US approval.

**Methods:** Data relevant to LDX non-medical use were collected from DAWN Live!, Internet and media monitoring, supply chain monitoring, and postmarketing adverse event (AE) reports (through February 2010), and Drug Diversion and Poison Centers Programs from the RADARS® (Researched Abuse, Diversion and Addiction-Related Surveillance) System (Q3 2007-Q1 2010).

**Results:** From launch to February 2010, 10.4 million prescriptions were filled for LDX for nearly 2 million patients. During the relevant analysis periods there were 78 AE reports of non-medical use and 99 DAWN Live! cases. LDX Internet postings discussed potential methods of tampering, liking/disliking, and polydrug use. No exceptional orders were identified in supply chain monitoring nor did product complaints suggest diversion. Q1 2010 Drug Diversion Program rates for LDX were 0.075/1,000 Unique Recipients of Dispensed Drug (URDD, to account for product availability), compared to extended release (ER) amphetamines, 0.062/1,000 URDD, and ER oral methylphenidate, 0.049/1,000 URDD. Poison Center Program call rates were 0.201/1,000 URDD, 0.153/1,000 and 0.215/1,000, respectively. RADARS® System trend data are presented for Q3 2007-Q1 2010.

**Conclusions:** Non-medical use of LDX was minimal during its first 36 months of marketing, based on data from DAWNLive!, Internet and media monitoring, supply chain monitoring, AE reports, and the RADARS System.