

# RADARS<sup>®</sup>

S Y S T E M

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| <b>Title:</b>   | Non-medical use surveillance and signal identification of lisdexamfetamine dimesylate, a pro-drug stimulant for the treatment of Attention-Deficit Hyperactivity Disorder |
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## Abstract:

At the end of this session, participants will be able to:

1) Describe the surveillance tools used for qualitative and quantitative monitoring and assessment of nonmedical use of a prescription stimulant; 2) understand different types of nonmedical use; that is, abuse and misuse; and 3) describe and compare the nonmedical use of a prodrug stimulant and immediate-release stimulants.

Our aim is to identify signals of misuse, abuse, diversion, and intentional overdose (nonmedical use) of the prodrug stimulant lisdexamfetamine dimesylate (LDX), during its first 30 months of approval in the United States. Data relevant to LDX nonmedical use were collected from postmarketing adverse event (AE) reports, DAWN Live!, internet and media monitoring, and supply chain monitoring (through August 2009), and Drug Diversion and Poison Center Programs from the Research Abuse, Diversion and Addiction-related Surveillance (RADARS<sup>®</sup>) System (Q3 2007-Q3 2009). Through August 2009, 7 385 712 prescriptions were filled for LDX. During the respective analysis periods there were 54 AE reports of nonmedical use and 73 DAWN Live! mentions. internet postings about LDX discussed potential methods of tampering, liking or disliking, and polydrug use. No exceptional orders were identified in supply chain monitoring, and no product complaints suggested diversion. As of Q3 2009, drug diversion program rates for LDX were 0.043/1000 unique recipients of dispensed drug (URDD, to account for product availability), compared with immediate-release amphetamines at 0.138/1000. Population rates were 0.012/100 000 and 0.127/100 000, respectively. Likewise, Poison Center Program call rates were 0.204/1000 URDD and 0.207/1000, and 0.062/100 000 population and 0.204/100 000, respectively. RADARS system trend data will be presented for Q3 2007-Q4 2009. We anticipate having an additional 6 months of data to present. nonmedical use of LDX was minimal during its first 30 months of marketing, based on data from AE reports, DAWN Live!, internet and media monitoring, supply chain monitoring, and the RADARS system.

**References:**

1. Cicero TJ, Dart RC, Inciardi JA, et al. The development of a comprehensive risk-management program for prescription opioid analgesics: Researched Abuse, Diversion and Addiction-related Surveillance (radars). *Pain Med.* 2007;8(2):157-170.
2. Substance Abuse and Mental Health Services Administration, Office of Applied Studies. Drug Abuse Warning Network: sample design and estimation procedures (technical report). Rockville (MD): Substance Abuse and Mental Health Services Administration; 1998. DAWN series m-2, DHHS publication no (SMA) 98-3178.