Risk Management Case Study: The RADARS® System

J. David Haddox, DDS, MD
Vice President
Risk Management & Health Policy
Purdue Pharma L.P.

26 August 2005

1

Purdue Pharma L.P. Position
Risk Management Programs

Needed for all strong opioid medications

Must be consistent within a given schedule under the Controlled Substances Act

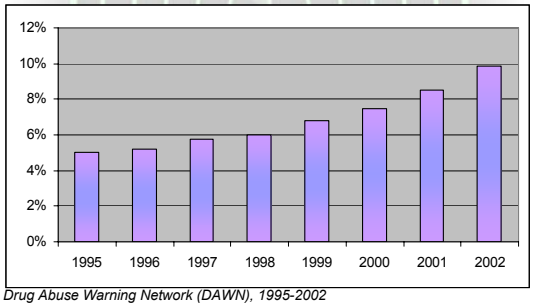
Must balance the legitimate needs of patients against the abuse potential of the medicine

Must address four distinct populations:

- Patients (Goal: Facilitate Proper Use)
- Children (Goal: Avoid Pediatric Exposure)
- Abusers (Goal: Reduce Abuse)
- Criminals (Goal: Minimize Diversion)

2

Narcotic Analgesics DAWN ED Mentions
Percent of Total Drug Abuse Mentions



Drug Abuse Warning Network (DAWN), 1995-2002

3

Review of National Databases

National Survey on Drug Use and Health
(formerly National Household Survey on Drug Abuse)
Drug Abuse Warning Network (DAWN)
Monitoring the Future
Treatment Episode Data Set

Not timely in reporting (9-12 month delay)

Some questions antiquated

Not reported geographically

Limited data on specific branded drugs

Little context to data in terms of rate

4

Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System Goals

- Study the nature and extent of abuse of scheduled prescription opioid medications
- Obtain data in a timely fashion
- Geospatially locate data
- Develop and suggest interventions to reduce diversion and abuse

5

The RADARS® System Drugs

1. buprenorphine
2. fentanyl (e.g., Duragesic®, Actiq®)
3. hydrocodone (e.g.,Vicodin®)
4. hydromorphone (e.g., Dilaudid®)
5. methadone
6. morphine (e,g., MS Contin®, MSIR®)
7. oxycodone (e.g., OxyContin®, Tylox®)

6

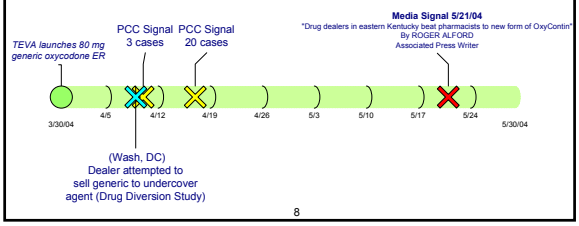
Signal Detection Studies

- Funded by Purdue Pharma L.P.
- Studies conducted at major research institutions under direction of Principal Investigators
- Data independently housed at study site
- Data reports presented to the EAB and Purdue on at least a quarterly basis

7

Timeliness, Product Specificity and Geospatial Specificity Demonstrated

The RADARS® System Signal Detection Studies began picking up cases of generic oxycodone extended-release one week after launch.



8

Law Enforcement Drug Diversion

James Inciardi, PhD, Principal Investigator
University of Delaware

Rationale

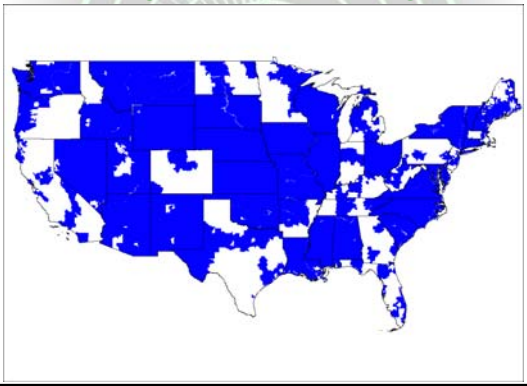
- Determine relative diversion of RADARS® System drugs compared to other drugs in a specific geographic locale

Objective

- Determine the extent of diversion from a national sample of police diversion units

9

Drug Diversion Coverage

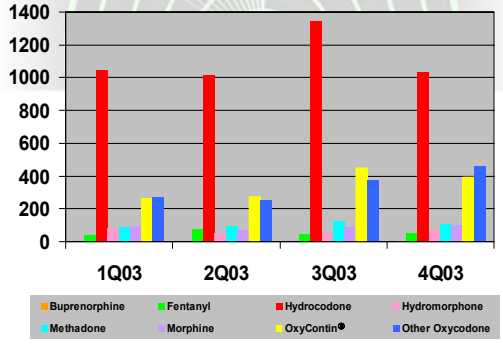


Drug Diversion

	1Q03	2Q03	3Q03	4Q03
Sites Contacted	207	223	265	225
Sites Responding	147	144	167	169
Total Diversion Cases Reported	3075	2633	3278	3007

11

Drug Diversion Total Mentions 2003



12

Key Informant Network

Theodore Cicero, PhD, Principal Investigator
Washington University

Rationale

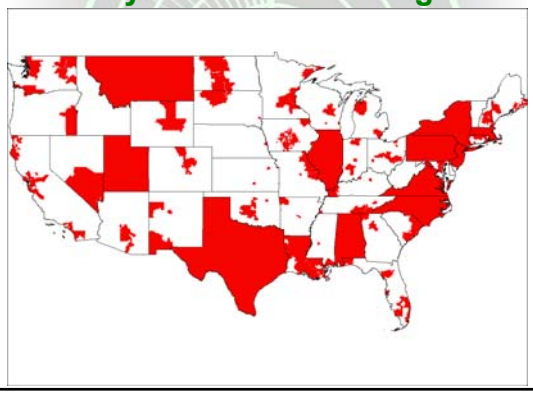
- Need to establish an extensive network of specialists to proactively seek out documented cases of abuse

Objectives

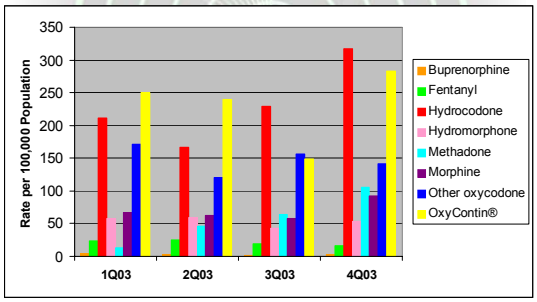
- Use key informants to proactively count the cases of abuse & addiction of RADARS® System Drugs in specific geographic locations
- Monitor the number of cases of abuse and addiction of the RADARS® System Drugs over time

13

Key Informant Coverage



Key Informant 2003



15

Poison Control Centers (PCCs)

Richard Dart, MD, PhD, Principal Investigator
University of Colorado

Rationale

- PCC network will provide another sensitive means of detecting emerging abuse trends in a timely manner

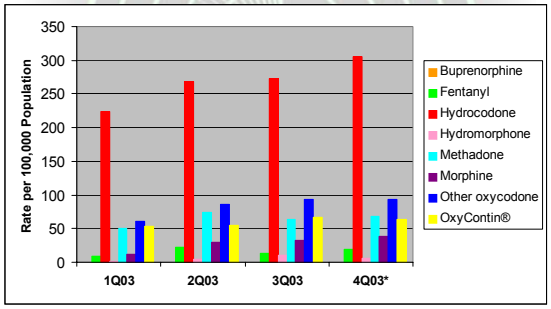
Objectives

- Prospectively monitor exposure and information calls involving the RADARS® System Drugs reported to 17 Poison Control Centers
- Monitor the changes in these calls over time

16

RADARS® PCC Coverage Area

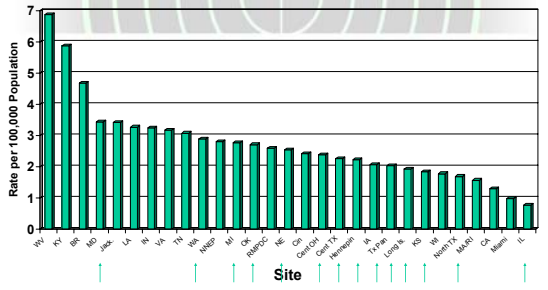
PCCs 2003



*4th quarter incomplete [includes RMPDC, NNEP (Northern New England PC), Blue Ridge, Kentucky, Miami, CA, and partial data from the VA poison center]

18

Intentional Exposure Rates by Site, 1Q05



19

Methadone Signal Rates, 1Q05

New Signal Detection Study

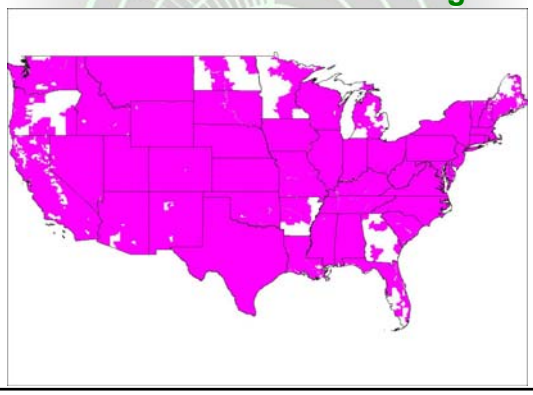
"Survey of Opioid Abuse Among Methadone Enrollees"

AATOD
American Association for the Treatment of Opioid Dependence

- In coordination with National Development and Research Institutes, Inc. (NDRI)
- Data collected from selected methadone clinics (public and private)
  - Over 50% of methadone clinics are proprietary
- Data collection started 3Q04

21

Combined Studies Coverage



Preliminary Conclusions from Principal Investigators

- Abusers of a given opioid are similar to abusers of other prescription opioids
- Typically seen in those with a history of abuse of multiple drugs, both licit and illicit
- Generally not a problem of ethnic minorities
- Endemic in some rural areas

23

Conclusions

- The RADARS® System is an integrated network of ongoing studies that augment our traditional drug safety and pharmacovigilance activities, giving us the ability to recognize trends in abuse and diversion of the monitored prescription opioids in a more timely and geographically specific manner than is possible with existing federal government studies.
- Early recognition allows interventions that are appropriate to the character of the signal detected.
- This represents a novel approach to surveillance for behaviors that might not be captured by typical drug safety activities.

24