

OXYCONTIN[®]

Diversión & Abuse

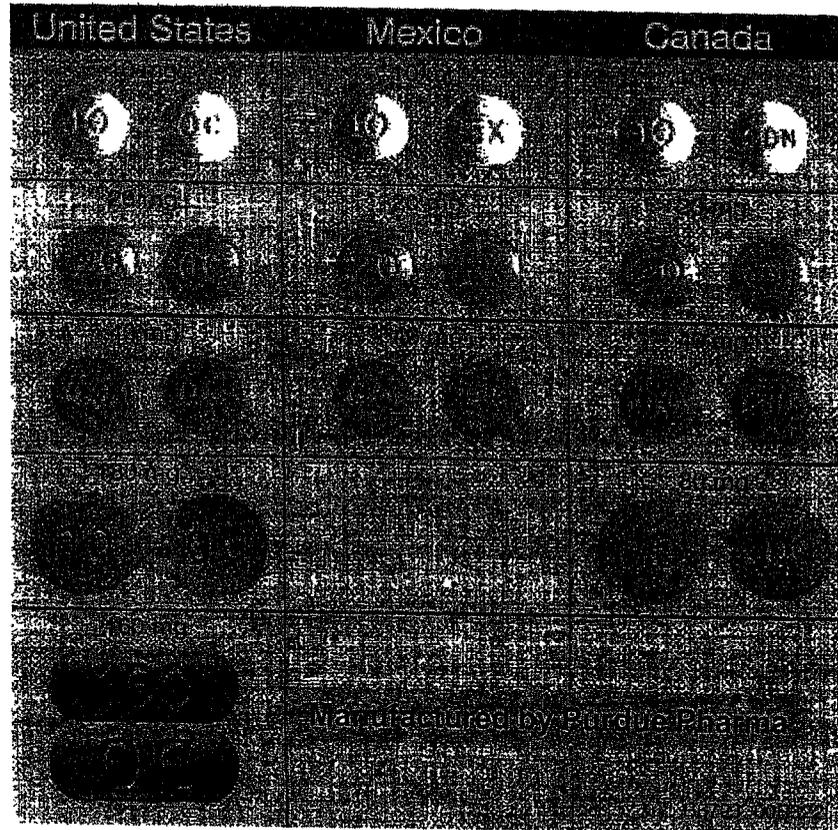
Drug Enforcement Administration
Office of Diversion Control
May 2003



OXYCONTIN®

OXYCONTIN® II (OXYCODONE HCl CONTROLLED-RELEASE) TABLETS

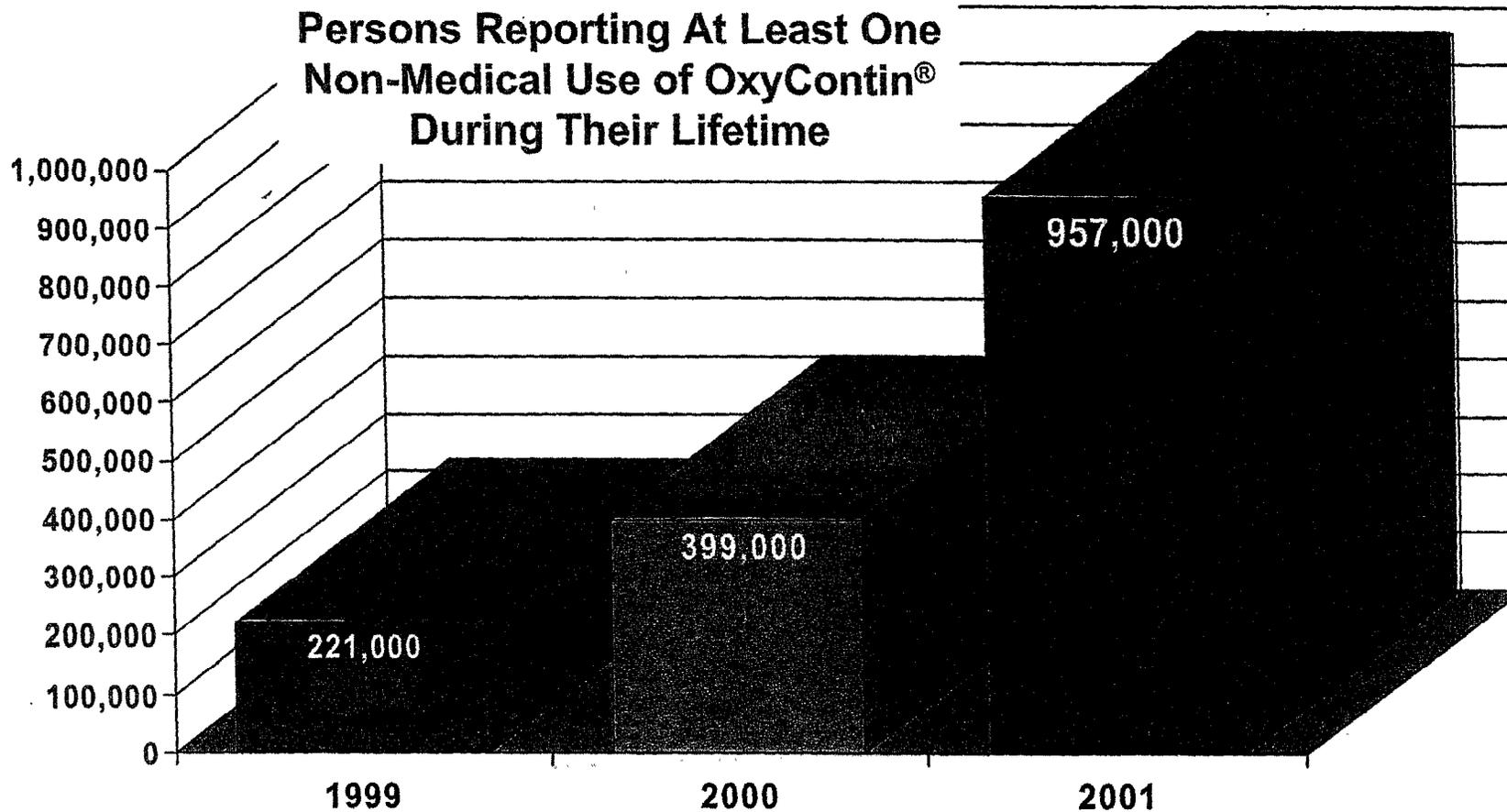
- OxyContin® is a controlled release form of Schedule II oxycodone
- Manufactured in tablet form and intended for oral ingestion



- Controlled release allows for longer duration of drug action
- Legitimately used as a medication to treat moderate to severe pain



Non-Medical Use of OXYCONTIN®



Source: 2001 National Household Survey on Drug Abuse
Dept of HHS / Substance Abuse and Mental Health Services Administration (SAMHSA)



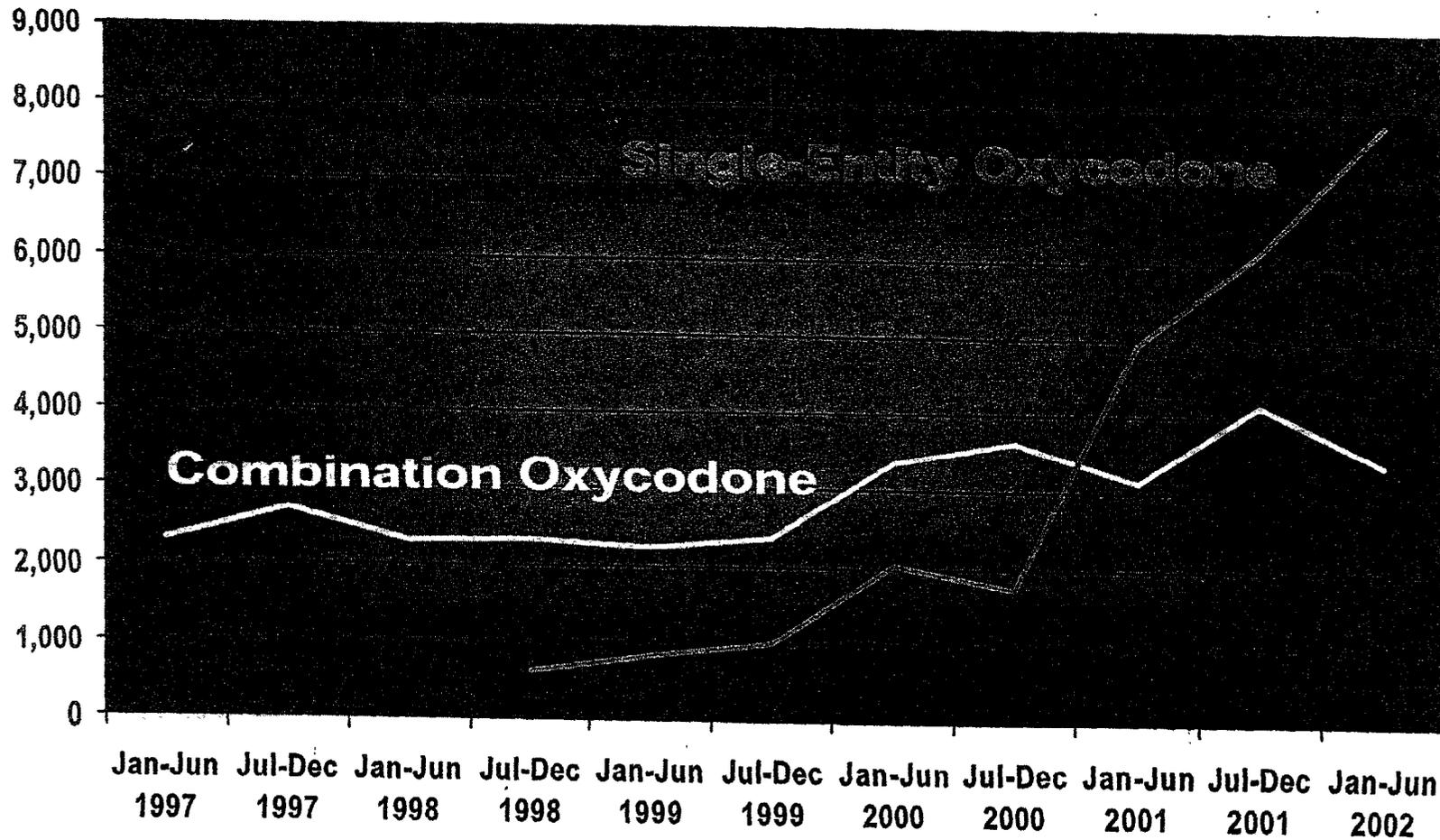
OXYCONTIN[®]

- The controlled release method of delivery used in OxyContin[®] allows for a longer duration of drug action, and consequently, it contains much larger doses of the active ingredient
- OxyContin[®] is a single-entity oxycodone product ~ most other oxycodone products contain aspirin or acetaminophen (*'combination oxycodone'*)
- OxyContin[®] is highly-addictive ~ Abusers can easily compromise the controlled release formulation for a powerful morphine-like high



Emergency Department (ED) Mentions of Single-Entity and Combination Oxycodone

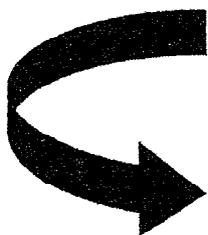
Source: ED Trends from the Drug Abuse Warning Network, Final Estimates 1994-2001
 ED Trends From Dawn, Preliminary Estimates January-June 2002
 Dept of HHS / Substance Abuse and Mental Health Services Administration (SAMHSA)





OXYCONTIN®

- Addiction, crime, and fatal overdoses have all been reported as a result of OxyContin® abuse
- The FDA has approved a new package insert for OxyContin® with a “Black Box” warning that includes:



OXYCONTIN®

(Oxycodone HCl Controlled-Release) Tablets
10 mg 20 mg 40 mg 80 mg* 160 mg*

* 80 mg and 160 mg for use in opioid-tolerant patients only

OT00367

065570-DE-001

WARNING:

OxyContin is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine.

Oxycodone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OxyContin in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

OxyContin Tablets are a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

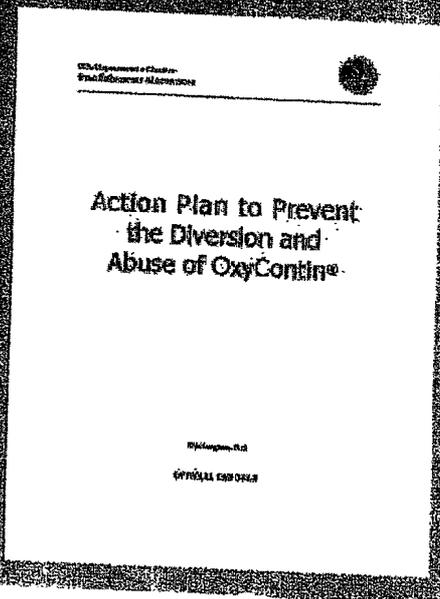
OxyContin Tablets are NOT intended for use as a prn analgesic.

OxyContin 80 mg and 160 mg Tablets ARE FOR USE IN OPIOID-TOLERANT PATIENTS ONLY. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids.

OxyContin TABLETS ARE TO BE SWALLOWED WHOLE AND ARE NOT TO BE BROKEN, CHEWED, OR CRUSHED. TAKING BROKEN, CHEWED, OR CRUSHED OxyContin TABLETS LEADS TO RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF OXYCODONE.

DEA's National OXYCONTIN[®] Action Plan

► Initiated Spring 2001





OXYCONTIN[®] Action Plan

1. Enforcement & Intelligence

- Coordinated operations have been initiated in DEA field offices to target individuals and organizations involved in the diversion and abuse of OxyContin[®]. This includes coordination with federal, state, and local agencies.



OXYCONTIN[®] Action Plan

2. Regulatory & Administrative

- DEA is utilizing the full range of its regulatory and administrative authority in pursuing action that will make it more difficult for abusers to obtain OxyContin[®]. DEA is working closely with the FDA to strongly urge the rapid reformulation of OxyContin[®] by Purdue Pharma, to the extent that it is technically possible, in order to reduce the abuse of the product, particularly by injection.



OXYCONTIN[®] Action Plan

3. Industry Cooperation

- DEA continues to stress the importance of voluntary cooperation from industry in adhering to the spirit and substance of existing law and regulation. The agency is increasing its cooperative efforts with all levels of industry in order to stem the abuse and diversion of OxyContin[®]. As the sole manufacturer of OxyContin[®], the cooperation of Purdue Pharma is integral to the success of DEA's Action Plan.



OXYCONTIN[®] Action Plan

4. Awareness / Education / Outreach Initiatives

- An aggressive, national outreach effort is being made to educate the public, schools, the healthcare industry, and state and local governments on the dangers related to the abuse of OxyContin[®]. DEA is also pursuing federal legislative initiatives to assist states with funding for prescription data collection and analysis.