



Buprenorphine:

From Basic Human Research to Clinical Application

**Clinical Trials Network
Detroit Blending Conference
Workshop III
Monday Sept. 27, 2004
2:30 - 5:00 pm**



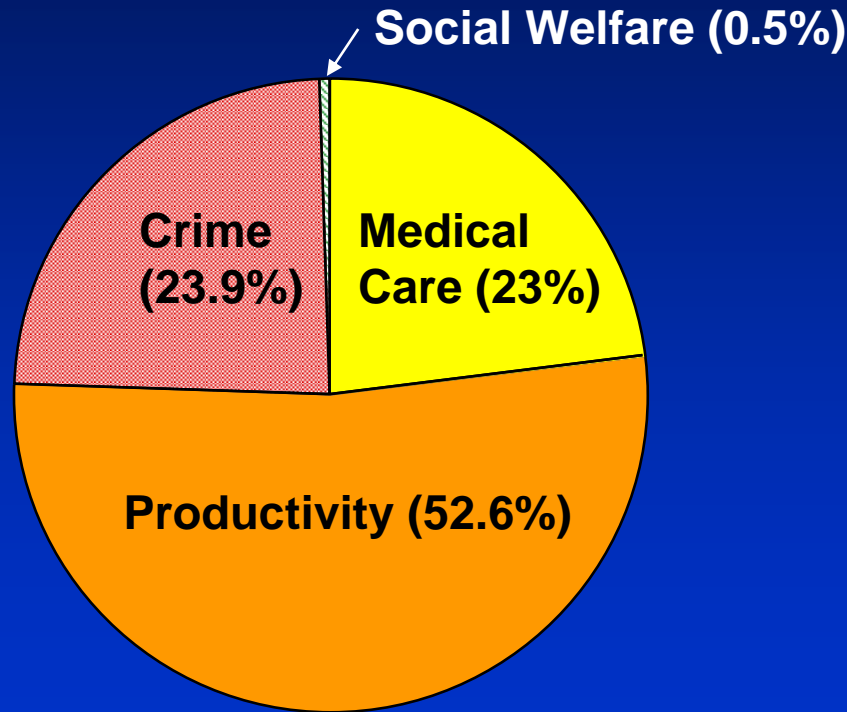
Participants and Content

- **Mark Greenwald, Ph.D.**
 - Introduction
 - “Buprenorphine’s Effects on Brain Function and Behavior: Clinical Implications”
- **Walter Ling, M.D.**
 - “Buprenorphine Research to Practice: View from the Other Side”
- **Allan Cohen, M.A., M.F.T.**
 - “Buprenorphine in the Clinical Trials Network: The Community Treatment Provider’s Experience and Legacy”
- **Virginia Ryan, Ph.D.**
 - “Introducing Buprenorphine into a Therapeutic Community”
- ***Synthesis & Discussion (blending)***

***Epidemiology of Opioid Abuse:
Trends in
Prevalence, Harm and Treatment***

Epidemiology

**Estimated Total Costs of Heroin Addiction
\$21.872 Billion (Mark et al., 2001)**



Heroin Epidemiology

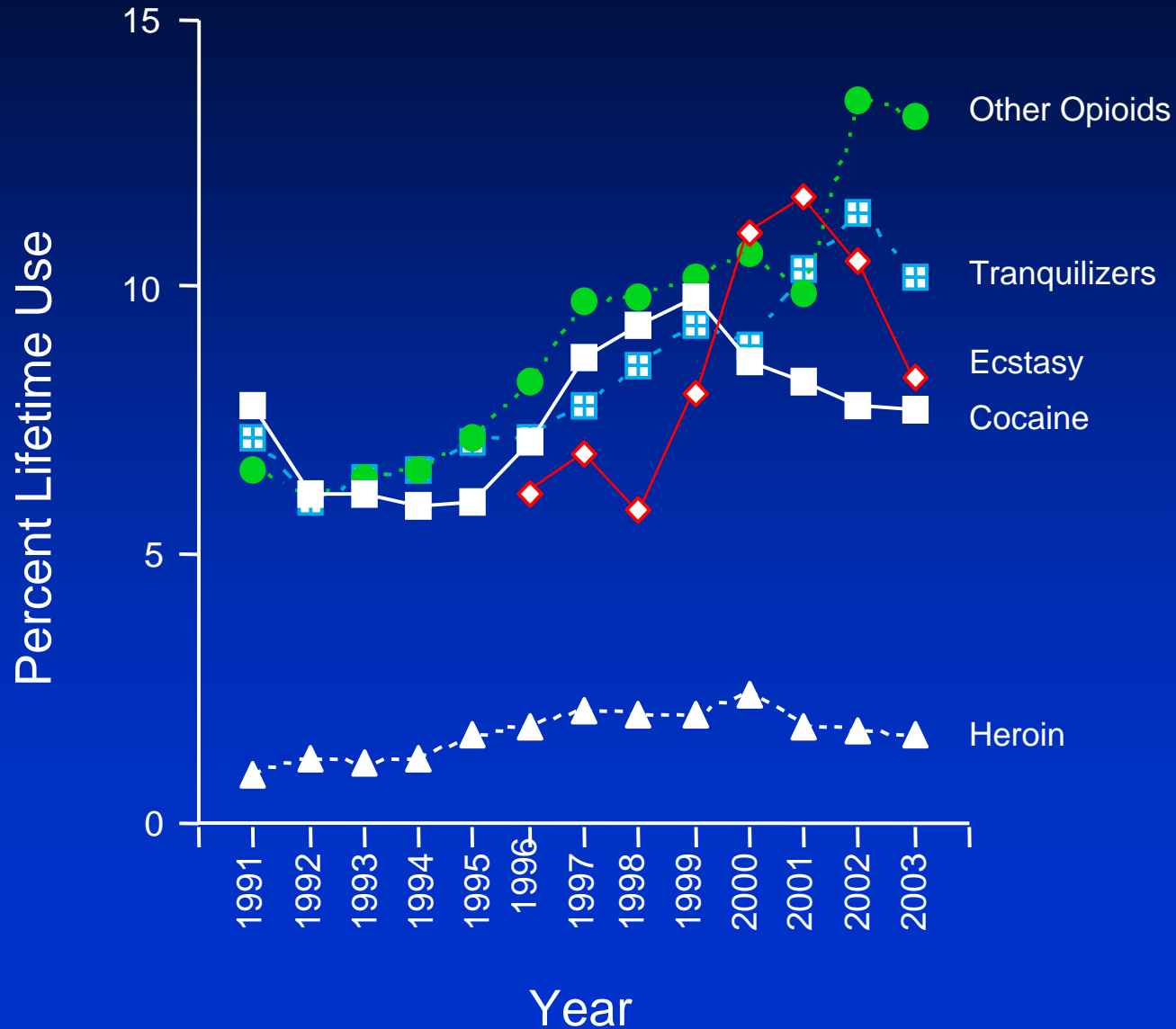
- Prevalence
 - 2.4 million lifetime, 1.0 million use weekly, 0.8 million chronic
- Harm
 - ED mentions nearly tripled during 1990s (DAWN)
 - Purity doubled, price more than halved (DEA)
- Treatment
 - About 85% report daily use
 - Increased 44% overall from 1992 to 2000
 - In 2000, leading illicit drug among all Tx admissions

Emergence of a disturbing trend ...



Epidemiology

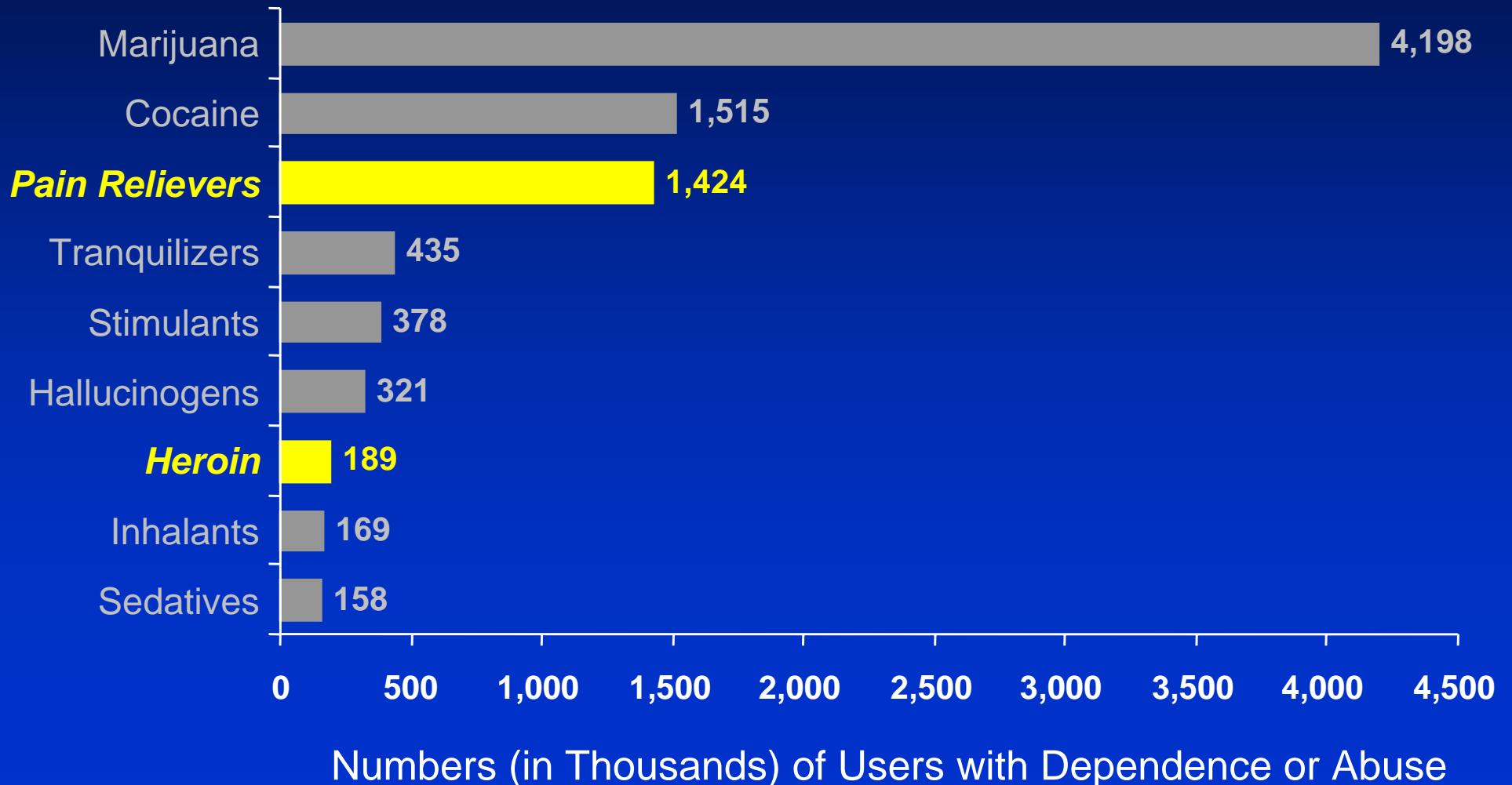
Lifetime Illicit Use Among 12th graders



Source:
Monitoring the
Future: National
Results on
Adolescent Drug
Use
Johnston *et al.*
2004

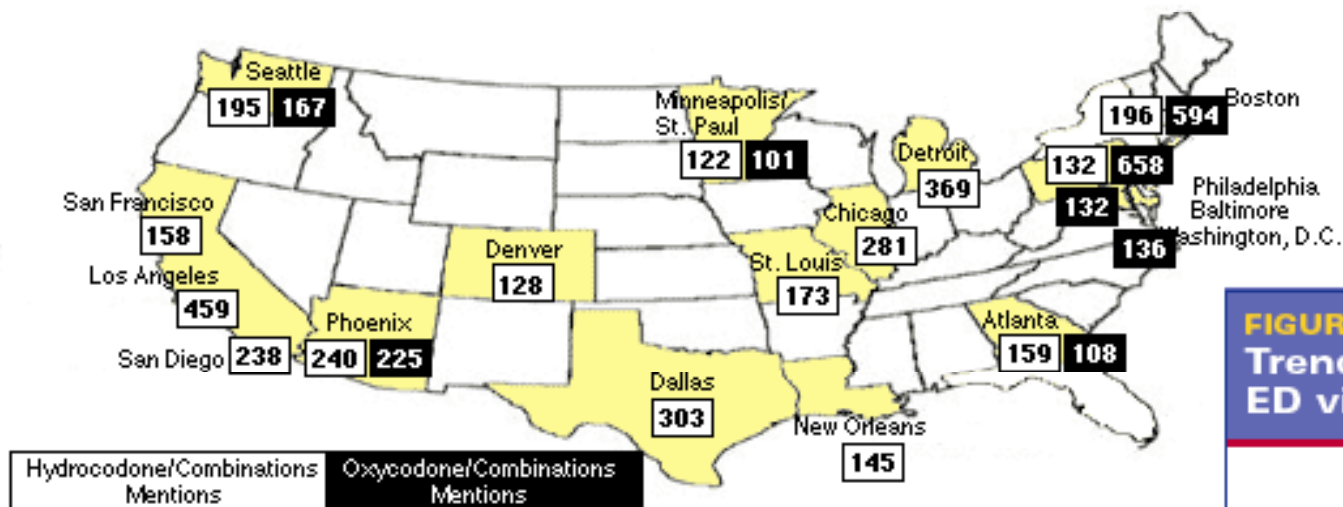
Epidemiology

Past-Year Abuse or Dependence, Age 12 or Older (National Survey of Drug Use and Health, 2003)



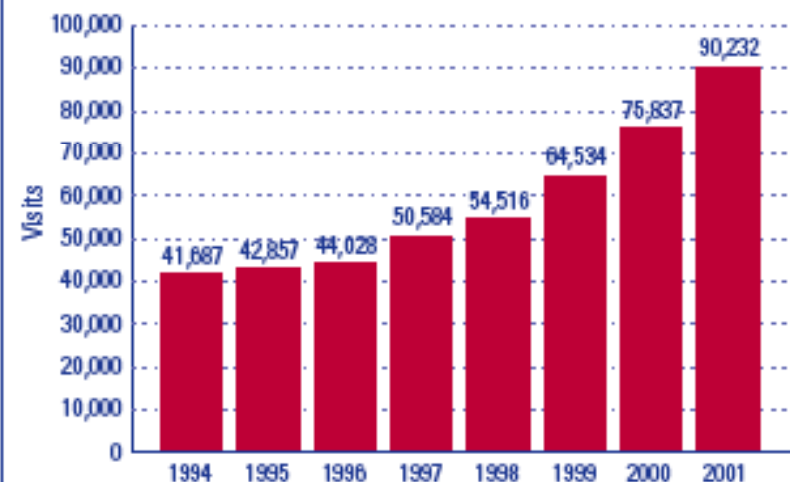
ED Mentions: Opioid Analgesics

Exhibit 8. CEWG Areas with the Highest Number of Hydrocodone/Combinations and Oxycodone/Combinations ED Mentions¹: 2000



Source: DAWN, Jan. 2003

FIGURE 1
Trends in narcotic analgesic-related ED visits: 1994-2001



Take-Home Points

- Prevalence and harms of heroin and Rx opioid abuse have been increasing
- These problems may be complicated by
 - Decreased cost and increased purity of heroin
 - Increased availability (# prescriptions) of opioid painkillers
- Treatment system strained
 - Increasing admissions
 - Fortunately, buprenorphine is available and appropriate for treating heroin or Rx opioid abuse

***Drug Abuse Treatment Act
(DATA), 2000***

Clinical Need for Buprenorphine

- Access is restricted
 - too few slots, highly regulated
- Patients' negative attitudes toward methadone
 - pharmacokinetics, beliefs
- Societal stigma
 - heroin users, methadone treatment and clinics
- Service delivery
 - inflexible, better to bundle care

Clinical Need for Buprenorphine

Drug Abuse Treatment Act (DATA)

HR4365 – Children's Health Act of 2000

- Waives requirements of Narcotic Addict Treatment Act, which had restricted use of Schedule III, IV and V opioid agonist medications to specially regulated clinics (NTPs). This is a new outlet for both maintenance and detoxification.
- DATA permits qualified physicians to prescribe BUP to ≤ 30 patients in their practice
- FDA approved buprenorphine on October 8, 2002. DEA classified it under Schedule III. WSU is coordinating a post-marketing surveillance trial to assess its abuse relative to other opioids.