

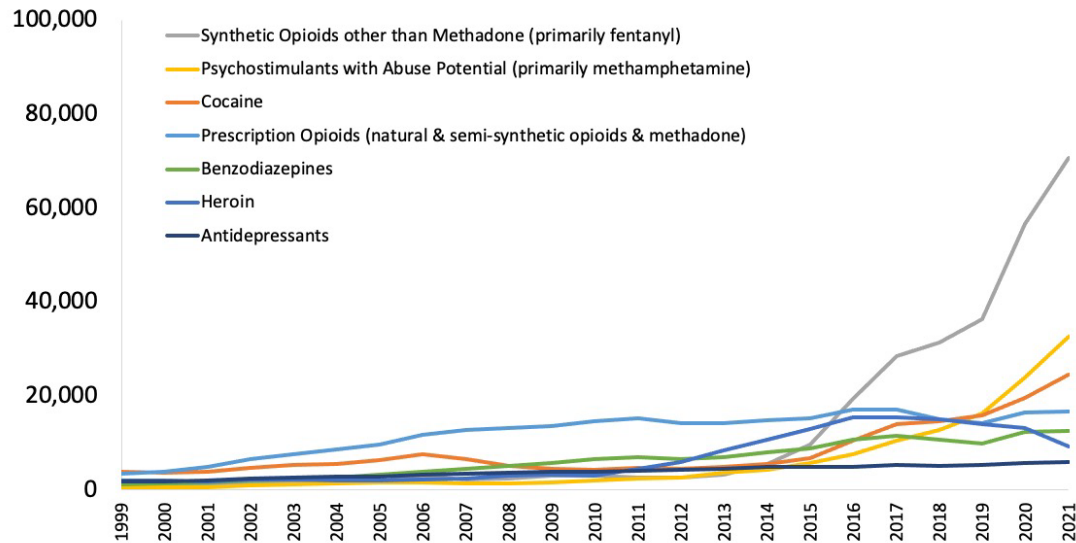


America's Opioid Crisis

Origin of the Epidemic, the Role of the Pharmaceutical Industry, and the Current Situation

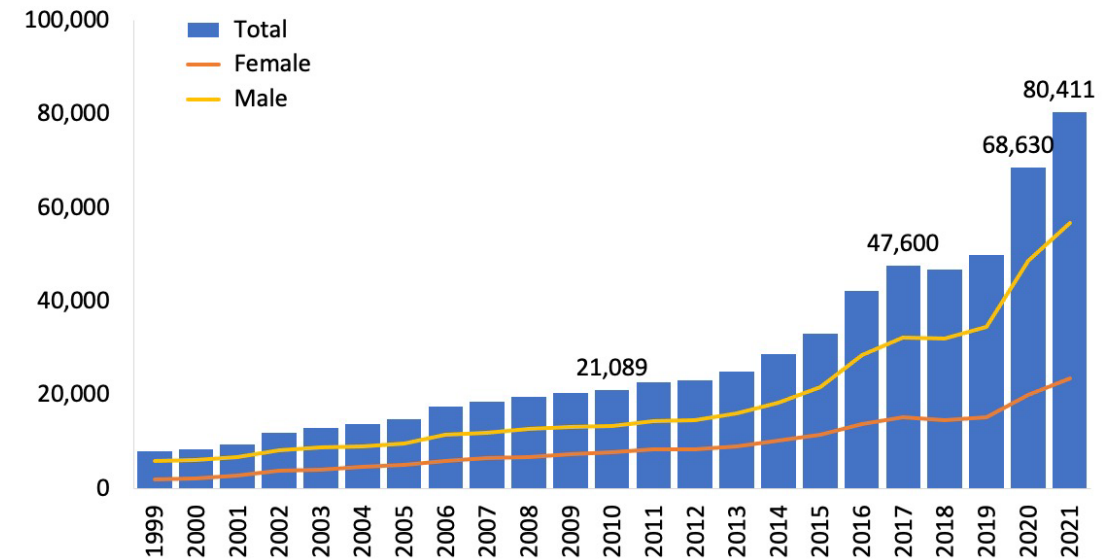
The American Opioid Crisis

Figure 1 National Drug-Involved Overdose Deaths*, Number Among All Ages, 1999-2021



National Institute on Drug Abuse (NIDA), 2023

Figure 2 National Overdose Deaths Involving Any Opioid*, Number Among All Ages, by Gender, 1999-2021



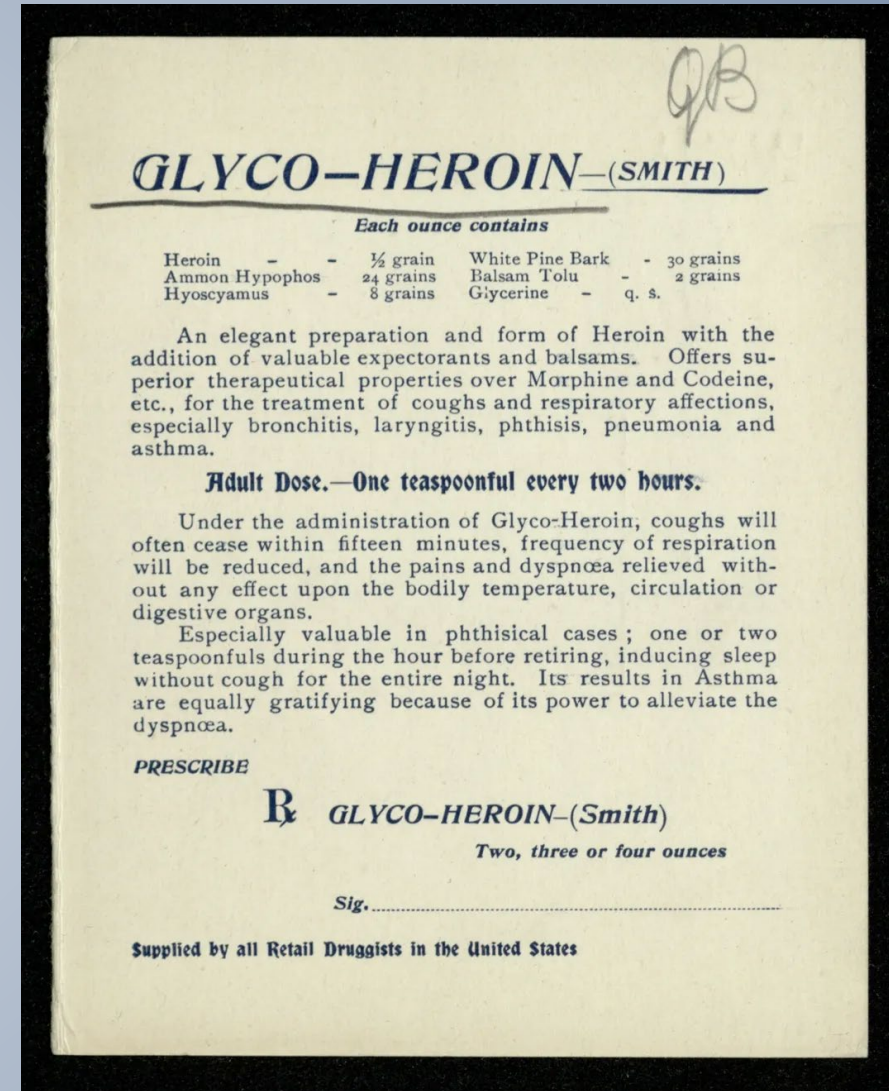
National Institute on Drug Abuse (NIDA), 2023

<https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates>

- › Over 80% of drug overdose deaths are attributable to opioid drugs.
- › 80,400 opioid overdose deaths in 2021. More than 1500 overdose deaths per week.
- › More than 1 million more people may die of opioid overdose by the end of the decade.

Opioids in Early 20th Century USA

- › 1 in 200 Americans already addicted to opiates.
- › **Bayer starts commercially producing heroin in 1898.** Considered a “wonder drug”. Widely used as an analgesic and cough-suppressant.
- › Campaigns started around this time targeting recreational opium use.
- › **Smoking Opium Exclusion Act, 1909.** Bans non-medical possession, import and smoking of opium. Drives demand for illicit supply of heroin, morphine.
- › Addictive potential of heroin started to be recognised in the 1920s. Heroin sale, manufacture and import (for any use) made illegal with **Anti-Heroin Act, 1924.**



Original Image In: Glyco-Heroin-(Smith), Martin H. Smith Company, New York, ca 1900-1920, 2., Medical Trade Ephemera Collection, Historical Medical Library of the College of Physicians of Philadelphia

Opioids in 1970-1980

- › Vietnam War saw a wave of heroin addiction among returning veterans. 1971 Congress report estimates 10-15% addiction rate.
- › Nixon administration declares drug abuse “public enemy number one”, and heroin use specifically targeted. Birth of DEA.
- › 1970s, Vicodin and Percocet enter market, but widespread reluctance to prescribe opioids.
- › **1980 – Letter in NEJM suggests 1% opioid addiction risk in hospital setting. Widely cited and often misquoted.**

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug
Surveillance Program
Boston University Medical Center

Waltham, MA 02154

1. Jick H, Mietinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. *JAMA*. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. *J Clin Pharmacol*. 1978; 18:180-8.

Porter, J. & Jick, H. Addiction Rare in Patients Treated with Narcotics. New England Journal of Medicine, 1980, 302(2), 123.

Changing Attitudes to Pain Treatment

1980s → Opioids commonly used to treat acute pain, cancer pain and pain in terminal patients in hospital setting.

1990s → Some clinicians argue chronic pain systematically undertreated. Growing support for use of opioids in chronic non-cancer pain, despite lack of demonstrated efficacy.

1996 → American Pain Society and Veteran's Health Administration pushes for pain to be recognised as the "fifth vital sign" and checked routinely at every patient encounter. Also push for routine opioid use. APS cites 1980 NEJM letter.

1998 → Federation of State Medical Boards endorses opioid use for chronic non-cancer pain. Becomes standard of care.

2001 → Joint Commission recognises pain as fifth vital sign.



Introduction and Marketing of OxyContin

- › In 1996, Purdue Pharmaceuticals introduced a time-released oxycodone formulation called OxyContin.
- › **Aggressive marketing campaign:**
 - Advertising to public and prescribers (often false or misleading claims).
 - Sponsored pain-management and training conferences for clinicians.
 - Large “relentless” sales force.
 - Personalised prescriber profiles.
 - Substantial bonus/incentive system for sales reps.
 - Branded gifts for physicians, “unprecedented for Schedule II opioids” (DEA).
- › Other companies used similar tactics, e.g., Insys Therapeutics, Abbot Laboratories

When you know NSAIDs or acetaminophen will not be enough...



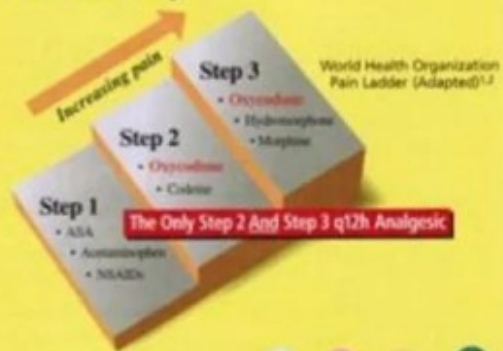
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OxyContin[®] q12h

Controlled release oxycodone tablets



- Rapid onset of analgesia within 46 minutes^{1,2}
- Full 12 hours of pain relief¹
- No risk of acetaminophen or ASA toxicity^{1,4,7,8}



OxyContin[®] q12h 10 mg 20 mg 40 mg 80 mg
Small, colour-coded tablets

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Easy to Dose, Easy to Titrate

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¹Median time to onset of analgesia after single dose Oxy-IR 15 mg (N=21186) and OxyContin 30 mg (N=22182) was 41 minutes and 46 minutes, respectively (N=42180). (P<0.001 in patients following abdominal or gynecologic surgery; 16 groups of 30 each).^{1,2}

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- Single-entity agent—contains no acetaminophen or aspirin—can be used concomitantly with NSAIDs

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Please read brief summary of professional prescribing information on adjacent page.

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RDUE

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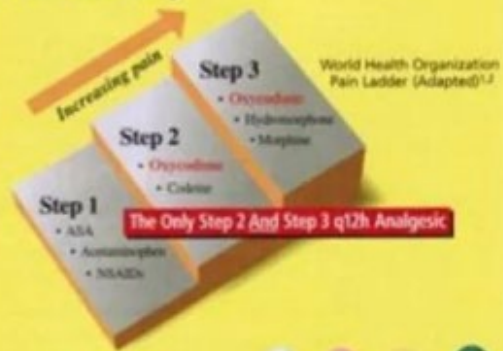
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Purdue Pharma Inc. A Trusted Partner in Pain Care

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²(N=220) in patients following abdominal or gynecologic surgery. 16 groups of 10 each.^{1,2}

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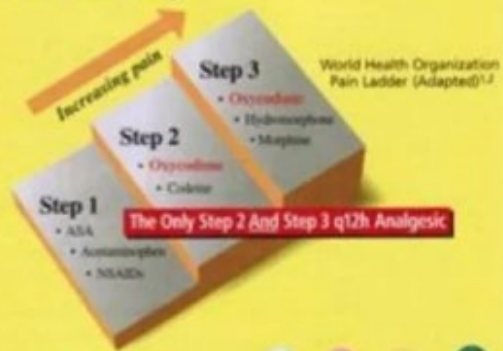
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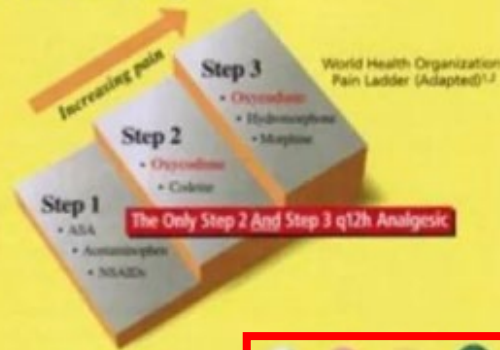
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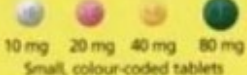


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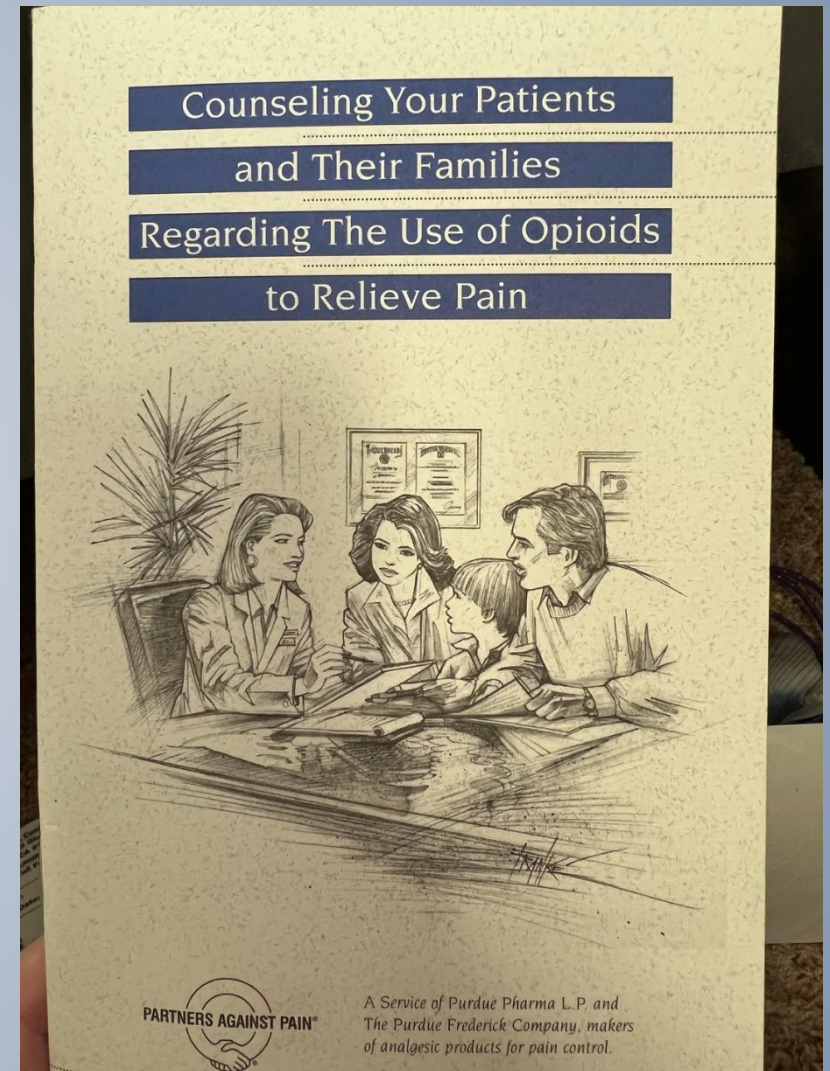
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Treatment-related ADEs were reported in 65% of patients (40% of placebo patients, 75% of CR Oxycodone 10 mg q12h patients and 82% of CR Oxycodone 20 mg q12h patients). The body systems most commonly involved were the digestive and nervous system. The most common ADEs can be seen in Table 2.

The most serious risk associated with opioids, including OxyContin, is respiratory depre... Common opioid side effects are constipation, nausea, sedation, dizziness, vomiting, pr headache, dry mouth, sweating, and weakness.

Pharmaceutical Industry Involvement in Pain Advocacy

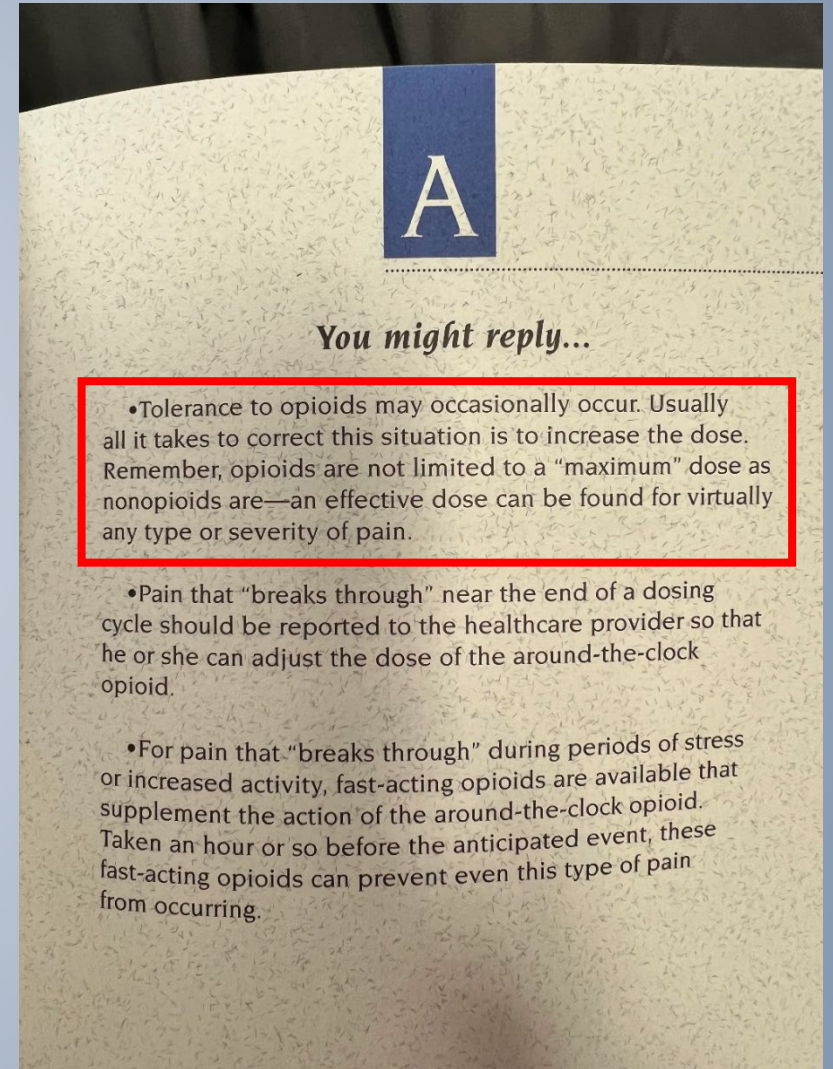
- › Sponsorship of more than 20,000 pain-related educational programs targeting physicians and other hospital staff.
- › Funding to societies and professional groups who then advocated for opioid use to aggressively treat pain.
- › “Partners against Pain” launched. “Alliance of patients, caregivers, and health care providers” controlled by company.

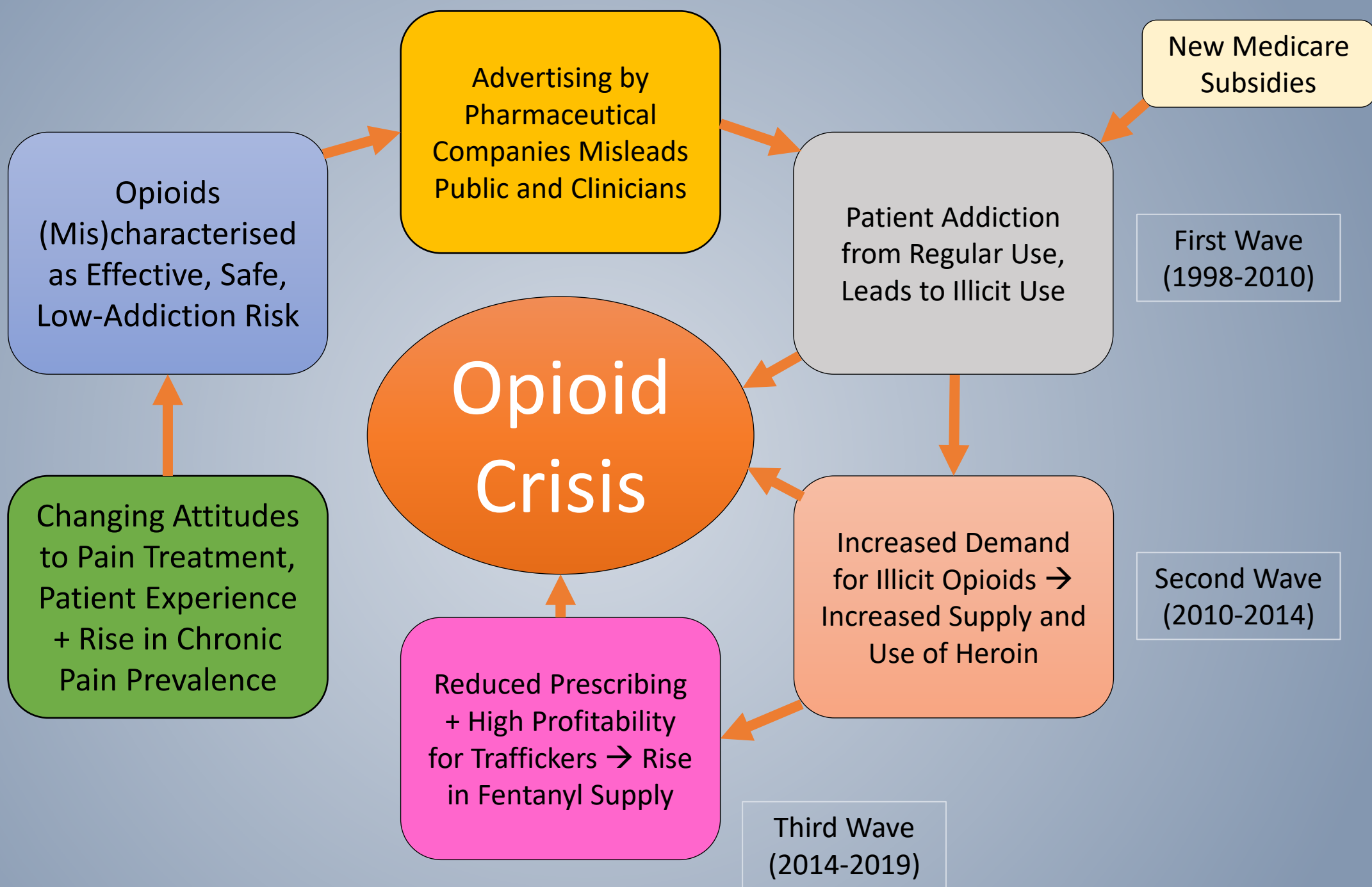


Purdue Pharma. Counseling Your Patients and Their Families Regarding the Use of Opioids to Relieve Pain. Partners Against Pain. Norwalk, CT. 1997. PDF available from <https://repository.library.brown.edu/studio/item/bdr:841753/>

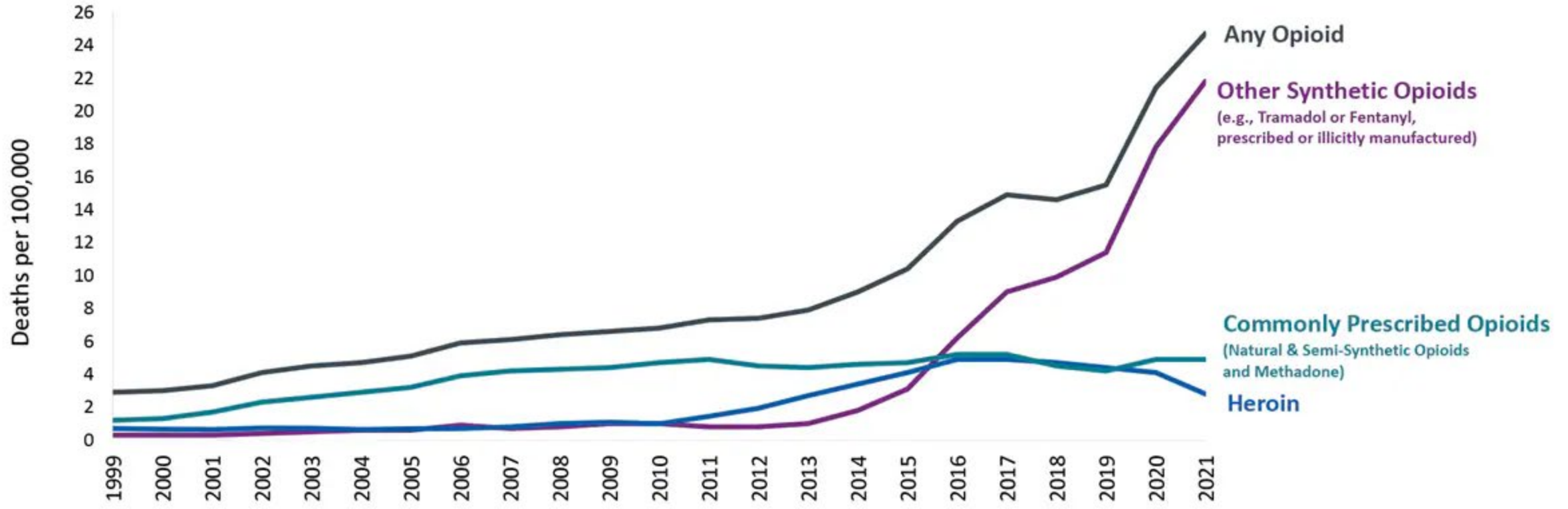
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Three Waves of Opioid Overdose Deaths



↑
Wave 1: Rise in Prescription Opioid Overdose Deaths Started in the 1990s

↑
Wave 2: Rise in Heroin Overdose Deaths Started in 2010

↑
Wave 3: Rise in Synthetic Opioid Overdose Deaths Started in 2013

SOURCE: National Vital Statistics System Mortality File.

Tackling the Crisis – Public Health Policy

- › **2014** → National Institutes of Health Pathways to Prevention Workshop + AHRQ Evidence Report - No evidence that long-term opioid use is effective for chronic pain treatment but carries dose-dependent risk of ADEs.
- › **2014** → American Medical Association + American Academy of Family Physicians withdraw recognition of pain as 5th vital sign.
- › **2016** → CDC Guideline for Prescribing Opioids for Chronic Pain. Opioids no longer first-line medication for chronic pain treatment.
- › **2017** → US Dept. Health and Human Services announces 5-point Opioid Strategy
- › **2018** → SUPPORT for Patients and Communities Act – improving Medicare and Medicaid funding for treatment, recovery and prevention.
- › All states have implemented Prescription Drug Monitoring Programs. Database with individualised data on patient opioid prescriptions.
- › Medication-Assisted Treatment (MAT) using addiction-reversal medications, counselling and behavioural therapies.

Tackling the Crisis – Current Challenges

- › Annual death rate due to fentanyl overdose continue to rise.
- › Failure to stop flow of fentanyl.
- › Since 2019, rising overdoses involving strong opioids and stimulants together.
- › Significant increase in use during pregnancy.
- › Uneven implementation of policy measures.
- › Not all states have implemented MAT. Only reaching a minority of target group.
- › Covid-19 → Rapid worsening of epidemic in 2020-21.
- › Substantial harm due to War on Drugs. Overcriminalisation and aggressive enforcement, disproportionately affecting poor minority communities. Mortality highest in areas of socioeconomic deprivation and rural areas.