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**WHERE CLIENTS COME FIRST**

# **Opioids - Liability of Physicians, Pharmacists and Manufacturers**

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# What are Opioids?

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- A class of drugs that includes powerful pain relievers available by prescription, such as oxycodone (Oxycontin), hydrocodone (Vicodin), codeine, morphine, fentanyl, methadone, and many others.
- Opioids bind to receptors on the nerve cells in the brain and body to reduce pain when used legitimately, but can also cause intense euphoria or intense high that can lead to dependence and/or addiction, whether the drug ingested is heroin or a legally prescribed drug.
- First invented in 1803 with the development of morphine an extract from opium.
- Diacetylmorphine (brand name heroin) was synthesized and briefly promoted as more effective and less addictive than morphine. In the early 20th century, when heroin was legally marketed in pill form, it was used by young Americans to elicit intense euphoria by crushing the heroin pills into powder for inhalation or injection.



# History of the Opioid Crisis

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- 1995 - FDA Approves OxyContin. Soon after approval becomes the focal point of opioid abuse issues.
- 1996 - James Campbell, a neurosurgeon at Johns Hopkins, gives a speech to the American Pain Society and argues that physicians should consider pain a 5th vital sign next to blood pressure, temperature, heart rate and respiratory rate.
- 1996 - Purdue Pharma releases Oxycontin which is approved as a “minimally addictive” time-released pain reliever.
  - Begins aggressive marketing campaign (including journal articles claiming it was safe and effective)
- 1997-1999 Sales representatives for Purdue Pharma repeated use the words “street value”, “crush” and “snort” in internal notes regarding meetings with prescribers.
- From 1999-2015 the prescription rate for opioids triples.



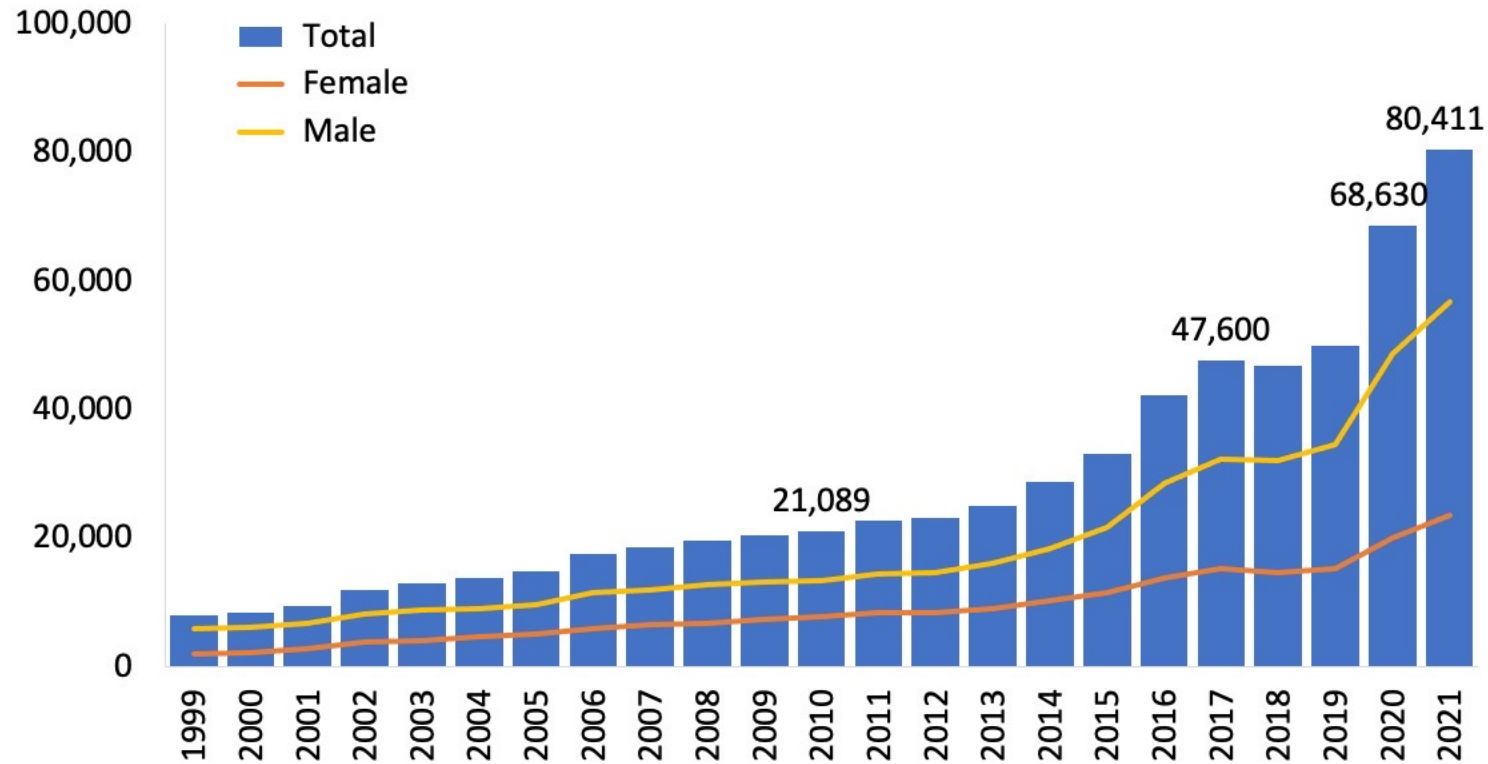
# History of the Opioid Crisis

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- 1997 Case - Sales reps to physicians
  - Substitute for Tylenol
  - Weaker than morphine (prescribe in higher doses)
- 1998 “Partners Against Pain” - small risk of addiction
- 2001 Joint Commission (accreditation body) issued pain standards (pain becomes the 5th vital sign)



### Figure 3. National Overdose Deaths Involving Any Opioid\*, Number Among All Ages, by Gender, 1999-2021



\*Among deaths with drug overdose as the underlying cause, the “any opioid” subcategory was determined by the following ICD-10 multiple cause-of-death codes: natural and semi-synthetic opioids (T40.2), methadone (T40.3), other synthetic opioids (other than methadone) (T40.4), or heroin (T40.1). Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2021 on CDC WONDER Online Database, released 1/2023.



**In 2021, 75% of  
preventable drug  
overdose deaths were  
caused by Opioids.**



**Since 1999, more than  
1,000,000 in the US  
have died as a result of  
Opioid overdose.**



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# Liability of Manufacturers

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In 2017, multi-district litigation in the U.S. alleges opioid manufacturers, distributors and pharmacies conspired to mislead medical professionals into prescribing. Between all defendants the total settlement is in the range of \$52 billion.



# Liability of Manufacturers

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- False and Deceptive Marketing
- State Consumer Protection Statutes
  - Deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service is unlawful.
- Can be broken down to three distinct theories.
  - False Advertising (overstating the value and understating the risks to physicians)
  - Deceptive or misleading business practices (misleading consumers)
  - Unfair trade practices (immoral, unethical, or unscrupulous act that offends public policy)



# Liability of Manufacturers

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- Failure to Warn of Side Effects
  - Proof
    - Identity of the Manufacturer
    - Duty to Warn
    - Standard of Care in Warning
    - Failure to Provide Adequate Warning
    - Proximate Cause of Injury



# Liability of Manufacturers

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- Design Defect
  - Safer designs
  - Tamper proof packaging
  - Cannot pursue claims if prescription drug is unavoidably unsafe.
- FDA approval does not preempt state law products liability claims of design defect.



# Liability of Manufacturers

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- Manufacturing Defect
- Not manufactured within specifications of the design
- Example: Fentanyl patches designed to safely release at a rate of 25 mcg/hour, but, because of a manufacturing defect, patches released at an excessive, potentially fatal rate. (1)



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# Liability of Pharmacies

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# Liability of Pharmacies

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- Traditionally only liable for failing to follow physician instructions.
  - Inaccurately processing prescription (wrong drug, wrong dosage etc).
- **Pharmacists' vs physicians' duties:** In general, under Illinois law, pharmacists filling prescriptions are shielded from negligence actions under the rationale that pharmacists should not be responsible for the choices made by prescribing physicians, without having a physician's knowledge of each patient. [Happel v. Wal-Mart Stores, Inc., 286 F. Supp. 2d 943 \(N.D. Ill. 2003\).](#)



# Liability of Pharmacies

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- Pharmacists in the U.S. have begun taking on new roles in the healthcare system.
  - Counseling consumers on types of drugs, side-effects, drug interactions
  - Prescribing some medications (emergency contraception pills)
- New state laws mandate pharmacists monitor patient use of medications, especially opioids.





# Liability of Pharmacies

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- New theories of tort liability begin to develop
  - Failure to warn (common law negligence)
  - Failure to monitor (imposed by state law)
- *Dee v. Wal-Mart Stores, Inc.*, 878 So. 2d 426 (Fla. Dist. Ct. App. 1st Dist. 2004)
  - Negligent dispensing of fentanyl prescription.
- Negligent advice - Pharmacists who answer a patron's questions are required to advise and act in a non-negligent manner.



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# Learned Intermediary Doctrine

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# Liability of Pharmacies

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- Pharmacies charged with distributing opioids knew, or should have known, with a degree of reasonable care;
- That providers were overprescribing opioids;
- Resulting in illegal diversion; and
- Ignored the information for profit.
- Nuisance claims by states and counties



# Liability of Pharmacies

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- National Opioid Prescription Litigation
  - Ohio pharmacies liable for nuisance not only for oversupplying opioids
  - But also for correctly filling knowing that the oversupply would lead to diversion and illegal use.



# Liability of Pharmacies

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- National Opioid Prescription Litigation
- 2021 - Settlements with McKesson, Cardinal Health, and AmerisourceBergen (Distributors) - \$21 billion paid over 18 years
- 2022 - CVS, Walgreens and Walmart \$12 billion + over 15 years



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# Liability of Physicians/Prescribers

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# Liability of Physician/Prescribers

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- Duty to comply with the standard of care. What would a reasonable physician do under the same or similar circumstances?
  - Were other medications attempted first?
  - Did the provider access medication databases run by the states?
- Documentation
- Off-Label Uses



# Liability of Physician/Prescribers

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- Failure to Properly Monitor and Ween Off Opioids
- Patient was a paraplegic as the result of a motor vehicle accident.
- Pain clinic incorrectly prescribed 1/2 of his normal dose of opioids.
- Patient ran out in 1/2 the time.
- When clinic refused to refill patient committed suicide in the parking lot.





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