The Opioid Epidemic: A Focus on Causes and Solutions
“Like no other particle on earth, the morphine molecule seemed to possess heaven and hell. It allowed for modern surgery, saving and improving too many lives to count. It stunted and ended too many lives to count with addiction and overdose... no other molecule in nature provided such merciful pain relief, then hooked humans so completely, and punished them so mercilessly for wanting their freedom from it.”

Sam Quinones,
Dreamland: The True Tale of America’s Opiate Epidemic
OPIUM IS DERIVED FROM THE OPIUM POPPY.
OPIUM IS FOUND IN THE FLUID ("LATEX") OF THE POPPY SEED POD.
DANGERS OF OPIUM KNOWN FOR OVER A CENTURY

The Deadly Poppy Field

“And now my beauties, something with poison in it I think, with poison in it, but attractive to the eye and soothing to the smell . . . poppies, poppies, poppies will put them to sleep.”

The Wonderful Wizard of Oz, First Edition, 1900
THE EPIDEMIC
Every day in America, more than 1,000 people are treated in emergency rooms for misuse of opioids.

More than 564,000 people died from overdoses involving any opioid, including prescription and illicit opioids, from 1999-2020.

Opioid deaths are now the number one killer of Americans under 50.

Annual Opioid deaths now exceed the number of Americans killed by gun violence and motor vehicle accidents each year and the total number of Americans killed during the Vietnam War.

A recent study estimated that aggregate societal costs exceed $78.5 billion.¹

- Based on data from 2013, which substantially undervalues the present economic impact

OPIOID OVERDOSE ER VISITS CONTINUE TO RISE

30%
Opioid overdoses went up 30% from July 2016 through September 2017 in 52 areas in 45 states.

70%
The Midwestern region witnessed opioid overdoses increase 70% from July 2016 through September 2017.

54%
Opioid overdoses in large cities increased by 54% in 16 states.

Emergency department visit rates because of an opioid overdose increased by 28.5% across the U.S. in 2020, compared to 2018 and 2019, recent Mayo Clinic research finds.
*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 1999-2020 on CDC WONDER Online Database, released 12/2021.
INCREASING PRESCRIPTIONS OF OPIOIDS

Opioids have expanded from being prescribed for short-term (traumatic injury or surgery) or severe pain (e.g., cancer or end-of-life care) to treatment for chronic pain (e.g., back pain).

<table>
<thead>
<tr>
<th>Year</th>
<th>Total U.S. Prescriptions</th>
<th>Total U.S. Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1992</td>
<td>112 million</td>
<td>$1 billion</td>
</tr>
<tr>
<td>2015</td>
<td>249 million</td>
<td>$9.6 billion</td>
</tr>
</tbody>
</table>

- **222% increase** in total U.S. prescriptions from 1992 to 2015
- **960% increase** in total U.S. revenue from 1992 to 2015
Experts estimate that a baby with NAS is born in America every 15 minutes.

NAS is Neonatal Abstinence Syndrome
The opioid epidemic has cost the U.S. more than a trillion dollars since 2001, according to a new study, and may exceed another $500 billion over the next three years.

The report by Altarum, a nonprofit group that studies the health economy, examined CDC mortality data through June of last year. The greatest financial cost of the opioid epidemic, according to the report, is in lost earnings and productivity losses to employers. Early deaths and substance abuse disorders also take a toll on local, state and federal government through lost tax revenue.

These costs are rising. One reason for the increase, says Corey Rhyan, a senior research analyst with Altarum’s Center for Value and Health Care, is that more young people are being affected as the epidemic moves from prescription opioids to illicit drugs like heroin and fentanyl.

"The average age at which opioid deaths are occurring — you're looking at something in the late 30s or early 40s," Rhyan says. "As a result, you're looking at people that are in the prime of the productive years of
DRUG OVERDOSE DEATH RATE INCREASES
2013-2017

Age-adjusted rate* of drug overdose deaths †, by state – 2013 and 2017 §
THE OPIOID CRISIS IN THE BUILDING TRADES

• The construction industry has *twice the national average* of employees with substance use disorders.

• Within union health and welfare plans, powerful painkillers are among the *top five medications prescribed* to members.

• The primary workforce in construction is male, and they’re *twice as likely* to abuse prescription drugs than females.

• The average construction worker addicted to opioids has been on pain medications for *at least six months*.

• The average age at which Ohio construction workers have died of opioid overdoses over the last seven years is *40 years old*.
The data behind this story comes from occupation information families provided on death certificates. The Ohio Department of Health compiled the data and released it to the (Cleveland) Plain Dealer who shared it with other media. To determine the rate of overdose death, we compared the number of deaths per job to the number of people working in that profession according to the Bureau of Labor Statistics.

Graphic by Katie Wedell.
Industry sectors with opioid-related overdose death rates significantly higher than the average rate for all workers, Massachusetts workers, 2011-2015, n=4,302

Rate for construction ~6 times the rate for all workers
The trillion-dollar industry has been hit harder than almost any other sector of the economy in a health crisis that takes nearly 100 American lives each day.

Construction workers, by the physical nature of their jobs, often suffer the wear and tear on the body that, in recent history, would have led doctors to prescribe opioid pain medication in order to allow them to return to the work site. But the short-term solution can have long-term ramifications, both personal and financial.

The Silent Killer On The Job Site: Inside Construction’s Battle With Opioids

The American opioid crisis was declared a national public health emergency Thursday, but the U.S. construction industry does not seem ready to take action regarding its own significant role in the deadly epidemic.

The trillion-dollar industry has been hit harder than almost any other sector of the economy in a health crisis that takes nearly 100 American lives each day. But it has been largely silent, more concerned about perception than the number of workers who are addicted to opioids.

Executives who are willing to speak on the record, some areThreshold analytics by the steel industry's ability to respond.

Executives who are willing to speak on the record, some areThreshold analytics by the steel industry's ability to respond.

Threshold analytics by the steel industry's ability to respond.
Outside Boston, public health workers researching opioid-related deaths found that **building and construction workers accounted for 42 percent of overdoses** in a swath of suburbs.

And, in 2010, **more than 80 percent of construction workers whose injuries were treated with medication were given narcotics**, according to BWC data. Often got medications like Vicodin, Percocet and OxyContin, which are opioids or semi-synthetic opioids.

The [union-funded rehab] programs can have an unintended consequence, some construction workers said. Once a person fails a drug test or asks for help with addiction, they are off the job. They can get treatment, but they **won't get paid** for union construction work while they do.
More than half of Medford’s opioid overdose victims worked in the trades — an umbrella term for everything from highly skilled people building skyscrapers to day laborers picking up the occasional painting job.

The public health group followed up with dozens of constructions workers who suggested one reason people in their industry may be vulnerable to addiction: a link between getting hurt on the job and then hooked on pain killers.

“They’re given a prescription ... to nullify the pain. And these drugs are very powerful,” said Funaiole. “They can really take over operations in your brain.”
THE OPIOID LITIGATION AND AFFECTING PUBLIC POLICY THROUGH LITIGATION

Over 3000 Suits Consolidated in the Northern District Of Ohio

Can This Judge Solve the Opioid Crisis?

Alarmed by the opioid epidemic, Judge Dan Polster wants to quickly settle some 400 lawsuits against drug makers and distributors. Lawyers are skeptical he can pull it off.
MAJOR DEFENDANTS
MANUFACTURER DEFENDANTS

Manufacture, Market and Sell Opioids
DISTRIBUTORS
Buy Opioids from Manufacturers, and
Sell to Customers

DISPENSERS
Sell Opioids at the Retail Level

Cardinal Health
AmerisourceBergen
Mckesson
Anda
Walgreens
CVS pharmacy
Rite Aid
Walmart
Walgreens
OPIOID DRUGS

Oxycontin
OPIOID DRUGS

Oxymorphone Hydrochloride

Hydromorphine

Oxycodone Hydrochloride

Hydromorphone Hydrochloride

Oxycodone Hydrochloride

Hydrocodone Bitartrate

Fentanyl

Fentanyl Transdermal System (Generic Duragesic Patch)

Oral Transmucosal Fentanyl Citrate (OTFC) (Generic Actiq)

Oxycodone Hydrochloride

Morphine Sulfate

Hydromorphine Hydrochloride

Hydrocodone Bitartrate and Ibuprofen (Generic Vicoprofen)

Hydrocodone Bitartrate and Acetaminophen

Kadian

Norco

Hydromet
OPIOID DRUGS

Oxymorphone Hydrochloride

Oxycodone Hydrochloride

Fentanyl

Morphine Sulfate

Hydromorphone Hydrochloride

Hydrocodone Bitartrate

Generic Percocet

Generic OxyContin

Generic Roxicodone

Oxycodone Hydrochloride and Aspirin

Oxycodone Hydrochloride and Ibuprofen

Fentanyl Transdermal System (Generic Duragesic Patch)

Oral Transmucosal Fentanyl Citrate (OTFC) (Generic Actiq)

Hydrocodone Bitartrate and Acetaminophen

Hydrocodone Bitartrate and Ibuprofen (Generic Vicoprofen)

Hydromet

Source: 02497 Sales Over Time Spreadsheet (Teva Opioids Over Time) TEVA_MDL_A_02419959
https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
OPIOID DRUGS

**Fentanyl Citrate**
- Actiq
- Fentora

**Oxycodone Hydrochloride**
- Generic Oxycontin ER
- 10
- 20
- 40
- 80

**Actiq**

**Fentanyl Citrate**
- Oral Transmucosal Fentanyl Citrate (OTFC) (Generic Actiq)

**Oxymorphone Hydrochloride**
- Oxymorphone

**Morphine Sulfate**

**Hydromorphone Hydrochloride**

**Hydrocodone Bitartrate**
- Hydrocodone Bitartrate and Ibuprofen (Generic Vicoprofen)

**Vantrela ER**

Source: 02497 Sales Over Time Spreadsheet (Teva Opioids Over Time) TEVA_MDL_A_02419959
https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
FALSE & MISLEADING MARKETING
• The FDA relies on manufacturers to be honest about their drugs
• With FDA approval comes very strict rules for marketing and promotion
• Marketing and promotion must be truthful and not misleading
  • can’t understate risks or overstate benefits
  • can’t engage in misleading promotion under the guise of third parties
  • can’t promote for unapproved or “off-label” use
Identifies Defs’ Departures from Accepted Drug Regulatory Standards

David A. Kessler, M.D.

- Expert on FDA Standards and implementation
- Former FDA Commissioner from 1990 – 1997
- Discusses manufacturer obligations under U.S. food and drug laws
- Discusses departures from industry standards
PURDUE’S MARKETING
PURDUE’S MARKETING

• Recruited 5,000+ physicians, nurses, and pharmacists during all-expenses-paid conferences

• Targeted the physicians who were the highest prescribers for opioids across the country

• Purdue paid $40 million in sales incentive bonuses to its sales representatives

• Distributed OxyContin-branded promotional items to health care professionals, such as OxyContin fishing hats, stuffed plush toys, and music compact discs (“Get in the Swing With OxyContin”)

Purdue Aggressively Marketed Oxycontin

- Oxy prescriptions for chronic pain rose from 670,000 in 1997 to 6.2 million in 2002
- In 2007, Purdue and three executives plead guilty to misdemeanor charges of false branding of OxyContin; fined $634 million
- In 2008, drug overdoses, mostly from opiates, surpassed auto fatalities as leading cause of accidental death in the United States
- Overdose deaths involving opiates rose from ten a day in 1999 to one every half hour by 2012. Abuse of prescription painkillers was behind 488,000 emergency room visits in 2011, almost triple the number of seven years before
THE PURDUE BANDWAGON
BRANDED MARKETING vs UNBRANDED MARKETING
5TH VITAL SIGN

Manufacturers Encourage Prescribers To Assess Pain For Every Patient

PAIN ASSESSMENT TOOL

No Pain

Mild

Moderate

Severe

Very Severe

Worst Pain Possible

0

1-3

4-6

7-9

10
MANUFACTURER DEFENDANTS SAID THAT THE RISK OF OPIOID ADDICTION WAS RARE
**Substance Abuse** will be seen in a few patients in every CBP practice, perhaps largely because patients attempting to obtain opioids will eventually end up at a pain management practice. However, despite the continued unscientific beliefs of some clinicians, there is no evidence that simply taking opioids for a period of time will cause substance abuse or addiction. It appears likely that most substance-abusing patients in pain

- **Tolerance**, physical dependence, and addiction are often of concern to patients and professionals. Under medical supervision, appropriate use of opioids rarely leads to addiction.
In essence, pseudoaddiction is understood as the social judgment of blame on the physician for not giving opioids to patients when they should, while addiction is blame put on the patient in wanting opioids when they should not.

MANUFACTURING DEFENDANTS PROMOTED THE FALSE IDEA OF PSEUDOADDICTION
Pseudoaddiction:

Behaviors (that mimic addictive behaviors) exhibited by patients with inadequately treated pain.

Certain behaviors are sometimes mistaken for addiction. If patients receive inadequate pain relief, they may exhibit drug-seeking behaviors. This is called pseudoaddiction. When these patients receive adequate pain management, they no longer exhibit the same behaviors. Patients in pain do not usually become addicted to opioids. [Kahan, 2006, 1982-1983; NPC and JCAHO, 1985-1987]
MANUFACTURING DEFENDANTS FALSELY CLAIMED THERE WAS NO DOSING LIMIT

Manufacturing Defendants falsely state and said there was no limit to the amount of opioids patients could take. As a result, doctors continued to up the dose. . .
Managing Chronic Pain and the Importance of Customizing Opioid Treatment

Morphine Is the Benchmark Analgesic

- The gold standard in pain control—reliable, with proven efficacy and safety when taken appropriately
- Improves quality of life for patients, helping to maintain daily activity, independence, mental awareness, and dignity
- Appropriate for both malignant and nonmalignant chronic pain
- No ceiling dose or acetaminophen toxicity

The other opioids can relieve severe pain. Their doses can be gradually increased over time. There is no ceiling dose as there is with the NSAIDs. As pain worsens, these medications continue to be useful unless side effects occur. It is a myth that opioids, like morphine should only be used at the final stages of a seriously painful disease. When pain is severe, opioids should be considered.
THE MARKETING EVIDENCE ESTABLISHED:

- Sophisticated, well-developed brand and generics marketing departments
- All national marketing policies were employed in San Francisco
- DDMAC Warning Letter
- Continued to market opioids with messaging DDMAC found misleading
THE MARKETING EVIDENCE ESTABLISHED:

- All sales reps trained with misleading messages about opioids
- Sales force tasked with selling brand and generic opioids
- “Main messages” being “long history of safe and efficacious use, favorable formulary position and copay program”
- Mail campaign targeted top 10,000 highest prescribers to sell Opana ER
THE MARKETING EVIDENCE ESTABLISHED:

- Incentive compensation, “Contest” and “bonus plan” for sales reps that sold most opioids
- Sales force target: 1306 generic kadian prescriptions per day
- Sales force targeted 5500 of highest prescribers to sell generic kadian
MANUFACTURERS

Trained All Sales Reps with False Messaging

- Used IMS to track prescription level data
- Paid Valutrack for unblinding of pharmacy data
- Trained all sales reps around the country with same materials
- Targeted “high-volume generic MS writers” “to drive growth”
- Goal: 26,000 generic kadian Rx’s per week
- Goal: 1306 generic kadian Rx’s per day
THE MARKETING EVIDENCE ESTABLISHED:

Manufacturer Trained Its Sales Reps to Downplay Risks ...

Opiophobia, or fear of prescribing opioids, extends to physicians as well as patients. A number of physician surveys have indicated that clinicians are reluctant to prescribe opioid analgesics in noncancer patients due to fear of iatrogenic addiction, lack of understanding of addiction, concerns about differentiating drug-seeking patients from those with legitimate pain, and regulatory scrutiny. Therefore, opophobia leads to undertreatment of patients who are suffering from pain, but, according to the statistics, does not seem to be reducing misuse, abuse, and diversion.

“Patients with chronic pain need medications; the potential for abuse should not deter physicians from prescribing appropriate medications in adequate dosages. To help primary care providers confidently select the most appropriate medication for the situation, NIDA is working to develop screening and diagnostic tools that primary care physicians can use to assess the potential for misuse, abuse, and dependence on prescription drugs in their patients.”

Exposure to a potentially addictive drug, such as an opioid, does not necessarily result in addiction. Although the actual risk of addiction is unknown, in general, patients in pain do not become addicted to opioids. One study cited by the NIDA found that only 4 out of about 12,000 patients prescribed opioids for acute pain became addicted; in one small study of patients with chronic pain who received opioids for 4 to 7 years, about 5% (2 of 38) became addicted, and these patients had a prior history of drug abuse. Genetic, social, and psychological factors appear to be stronger determinants of addiction than does drug exposure alone. However, surveys suggest that clinicians often overestimate the risk of addiction.
... while driving them to make more money.
MANUFACTURER
SUSPICIOUS ORDER
MONITORING
PROGRAMS
In 1970 Pres. Nixon signed into law the “Controlled Substances Act” (the “CSA”)

Controlled Substances Act Title 21 U.S.C. 801(2)

The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.
December 27, 2007 Letter
From: Joseph T. Rannazzisi, DEA
To: Every DEA Registered Manufacturer

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the

When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating “excessive purchases” do not comply with the requirement to report suspicious orders, even if the registrant calls such reports “suspicious order reports.”
THE EVIDENCE WILL SHOW THAT:
Dispensers Received **Almost 9 Billion** MME Of Opioids

Between 2006 and 2014, Dispensers in San Francisco County, CA received nearly **8.8 billion** MME of opioids.

Given the county’s 809,711 population, Dispensers received **enough opioids for every resident** to consume **1,205 MME** every year from 2006 to 2014.
HEALTH ECONOMIST EXPERT

Showed Defs’ Causation Analysis is Irrelevant

David M. Cutler

• Nationally, areas with more shipments experienced more opioid-related harms from 1993 – 2019
HEALTH ECONOMIST EXPERT
Showed Defs’ Causation Analysis is Irrelevant

David M. Cutler

- Nationally, market for rx opioids changed dramatically in 2010 due to increased regulatory oversight, the release of the abuse deterrent opioids, and the reversal of 15 years of increasing shipments
- Nationally, these market changes decreased supply of rx opioids and increased the demand for illicit opioids
“A nuisance is “[a]nything which is injurious to health . . . or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property . . . .”


Public nuisances “affect[] at the same time an entire community or neighborhood, or any considerable number of persons . . . .”

*Id. § 3480.*

[The People] allege[] that Defendants’ conduct created a public nuisance—the opioid epidemic—in San Francisco. FAC ¶¶ 223, 892–906.”

*Breyer, Mtd Order at 59.*
Unfair Competition Law

Prohibits “unfair competition” defined as “any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising . . . .”


Three Prongs:

1. Unlawful
   “Anything that can properly be called a business practice and that at the same time is forbidden by law.”
   
   • Violation of Controlled Substances Act - requires defs to identify, report and halt suspicious orders and provide effective controls against diversion. 21 C.F.R. §§ 1301.71, 1301.74 and Cal. Bus. & Prof. Code §§ 4301 and 4164.
   
   • Violation of Consumer Legal Remedies Act – prohibits “unfair methods of competition and unfair or deceptive acts or practices... intended to result or which result in the sale or lease of goods or services to any consumer.” Cal Civil Code § 1770(a).
Unfair Competition Law

Prohibits “unfair competition” defined as “any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising . . . .”


Three Prongs:

2. **Fraudulent**
   Likely to deceive members of the public. MTD Order at 80.

3. **Unfair**
   Harm to the victim outweighs any benefit. MTD Order at 80.
SF’S PARK RANGERS HAVE COLLECTED THOUSANDS OF NEEDLES

Sergeant Maja Follin
SF Dept. of Recreation & Parks

- Recreation & Parks has a dozen outreach rangers
- They support homeless population in SF’s Parks
- They encounter numerous overdoses
- They are trained to and frequently administer Narcan
- They are hazmat trained for safe needle pickup
WORSENING EPIDEMIC REQUIRES SF STREET OVERDOSE RESPONSE TEAM (“SORT”)

• Worked with City of SF since 1989
• Observed the opioid epidemic worsen over the years
• Dramatic increase in Narcan administrations needed
• Dramatic increase in overdose deaths
• Street Overdose Team Created in 2021 to address overdose incidents on streets of SF

Overdose Response Team Hits San Francisco Streets

By Sunni Khalid
August 3, 2021 at 3:44 PM PDT

That includes dispensing buprenorphine, which is used to treat opioid addiction. They’ll also provide rescue kits that contain the opioid-blocker Naloxone. They’ll share educational materials, and help get folks into substance use treatment.
FOR WALGREENS

“Everything was about numbers, always”
Victor Lo, Trial Tr. 918:16-919:4

“86,904 opioid pills”
dispensed by Walgreens for Dr. Guido Gores after learning of his suspicious practices.

478% per year”
increase in opioid overdose deaths from 2015 to 2020.

584 opioid overdose deaths in 2020.

P-27532; P-28518_Gores_Excerpt; Trial Tr. 3052:10-3062:13.

Zevin Trial Tr. 632:4-18.

Coffin Decl., ¶39.
“Everything was about numbers, always”
Victor Lo, Trial Tr. 918:16-919:4

“2,998 visits in 2020 (1,086) involved prescription opioids.”
Coffin Decl. ¶40

“7,600 doses of Naloxone”
doses of Naloxone administered by SFFD “July 2018 and March 2022”
Tong Decl., ¶6.

“over 95,000 needles”
per year collected by DPW from 2017-2021.
PUBLIC NUISANCE IN SAN FRANCISCO
The aggregate evidence that Plaintiff presented at trial was not only adequate to establish Walgreens’ culpability—it was devastating.

a. The Orange County and West Virginia Cases are Factually Inapposite

In two recent decisions involving the nationwide opioid litigation, two separate courts held that the plaintiffs in those cases failed to prove causation. In November 2021, after a multi-month bench trial, judgment was entered in favor of various opioid manufacturer defendants in the Superior Court of California County of Orange. People v.
NATIONAL SETTLEMENTS ACHIEVED AND NEXT STEPS IN LITIGATION

- **Third Party Payor Litigation**
- **Additional Pharmacy Tracks** (Walmart, Walgreens, CVS, etc.)

**Settlements Achieved:**
- **Allergan** $6.5 bil.
- **Teva** $6 - 9 bil.
- **Purdue** $21 bil.
- **Cardinal Health** $1.6 bil.
- **Mckesson** $450 mil.
- **Mallinckrodt** $5 bil.

**Big 3 Distributors**
- Cardinal Health
- AmersourceBergen
- McKesson