

The Opioid Industry Documents Archive

Insights into the Opioid Industry's Role in the Opioid Crisis



University of California
San Francisco



JOHNS HOPKINS
UNIVERSITY



Trigger/ Content Warning

- This presentation addresses substance use, and substance use disorders.
- This material is presented using slides and video clips, some of which show images of drugs or talk explicitly about use.

Understanding the Opioid Crisis: Impact, Statistics, and Scope



Media: [7 Days | Arkansas PBS \(myarkansaspbs.org\)](https://www.arkansaspbs.org/)

Impact of the Opioid Crisis

Please keep in mind that behind each number and statistics, millions of real people and families were affected and their personal lives are important to note when discussing the impact of the opioid epidemic.



70,630

people died from drug overdose in 2019²



10.1 million

people misused prescription opioids in the past year¹



1.6 million

people misused prescription pain relievers for the first time¹



1.6 million

people had an opioid use disorder in the past year¹



2 million

people used methamphetamine in the past year¹



48,006

deaths attributed to overdosing on synthetic opioids other than methadone (in 12-month period ending June 2020)³



745,000

people used heroin in the past year¹



50,000

people used heroin for the first time¹



14,480

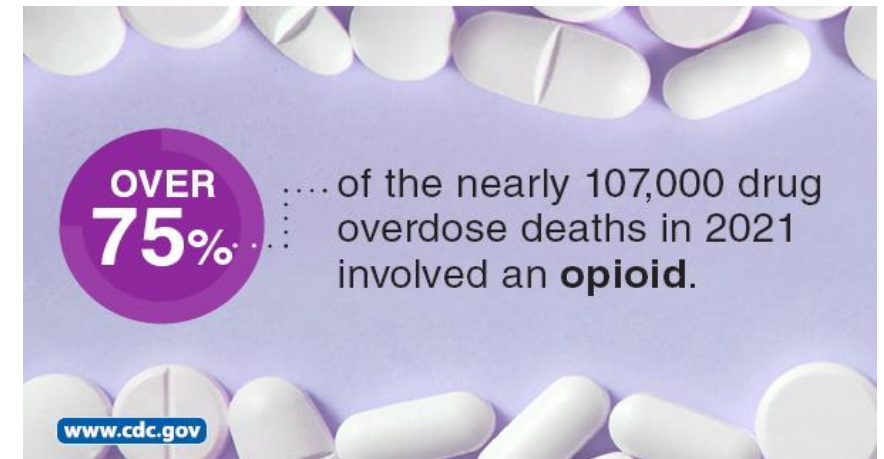
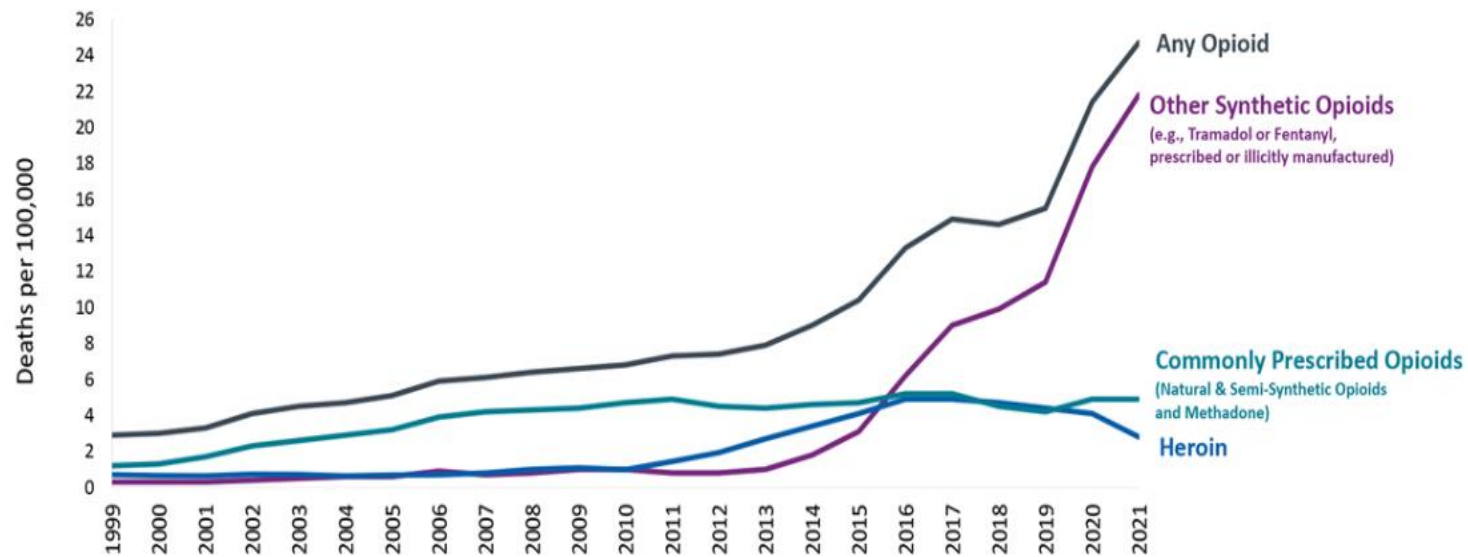
deaths attributed to overdosing on heroin (in 12-month period ending June 2020)³

SOURCES

1. 2019 National Survey on Drug Use and Health, 2020.
2. NCHS Data Brief No. 394, December 2020.
3. NCHS, National Vital Statistics System. Provisional drug overdose death counts.

image: <https://www.hhs.gov/opioids/statistics/index.html>

Surging drug overdose deaths in 2021 and trends in opioid categories over the years



Synthetic opioids have become the leading cause of overdose deaths, followed by prescription opioids in recent years

Image: <https://www.cdc.gov/opioids/basics/epidemic.html>

How frequently are prescription opioids misused?

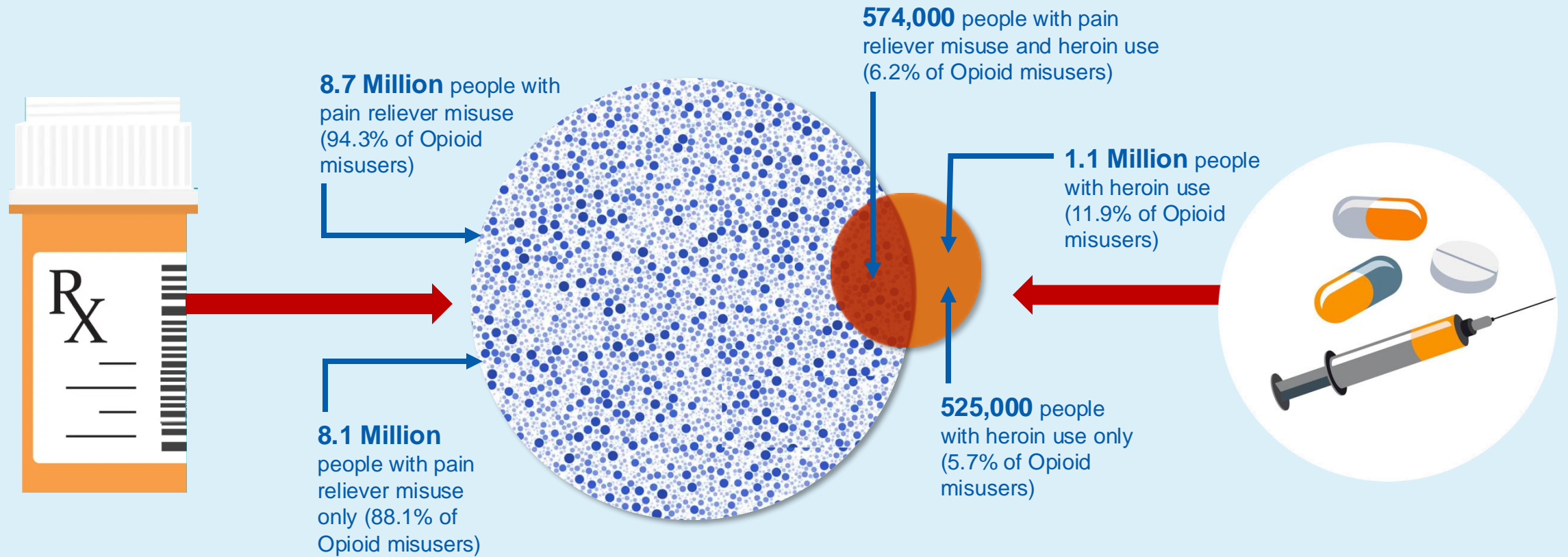


Image: <https://nida.nih.gov/publications/research-reports/prescription-opioids-heroin/prescription-opioid-use-risk-factor-heroin-use>

Poverty is a key driver of opioid mortality and misuse

- Compared to people living in households at least 5 times above the poverty line, people who lived at or below poverty were more likely to die from opioid overdoses.
- People living under poverty are more likely to misuse opioids comparing to those living in household at or above the poverty line as well.

Figure 1. Past Year Opioid Misuse and Use Disorder by Poverty Status, 2016

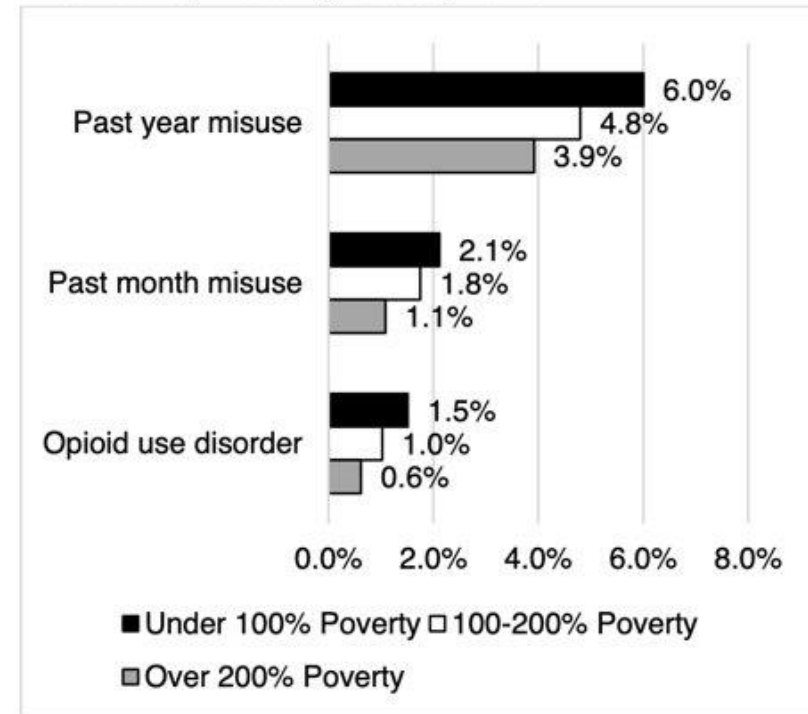
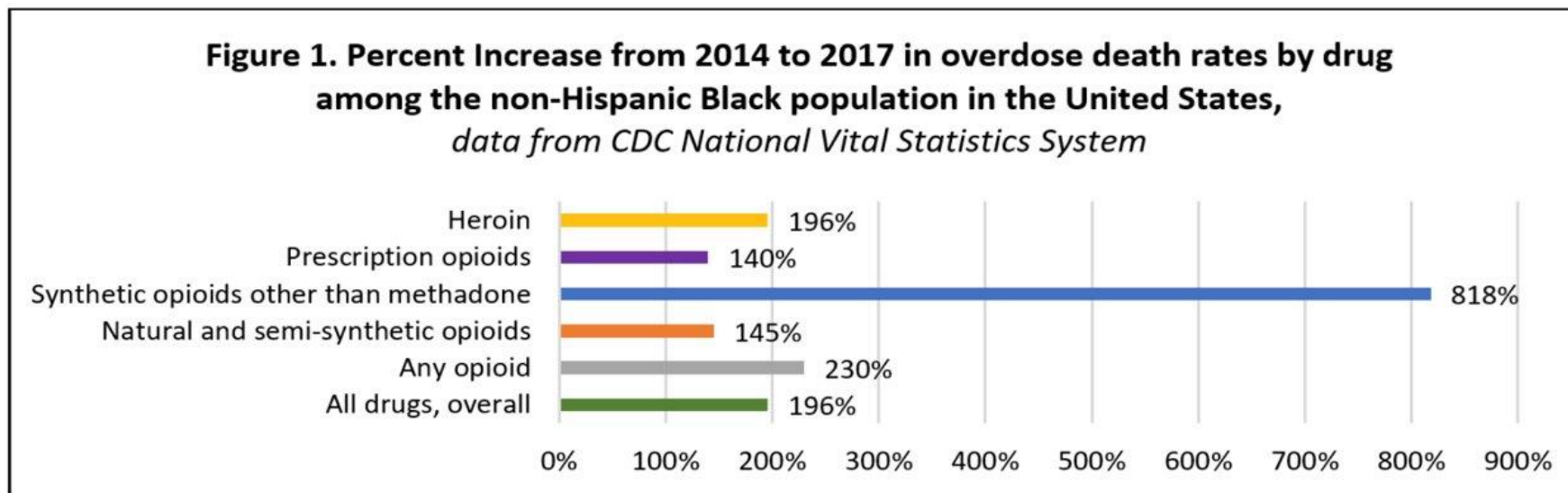


image: <https://aspe.hhs.gov/sites/default/files/private/pdf/259261/ASPEconomicOpportunityOpioidCrisis.pdf>

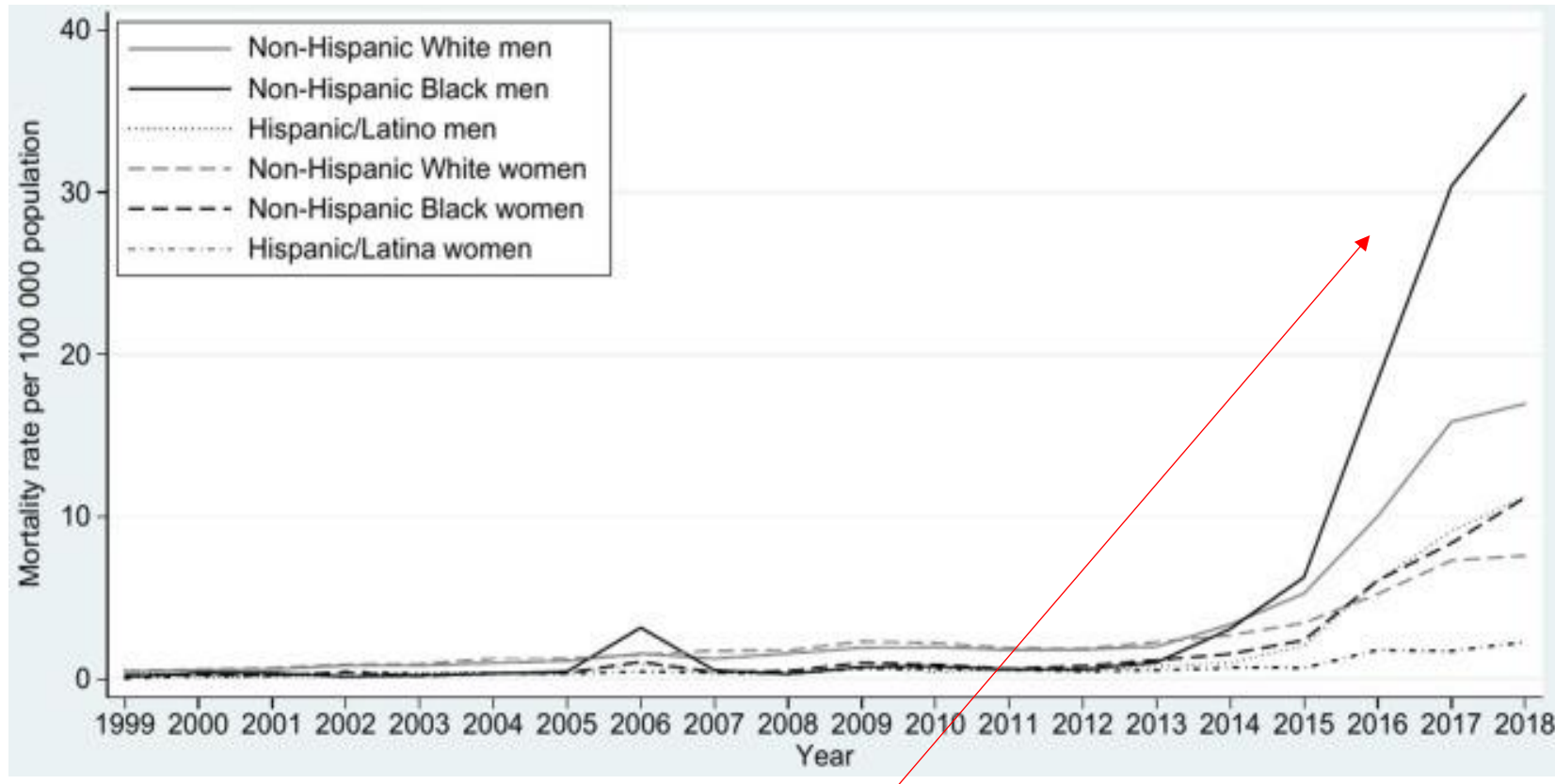
Structural racism: disproportionately large impact of opioid crisis on communities of color



Non-Hispanic Black individuals in four U.S. states experienced a 38% increase in the rate of opioid overdose deaths from 2018 to 2019, while the rates for other race and ethnicity groups held steady or decreased

Image: <https://store.samhsa.gov/sites/default/files/pep>

Synthetic opioid overdose mortality among adults 45-64 by race/ ethnicity (1999-2018).



A drastic increase in mortality for Non-Hispanic Black men compared to other race and gender categories

Oversight Undermined: Pharma's Influence on Regulatory Agencies



Image: <https://static01.nyt.com/images/2020/12/08/multimedia/08mckinsey-2/08mckinsey-2-superJumbo.jpg>

Governmental agencies that regulate opioids in the U.S.



The DEA was established in 1973 as the federal organization in charge of enforcing the controlled substances laws of the United States.



The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices.

Image: <https://www.fda.gov/themes/custom/preview/img/FDA-Social-Graphic.png> <https://www.dea.gov/who-we-are>

Key federal agencies 'captured' by commercial interests

Ex. Between 2002 and 2013, 41 DEA officials left the DEA to work for Big Pharma.

Ex. The FDA medical review officer who approved OxyContin leaves to work for Purdue two years later.

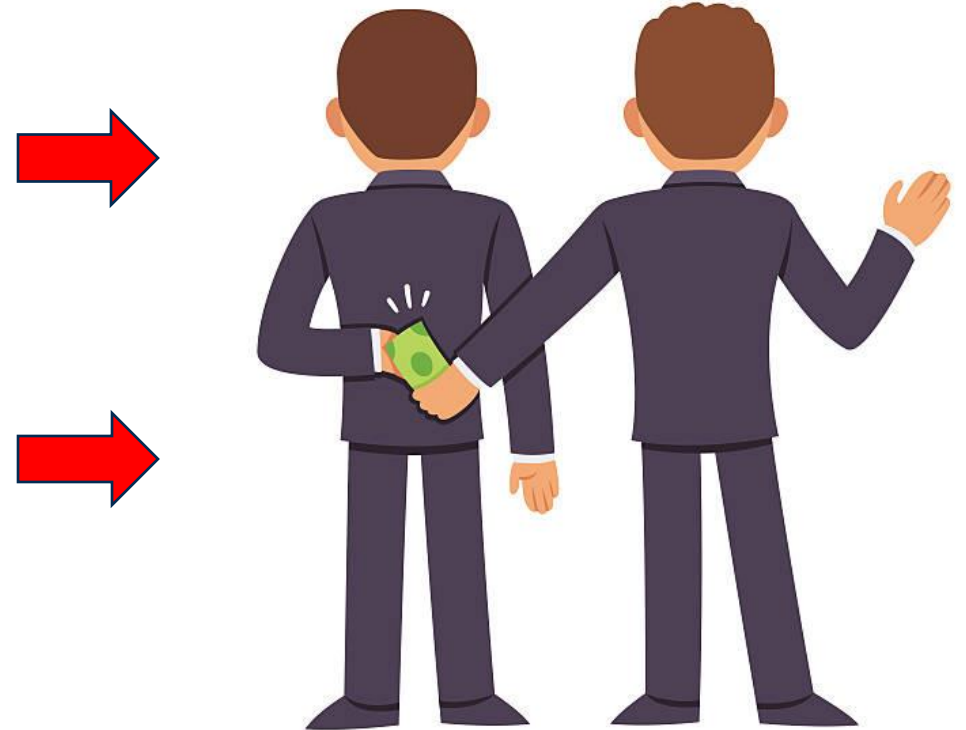


Image: <https://archive.org/details/screen-shot-2022-06-28-at-3.29.08-pm>

The early days: FDA approves Oxycontin and then expands its approved use



1995

FDA Approves
Purdue's
Oxycontin for
"moderate to
severe pain."

1996 – 2001

Purdue
spends
exponentially
more on ads
and sales
bonuses

1999

The first wave
of prescription
opioid
overdose
deaths starts

2001

Oxycontin sales
are \$1 billion, \$40
million spent on
sales bonuses,
and 4.6 million
spent on ads

2001

Under pressure
and with no new
evidence, the
FDA approves
"around-the-
clock" use of
OxyContin

Growth years: Pharma starts to hire away DEA staff while opioid sales burgeon



2003

Pharma begins to hire DEA employees

2004

50% of OxyContin prescriptions are written by primary care doctors

2005

DEA crackdown while increasing quotas of opioid production (e.g., Oxy up 39%, Fentanyl up 29%)

2006

OxyContin earns over 31 billion & DOJ fines Purdue 630 million

2008

DEA settles with Cardinal Health (\$34 m) and McKesson (\$13 m) for failure to report suspicious orders

Image: https://www.dea.gov/sites/default/files/styles/slide/public/2020-04/Mobile_Diversion_HiRes_111922019_%20%2824%29.jpg?itok=0LES6VFq

Second wave crests: DEA approves hundred billion of opioid pills and suspensions drop

2004

Second wave of opioid crisis

2009

DEA approves over 100 billion opioid pills to be shipped in US

2011

65 immediate suspension orders for not reporting suspicious orders and files 131 civil cases against manufacturers,

2014

The suspensions dropped to 9 and only 40 civil cases were proceeding.

Third wave: Lawsuits and settlements while limits are placed on manufacturing

2015

DEA settles again with Cardinal Health (\$44 m) for not reporting suspicious orders; New pharma friendly DEA chief

2017

Based on the Final Order opioid medication manufacturing is reduced by 25%.

2019

Congress requires DEA to consider diversion when setting drug quotas

“

The pharmaceutical industry clearly often succeeds at regulatory capture—ie, getting corporate interest prioritized over the public interest.

”

Responding to the opioid crisis in North America and beyond. Stanford-Lancet Commission

Quotation: <https://twitter.com/thelancet/status/1489238635119616009>

Manipulative Marketing: Pharma's Role in the Opioid Overdose Epidemic and Pursuing Litigation



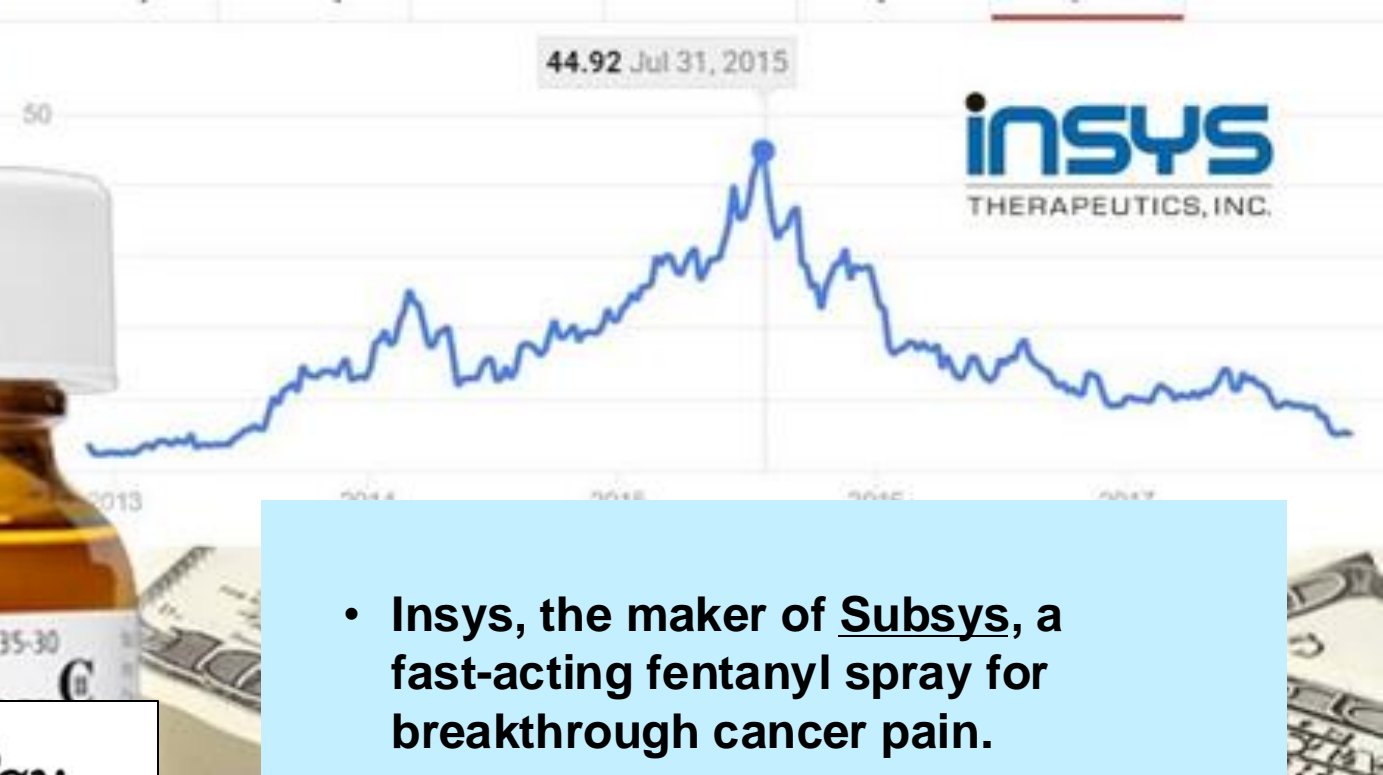
Image: <https://www.ncsc.org/courthouseplanning/the-courthouse/courtrooms>

Commercial Determinants of Health (CDoH)

“ Commercial Determinants of Health are the private sector activities impacting public health, either positively or negatively, and the enabling political economic systems and norms. ”

— The World Health Organization (WHO)

Quotation: https://www.who.int/health-topics/commercial-determinants-of-health#tab=tab_1



Insys, the Opioid Drug Maker, to Pay \$225 Million to Settle Fraud Charges

Federal prosecutors accused the company of illegally marketing its powerful fentanyl painkiller and of defrauding government health care programs.

June 6, 2019, Section A, Page 19
— The New York Times

- Insys, the maker of Subsys, a fast-acting fentanyl spray for breakthrough cancer pain.
- Targeted high-prescribers through bribery and misled insurers intentionally.
- Anti-racketeering laws used to indict founder, John Kapoor, who was sentenced to 5.5 years.

Image: [Insys Therapeutic, Inc's Synthetic Liquid THC = Schedule 2 - DEA - YouTube](#)

Mallinckrodt



Image: [Mallinckrodt Pharmaceuticals Opens Bedminster Office, Adds 330 New Jobs | Bernardsville, NJ](#)

Mallinckrodt Reaches \$1.6 Billion Deal to Settle Opioid Lawsuits

The company sold more opioids in the U.S. than any other manufacturer during the height of the addiction crisis, prosecutors have said.

Feb. 26, 2020, Section A, Page 17

The New York Times

- **Mallinckrodt**, a generic opioid manufacturer that sold more opioids than any other company
- First opioid pharmaceutical company to reach a settlement – 1.6 billion to clear liability

McKesson



McKesson, Drug Distribution Giant, Settles Lawsuit Over Opioids in West Virginia

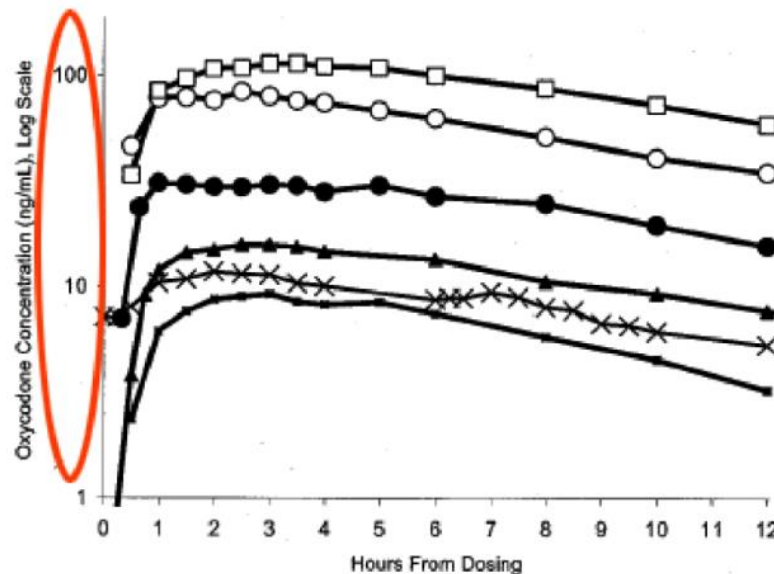
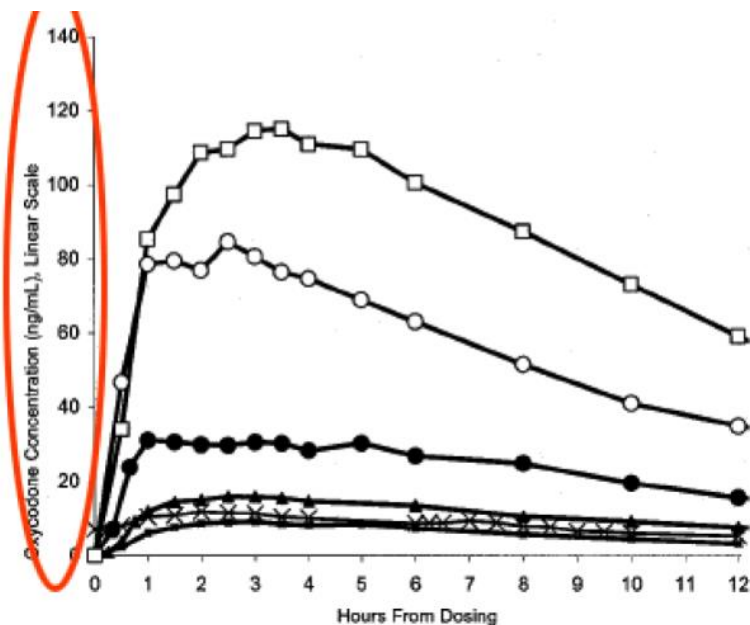
May 3, 2019, Section A, Page 17

The New York Times

- **McKesson, one of the largest drug distributors that “ failed to design ... an effective system to detect and report ‘suspicious orders.’”**
- **Paid a civil penalty of \$150 million and was banned from selling controlled substances in multiple states for years**

Image: <https://www.justice.gov/opa/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-opioid>

Purdue Pharma



- Maker of **OxyContin** (controlled release oxycodone) dosed every 12 hours.

- The graphs below represent the concentration of OxyContin in the bloodstream over time.
- The graph produced by Purdue Pharma as part of their marketing package, a **logarithmic y-axis** is presented, making the rate of change look smaller than it actually was, hence manipulating the science behind.

Image: [A History of Dangerously Misleading Data Visualization – Information Visualization \(prattsi.org\)](https://www.informationvisualization.org/2014/05/01/a-history-of-dangerously-misleading-data-visualization/)

McKinsey & Company



Media: [McKinsey: Last Week Tonight with John Oliver \(HBO\) - YouTube](#)

Behind the Scenes, McKinsey Guided Companies at the Center of the Opioid Crisis

McKinsey Opened a Door in Its Firewall Between Pharma Clients and Regulators

— The New York Times

- **McKinsey, a consulting company that worked for both Purdue Pharma and the FDA at the same time leading to concerns about conflicts of interest**

The corporate playbook: Tactics used by the pharma companies

- Intimidate and vilify critics
- Attack and undermine legitimate science
- Frame and reframe discussion and debate
- Camouflage actions
- Influence the political process
- Develop corporate alternatives to policies
- Deploy corporate social responsibility and partnerships
- Regulation and policy avoidance and evasion



Image: <https://mlt.org/advisory-services/playbook-icon/>

McKinsey on how to target physicians by type

Overview of the four distinct segments

NJE-162116.020-20090901-snchHR1
X% Percent of physicians treating moderate to severe pain

- I consider myself a pain expert
- I am among the first physicians to use new medications to treat pain; I like to use a broad range
- I spend a lot of time refining dosing
- I believe there is more risk of abuse/ diversion with IR than ER
- I like ER's because they are convenient and provide predictable pain relief

- I try to really understand how much pain my patients are in; many people underestimate their pain levels
- I would rather over-treat pain because it is very disruptive
- For many of my patients, I want to mitigate the pain because they suffer terribly from other things
- I don't believe in waiting to help my patients manage pain; I aggressively move them to ER's

- Treating pain patients is not what I like to do
- I am frustrated that patients think a medicine is THE only way to solve their pain vs. other things, and by the hassles around writing opioid prescriptions
- But, I want my patients to have the best care and if they come to me with a pain problem, I will usually see them

- Pain patients are very frustrating and distract me from the type of medicine I enjoy
- ER's make me nervous– they are very serious drugs, which patients may never come off of
- When I can not refer a patient out, I will use ER's only as a last resort, and will not use on opioid-naïve patients
- I'd rather use something that comes in generic and saves my patient money

“Pain management is the core of my practice. I take great pleasure in perfecting a treatment that minimizes my patient's pain.”



Early Adopting Experts

35%

“While I consider myself a pain expert, what is most important to me is efficiently improving my patient experience.”



Proactive Treaters

15%

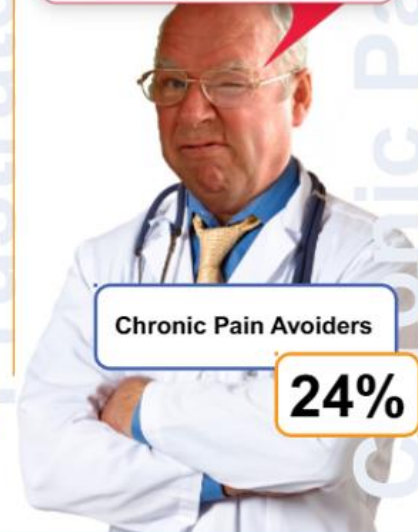
“I find treating chronic pain frustrating, but they are my patients, so I'm willing to help them solve the pain.”



Frustrated But Resigned Treaters

26%

“I find chronic pain utterly painful. If I could avoid those patients, I would do so immediately.”



Chronic Pain Avoiders

24%

Earnings above all

Media Outreach Initiatives

Reaching out to: *Youth*

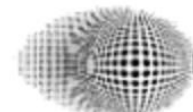
- reach early: elementary school level; via respected channels, e.g., coaches
- deliver a practical message: Pain is your body telling you something important.

Reaching out to: *Returning Veterans*

- where do they get their information about pain management
- change the paradigm of stoicism: the positive side of pain management

Reaching out to: *Media*

- capture venues that the media *want* to cover, e.g., art created by people in pain
- emphasize that the problem of poorly managed pain is often lost to the topic of fear of addiction, even though it is an issue of many magnitudes greater concern



Undermine legitimate science

Title: Affidavit of William T Fannin, MD in Commonwealth of Kentucky v Purdue Pharma

Date: 2014 July

Collection: Kentucky Opioid Litigation Documents

<https://www.industrydocuments.ucsf.edu/drug/docs/qgdf0232>

COMMONWEALTH OF KENTUCKY
PIKE CIRCUIT COURT
DIVISION II
CIVIL ACTION NO. 07-CI-01303

COMMONWEALTH OF KENTUCKY, *ex rel.* PLAINTIFF
v. AFFIDAVIT OF WILLIAM T. FANNIN, M.D.
PURDUE PHARMA, LP, et al. DEFENDANTS

Comes William T. Fannin, M.D., herein and after being duly sworn, states as follows:

1. My name is William T. Fannin, M.D.

2.
from 1986
3.
patients.
4.
marketing
abuse than

4. I was advised by the manufacturer of Oxycontin, through its employees and marketing materials, that Oxycontin was less addictive, less prone to tolerance, and less prone to abuse than other opiates.

5.

5. I relied upon these representations in prescribing Oxycontin to my patients.

6. As a result of the representations made by the manufacturer of Oxycontin as described above, I prescribed Oxycontin to patients who suffered adverse health consequences.

7. It is my belief, as a prescribing physician in Kentucky, the marketing of Oxycontin in the above-stated manner resulted in numerous health consequences to patients and other individuals in Kentucky, especially those in Eastern Kentucky.

Further the Affiant saith naught.

Frame and reframe discussion & debate

2006 Objectives for External Affairs Group

- Develop and execute a coordinated communications, government relations and advocacy strategy to:
 - Assure patient access
 - Establish Purdue as a leader in the fight against Rx drug abuse and diversion
 - Recognize the problem as Rx drug abuse, not the abuse of any single drug.
 - Reassure key audiences that lawsuits and other attacks on properly prescribed, FDA-approved pain medications represent an unjustified threat to good patient care.
 - Support Purdue's prescription and OTC product lines.
 - Enhance Purdue's reputation as a highly ethical corporate citizen.
 - Inform and motivate employees about the company's goals and values through regular communication.

Title: 2006 Objectives for External Affairs Group

Author: Purdue Pharma

Date: 2018 December 20

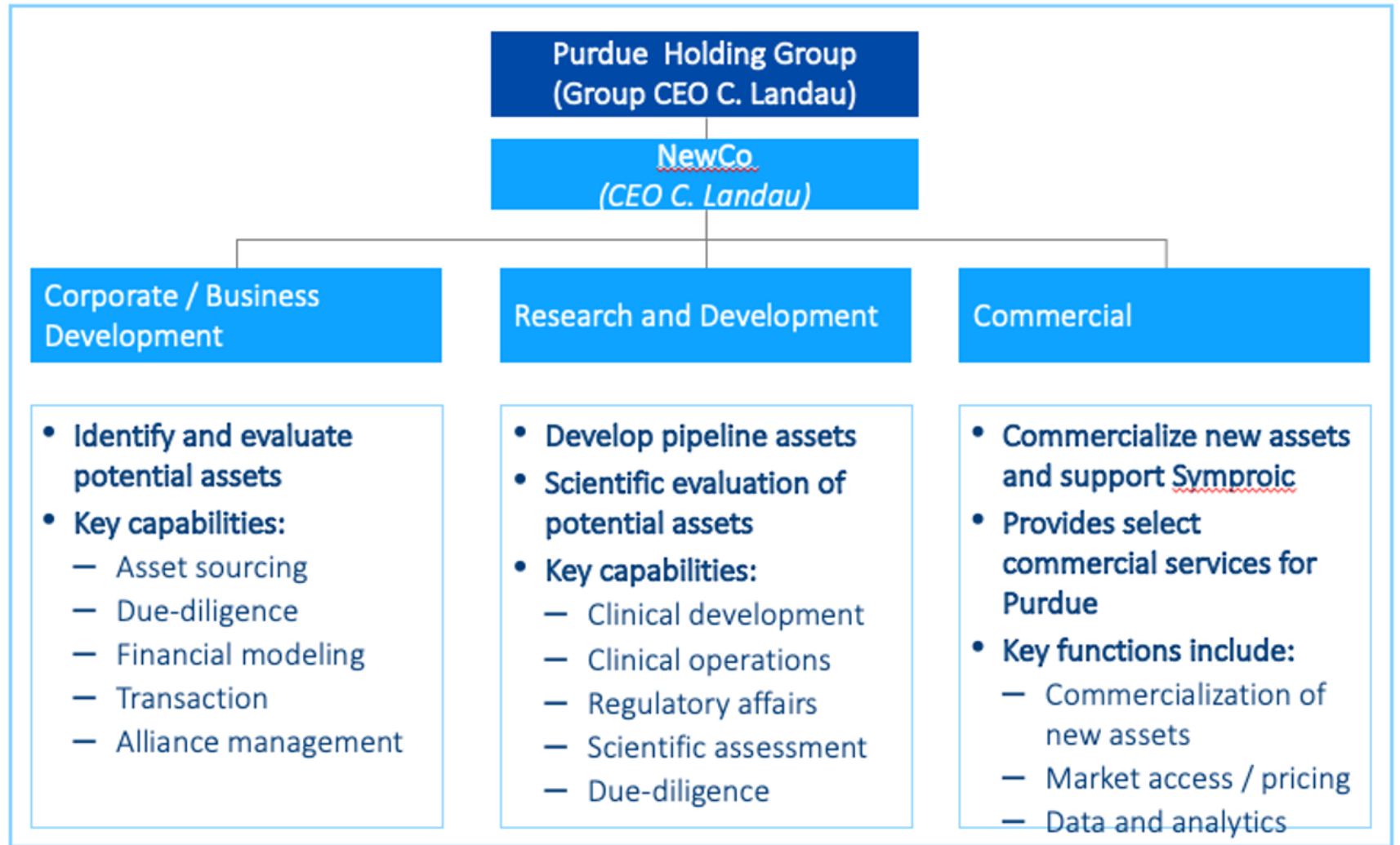
Collection: Oklahoma Opioid Litigation Documents

<https://www.industrydocuments.ucsf.edu/drug/docs/pxgg0230>



Camouflage actions

1 Organization model for “NewCo”



Influence the Political Process

“ A handful of members of Congress, allied with the nation’s major drug distributors, prevailed upon the DEA and the Justice Department to agree to a more industry-friendly law. ”

- The Washington Post

Overall, I thought the dialogue was robust and productive. There were basically three areas of attack identified:

1) Work on building a coalition effort
-the "Alliance" (TEVA, Cardinal, AMA, Prime Therapeutics)
- Explore NCPA effort - Doug Hoy has reached out to John Gray to start discussions on this
- Work on building relationships with NGA and AG's - Possible PSA's to educate media and public about our industry

2) DEA Specific Issues
- Let Marino/Blackburn bill float as is, but compile internal hot button's for DEA to prepare for blowback - this bill requires a process similar to the FDA's processes for allowing corrective action for violations or issues prior to issuing ISO's, drug testing for associates with access to the controlled drug storage areas (which we already do) and also has requirements regarding defining "imminent danger to the public"
- Convene a meeting in person to compile industry practices (member specific input to be masked through David Durkin's firm) to address Due Diligence and SOM systems.
- John Gray to attempt to set up a luncheon with Michelle Leonhart, General McCaffery and himself to discuss ways that we can start to build a collaborative relationship - the DEA has refused to come to the table in recent requests

3) HDMA Branding
- Utilize APCO material to conduct targeted media outreach to educate on value that distributors provide
- Prepare canned HDMA responses to be used when issues like WV and drug shortage issues surface. Rather than making no public statement and letting the public only hear what the media put's out, such as calling us "pill mills" with no regard for patient safety.
- Develop PSA's to educate on HDMA and the value we provide.

We also talked about developing and offering a solution suite of ideas that we could offer up to the DEA as a way to show that industry was concerned and open to other creative ways to stem prescription drug abuse. One idea was to create a new licensure type for pharmacies that were certified to dispense certain levels of pain medications that could be tied directly to a certified list of pain physicians.

My sense was that all were pretty passionate about going after this except Cardinal, which I believe was your read after the last EC meeting.

More to come.

Regulation and policy avoidance and evasion

marketing of the powerful prescription painkillers. The report said Insys allegedly created a business unit to intervene with pharmacy benefit managers and secure reimbursements for the fentanyl painkiller between January 2013 and October 2016 and falsified medical histories for prospective Subsys patients to boost approvals.

Insurers and PBMs often require additional approval before dispensing opioids to discourage abuse.

Though Subsys was touted for treating pain in cancer patients, an Oregon state investigation later found 78 percent of preauthorization claims the company submitted on behalf of Oregon patients were for off-label uses.

source

Title: Senate report flags drugmaker for tactics that boosted opioid prescriptions
Author: Purdue Pharma
Date: 2017 September 06
Collection: Mallinckrodt Litigation Documents
<https://www.industrydocuments.ucsf.edu/docs/jxhb0238>

- A practice of the Insys Reimbursement Center (IRC), an internal department where Insys employees would **pretend to be doctors' assistants** and **invented diagnoses** to smooth the approval process by insurers.

Opioid Industry Documents Archive



University of California
San Francisco



JOHNS HOPKINS
UNIVERSITY

OPIOID INDUSTRY DOCUMENTS ARCHIVE

Image: <https://www.ncsc.org/courthouseplanning/the-courthouse/courtrooms>



University of California
San Francisco



JOHNS HOPKINS
UNIVERSITY

Opioid Industry Documents Archive

What is the Opioid Industry Document Archive (OIDA)?

The Opioid Industry Documents Archive was created by UCSF and Johns Hopkins University in 2021. It preserves and provides permanent public access to previously-internal corporate documents released from opioid litigation and other sources. The documents shed light on the opioid industry during the height of the U.S. opioid crisis.

The screenshot shows the website's header with navigation tabs for 'ALL INDUSTRIES', 'TOBACCO', 'OPIOIDS', 'CHEMICAL', 'DRUG', 'FOOD', and 'FOSSIL FUEL'. The 'OPIOIDS' tab is selected. Below the header is a search bar with a 'SEARCH' button and an 'ADVANCED SEARCH' link. A 'CLEAR' button is also present. Below the search bar are checkboxes for 'Hide Restricted Documents', 'Hide Folders', and 'Hide Possible Duplicates'. There are also links for 'What can I search for?' and 'How do I search?'. A 'Search Options' dropdown menu is visible, showing 'Document Date Ranges (no dates selected)' and 'Opioids Collections (all opioids collections selected)'. Below the search options are four 'Highlights' cards: 'Popular Opioids documents' (with an image of pills), 'Insys Litigation Documents' (with the Insys Therapeutics logo), 'Mallinckrodt Litigation Documents' (with an image of a pill bottle), and 'McKinsey Documents' (with an image of people working at a desk).

How to access OIDA documents?

- **Direct URL:** <https://www.industrydocuments.ucsf.edu/drug/collections/opioids/>

OR

- **From the Main IDL homepage:**

Click on *Opioid Industry Documents* in the Highlights Section:

Highlights



Industry Videos



Popular Food Documents



Popular Tobacco Documents



Opioid Industry Documents

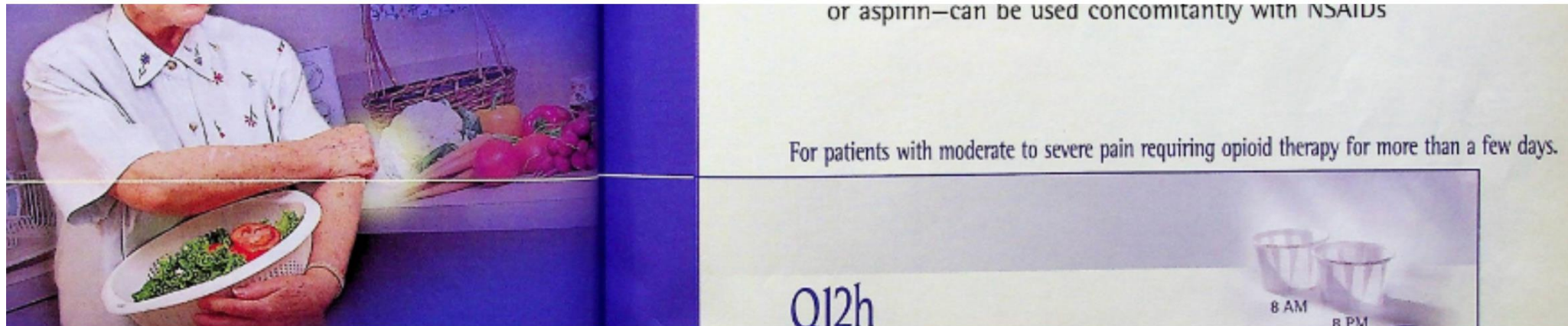
OR

- Click the **Collections drop-down menu** at the top right, scroll to **Drug Collections**, & click **Opioid Documents Collection**:

New OIDA Resource: Timeline

The Opioid Crisis: A Timeline

[HOME](#) / OPIOID CRISIS TIMELINE



The Opioid Crisis: A Timeline

<https://timeline.oida-resources.jhu.edu/>

New OIDA Resource: Image Collection



<https://images.oida-resources.jhu.edu/?pg=1>

Additional Resources

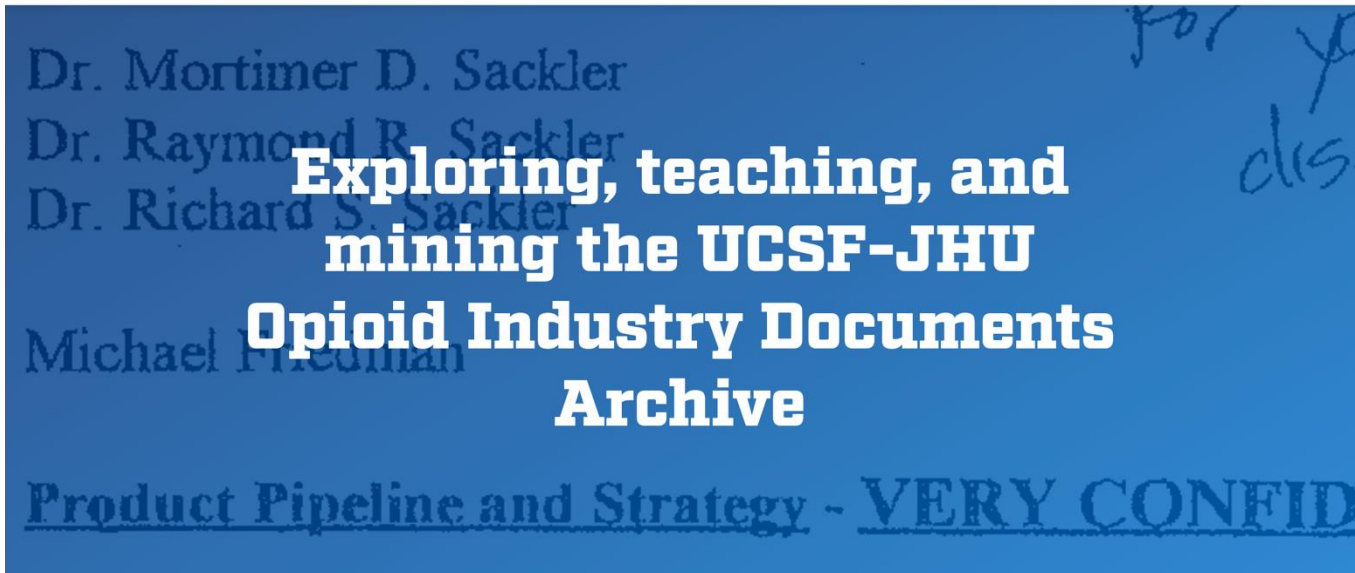


OIDA Resources

Search

CONTACT

[OIDA Curriculum Library](#) [OIDA Toolbox](#) [Opioid Crisis Timeline](#) [OIDA Events](#)



This file is part of the Opioid Industry Document Archive Curriculum Library. To explore additional materials and resources, visit the OIDA Curriculum Library, <https://oida-resources.jhu.edu/>.

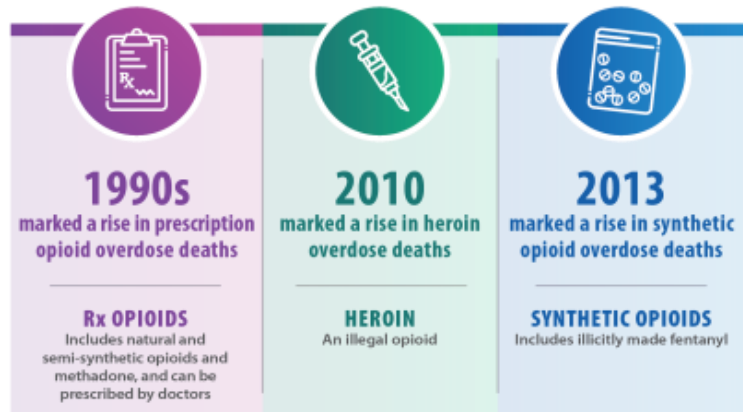
Conclusion

RISE IN OPIOID OVERDOSE DEATHS IN AMERICA

NEARLY
645,000
PEOPLE DIED FROM AN
OPIOID OVERDOSE
(1999-2021)

www.cdc.gov

A Multi-Layered Problem in Three Distinct Waves



Learn more about the evolving opioid overdose crisis: www.cdc.gov/drugoverdose

- The opioid overdose crisis has affected millions of lives and disproportionately impacted communities of color
- The regulating bodies (FDA and DEA) were strategically undermined in their regulation of prescription opioids by big pharma
- Making documents available through the OIDA means that we can better understand how companies influence health and target vulnerable populations
- Commercial determinants of health show how companies can undermine and profit from harming people

Image: [Opioid Data Analysis and Resources | Opioids | CDC](#)

UCSF

University of California
San Francisco



JOHNS HOPKINS
UNIVERSITY

Opioid Industry Documents Archive

<https://www.industrydocuments.ucsf.edu/collections/opioids/>

@industrydocs