

# The Opioid Industry Documents Archive

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

**UCSF**

University of California  
San Francisco



**JOHNS HOPKINS**  
UNIVERSITY



# Understanding the Opioid Crisis: Impact, Statistics, and Scope



Media: [7 Days | Arkansas PBS \(myarkansaspbs.org\)](#)

**UCSF**

University of California  
San Francisco



JOHNS HOPKINS  
UNIVERSITY

Opioid Industry Documents Archive

# Impact of the Opioid Epidemic



**70,630**

people died from drug overdose in 2019<sup>2</sup>



**10.1 million**

people misused prescription opioids in the past year<sup>1</sup>



**1.6 million**

people misused prescription pain relievers for the first time<sup>1</sup>



**1.6 million**

people had an opioid use disorder in the past year<sup>1</sup>



**2 million**

people used methamphetamine in the past year<sup>1</sup>



**48,006**

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



**745,000**

people used heroin in the past year<sup>1</sup>



**50,000**

people used heroin for the first time<sup>1</sup>



**14,480**

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

#### 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>

**UCSF**

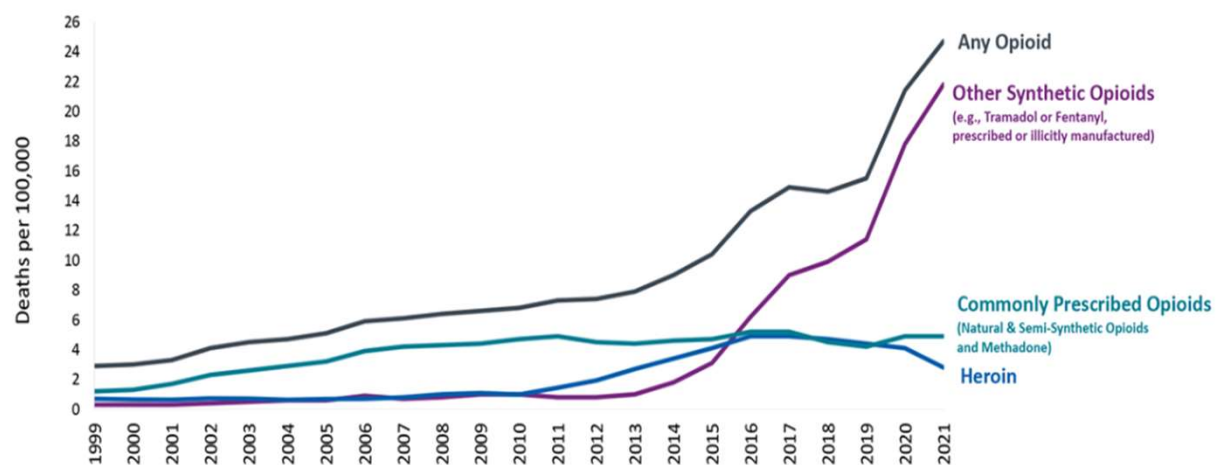
University of California  
San Francisco



**JOHNS HOPKINS**  
UNIVERSITY

**Opioid Industry Documents Archive**

# Surging drug overdose deaths in 2021 and trends in opioid categories – unequal impacts



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?

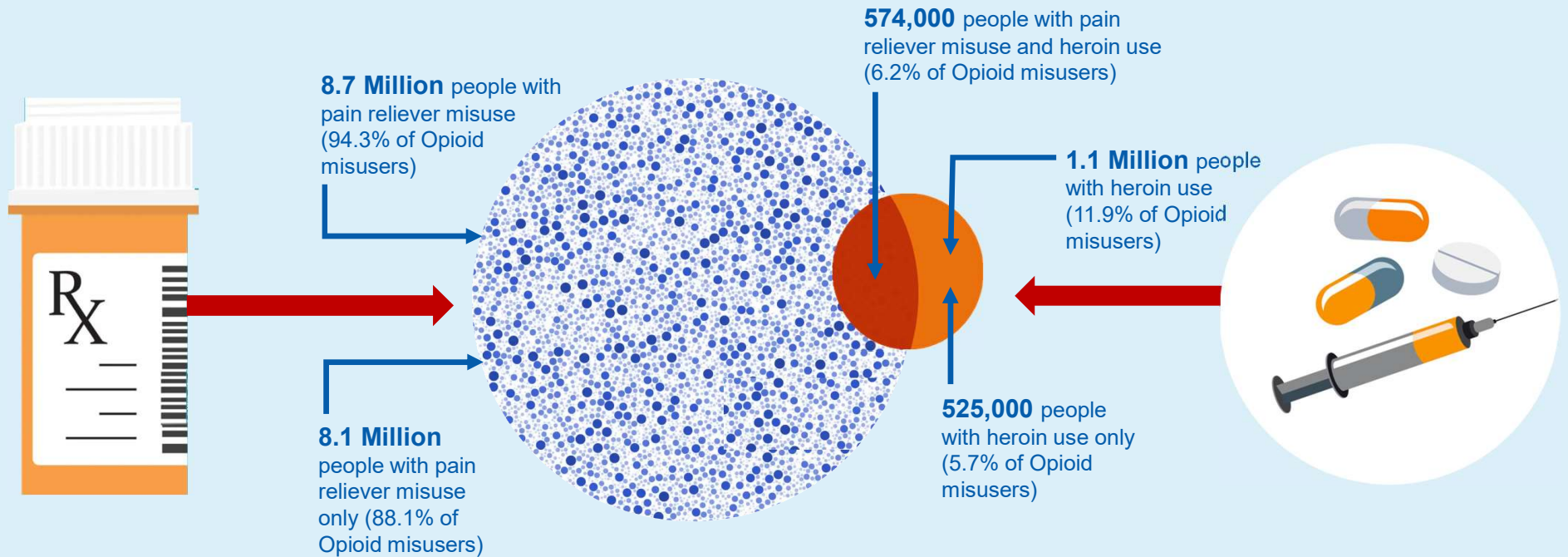


Image: <https://nida.nih.gov/publications/research-reports/prescription-opioids-heroin/prescription-opioid-use-risk-factor-heroin-use>

# 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](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.

”

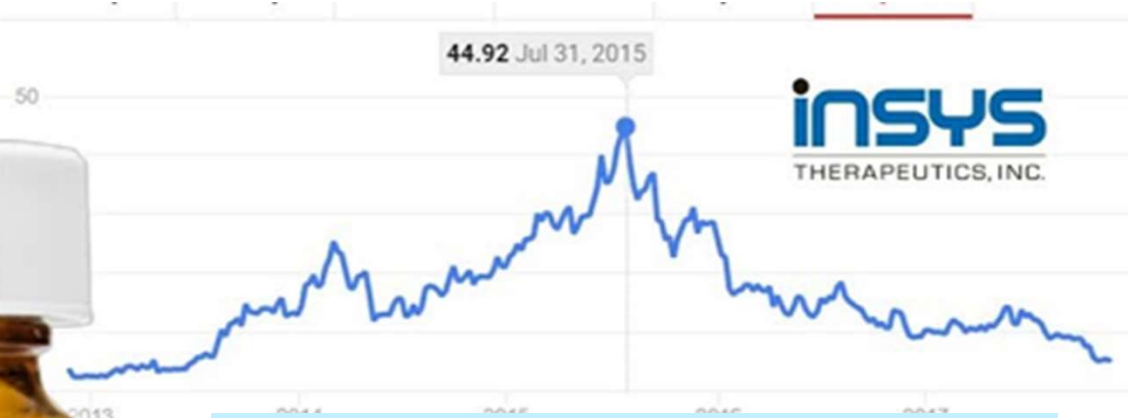
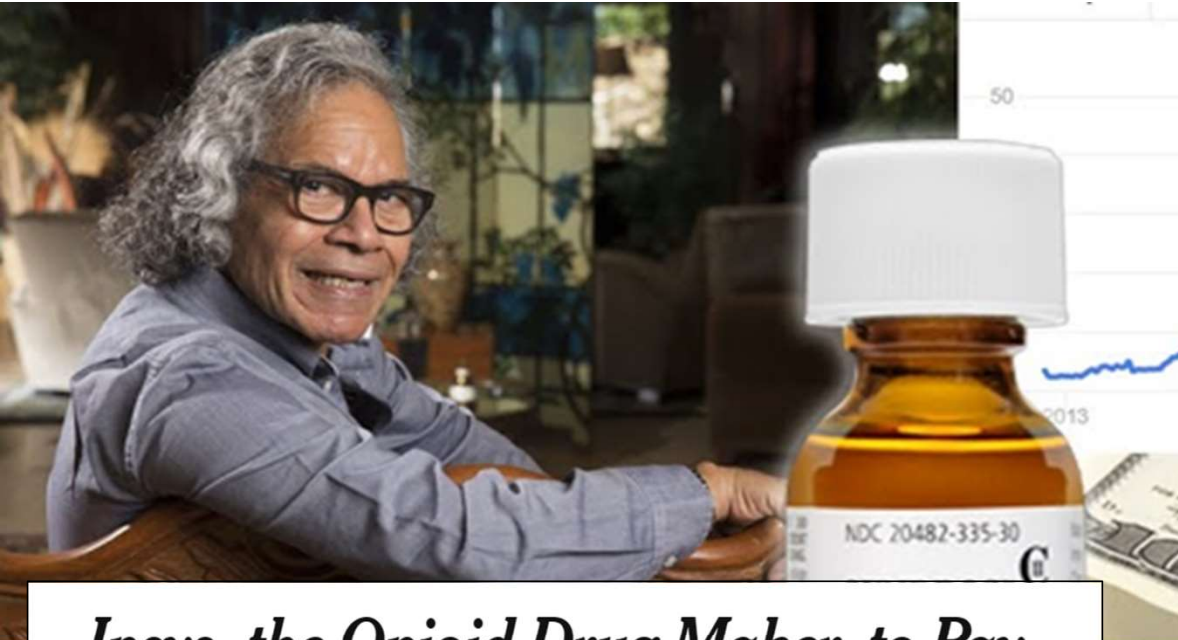
Responding to the opioid crisis in North America and beyond. Stanford-Lancet Commission

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

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



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



## ***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

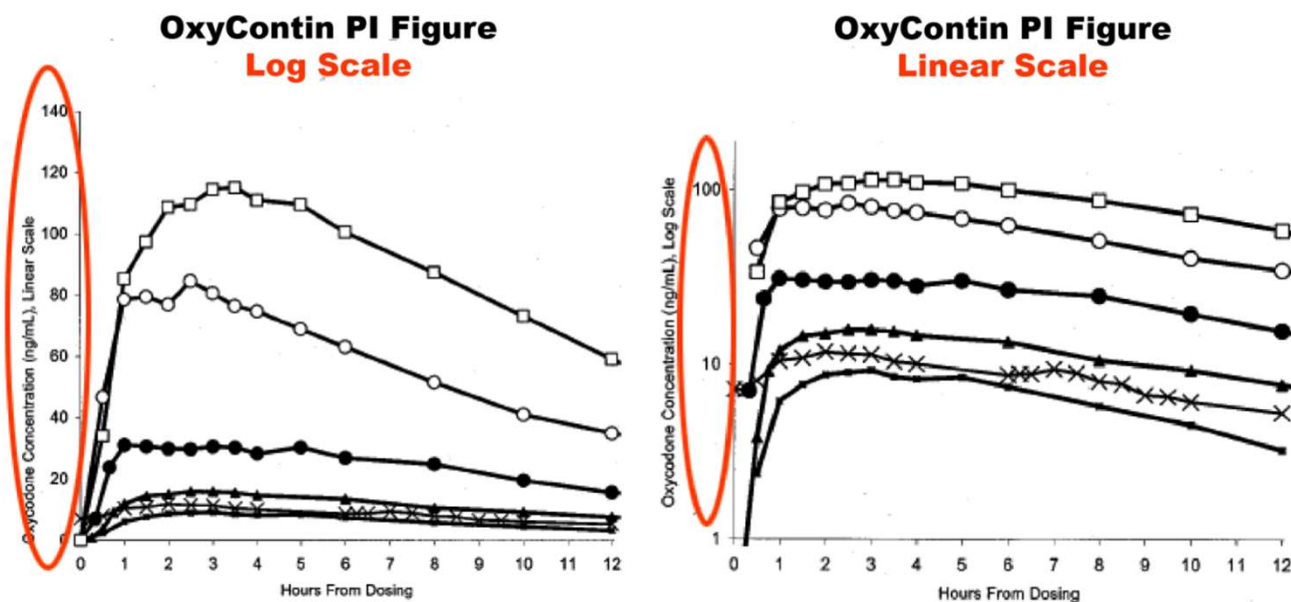
- **McKesson, one of the largest drug distributors that “ failed to design ... an effective system to detect and report ‘suspicious orders.’”**
- **Paid a civil penalty of \$150 million and was banned from selling controlled substances in multiple states for years**

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)

# 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**

# Commercial Determinants of Health (CDoH)

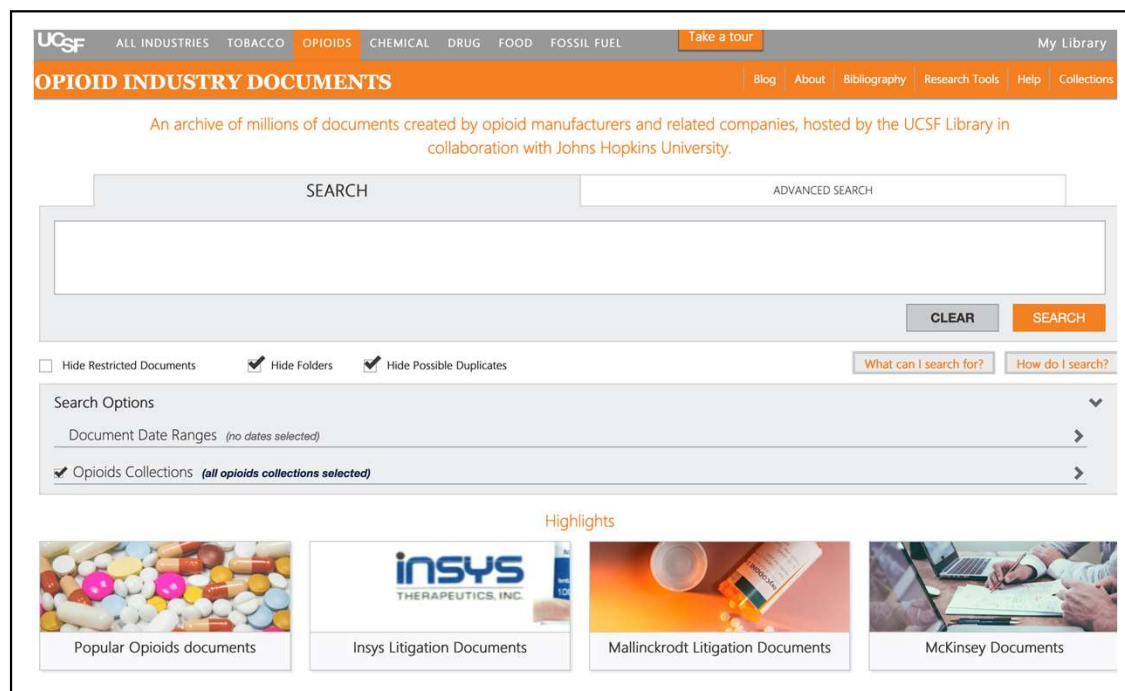
“ Commercial Determinants of Health are the private sector activities impacting public health, either positively or negatively, and the enabling political economic systems and norms. ”

— The World Health Organization (WHO)

Quotation: [https://www.who.int/health-topics/commercial-determinants-of-health#tab=tab\\_1](https://www.who.int/health-topics/commercial-determinants-of-health#tab=tab_1)

# 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.



# Explore the corporate “playbook” using OIDA documents in your breakout session

- 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

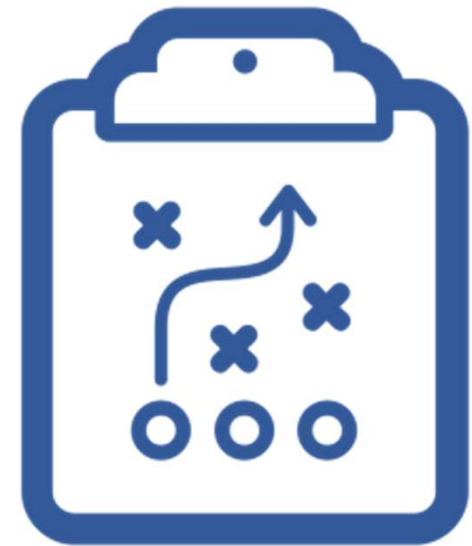


Image: <https://mlt.org/advisory-services/playbook-icon/>



JOHNS HOPKINS  
UNIVERSITY

Opioid Industry Documents Archive  
<https://www.industrydocuments.ucsf.edu/collections/opioids/>  
@industrydocs