

# *In re Purdue Pharma LP, et al.*

---

Joseph Hage Aaronson LLC

Counsel to Raymond Sackler Family ("Side B")

**Defense Presentation Part 6: Causation, Statutory Consumer Fraud, Public Nuisance, Claims By Opioid Users And Their Families**

April 27, 2021

# *Causation*

---

## Two Claimed Injuries

1. **Excess health care costs** for employees and others covered by governmental insurance plans or by Medicaid, **incurred by the Claimants as insurers and third-party payors** (consisting of reimbursed cost of prescribed opioids and costs of treatment for opioid addiction); and
2. **Expenses incurred by Claimants directly to combat the opioid epidemic**, including addiction treatment, emergency services, and law enforcement, criminal justice, social services, and through lost productivity.

*See, e.g.,* NY Municipalities' Master Long Form Complaint ("MLFC") ¶¶25, 26, 699, 707; 1/19/2018 Suffolk MTD Opp. at 56 (Dkt. # 287); MA AG FAC ¶¶906-907

## Two Claims

**Deceptive Marketing**

**Diversion Control Failures**

# Claimants Must Prove That Purdue And The Individuals Are Both The Cause In Fact And Proximate Cause Of The Claimed Injuries

*Small v. Lorillard Tobacco Co.*,  
252 A.D.2d 1, 15 (N.Y. App. Div., 1st Dep't 1998) (G.B.L.  
§§349, 350; common-law fraud)

N.Y. SOC. SERV. LAW §145-b(2)

*People ex rel. Spitzer v. Sturm, Ruger & Co.*,  
309 A.D.2d 91, 95-97 (1st Dept. 2003) (public nuisance)

*Pasquaretto v. Long Island Univ.*,  
106 A.D.3d 794, 795 (2d Dept. 2013) (negligence)

*Bilinski v. Keith Haring Found., Inc.*,  
96 F. Supp. 3d 35, 52 (S.D.N.Y. 2015) (unjust enrichment)

*State v. Lead Indus., Ass'n, Inc.*, 951 A.2d 428, 451 (R.I.  
2008) (lead paint public nuisance claims)

# Claimants Face Insurmountable Causation Problems

***Problem #1:***

Claimants Cannot Show Purdue Marketing Statements Caused Doctors To Write Medically Unnecessary Prescriptions

***Problem #2:***

OxyContin Has Always Had A Small Market Share — And It Has Declined Since 2003

***Problem #3:***

For A Decade, The Opioid Crisis Has Been Driven By Heroin, Street Fentanyl, And Other Illegal Drugs, Not Prescription Opioids

***Problem #4:***

The Risk of Addiction From Medically Prescribed Opioid Use Is Demonstrably Low

***Problem #5:***

Claimants Ignore Numerous Other Factors Causing Their Claimed Injuries

# Claimants Face Insurmountable Causation Problems

<b><i>Problem #6:</i></b>	Claimants Cannot Establish Their Injuries Were Caused By Purdue Opioids, As Opposed To Other Manufacturers'
<b><i>Problem #7:</i></b>	States, Municipalities And Other Claimants Continue To Approve And Reimburse Opioid Prescriptions
<b><i>Problem #8:</i></b>	The Individuals Did Not Make Or Participate In Making Any Purported Misstatement That Allegedly Caused Claimants' Losses
<b><i>Problem #9:</i></b>	No Evidence Alleged Purdue Diversion Control Failures Caused Claimants' Injuries
<b><i>Problem #10:</i></b>	Municipal Cost Recovery Rule Bars Lawsuits For Local Government Expenditures
<b><i>Problem #11:</i></b>	Derivative-Injury Rule Bars Claimants' Third Party Payer Claims

***Problem #1:***

***Claimants Cannot Show Purdue Marketing Statements Caused Doctors To Write Medically Unnecessary Prescriptions***

---



## Cases in 2003–08 Found No Causation In Patient/Survivor Claims

*Bodie v. Purdue Pharma Co.*, 236 Fed. App'x 511 (11th Cir. 2007)

No proof of causation because **patient's doctor testified he was aware of the risks of opioids, and prescribing decision unaffected by Purdue promotional literature**

*Foister v. Purdue Pharma, L.P.*, 295 F. Supp. 2d 693 (E.D. Ky. 2003)

No causation where **patients misused OxyContin contrary to label warnings** and warning to doctors was adequate

*Labzda v. Purdue Pharma, L.P.*, 292 F. Supp. 2d 1346 (S.D. Fla. 2003)

**Manufacturers not obligated to police prescribers; patient's intentional misuse broke causal chain**

*Koenig v. Purdue Pharma Co.*, 435 F. Supp. 2d 551 (N.D. Tex. 2006)

**Plaintiff failed to show OxyContin marketing caused doctors to prescribe it to him**

*McCauley v. Purdue Pharma, L.P.*, 331 F. Supp. 2d 449 (W.D. Va. 2004)

Failure to establish causation against Purdue where **patients took multiple opioids concurrently**

*Boysaw v. Purdue Pharma*, 2008 WL 4452650 (W.D. Va. Sept. 30, 2008), *aff'd*, 320 F. App'x 178 (4th Cir. 2009)

No proof of causation against Purdue because patient was taking **multiple opioids** in addition to OxyContin

*Timmons v. Purdue Pharma Co.*, 2006 U.S. Dist. LEXIS 3965, (M.D. Fla. Feb. 2, 2006)

Failure to show causation where **prescribers were aware of risks and were not influenced by Purdue marketing**

*Cornelius v. Cain*, 2004 WL 48102 (Fl. Cir. Ct. Jan. 5, 2004)

OxyContin **label warnings were adequate, doctors were aware of risks, and learned intermediary doctrine broke chain of causation**

*Harris v. Purdue Pharma, L.P.*, 218 F.R.D. 590 (S.D. Ohio 2003)

Finding lack of commonality in class action based on learned intermediary doctrine; **plaintiffs would have to show that each plaintiff's doctor was deceived**

## Cases Brought By States And Municipalities Face Additional Obstacles

They must:

- Establish additional causal steps between the patient and their damages
- Show that a vast number of prescribers were deceived by Purdue
- Show that Purdue's products caused their damages despite widespread use of other opioids
- Establish causal links to the Individuals, and
- Overcome statute of limitations problems in light of the 2007 settlements, allegations that damages were first suffered more than a decade ago, government investigations since 2007, and intense media coverage for years

# States And Municipalities Cannot Prove Causation

*City of New Haven v. Purdue Pharma, L.P.*, 2019 WL 423990, at \*3 (Conn. Super. Ct. Jan. 8, 2019)

Dismissed public nuisance and other claims against opioid manufacturers because the steps between the manufacturers' conduct and the local government plaintiff's injuries were too great to support causation:

*"[C]ourts can't credibly consider cases derived from harms allegedly connected to defendants by **lengthy, multifaceted chains of causation** that must weigh their conduct while trying to separate that conduct from **the myriad of independent factors** that make up most broadly defined social crises like . . . opioid abuse."*

# The Learned Intermediary Doctrine Breaks The Causal Chain

*Wolfgruber v. Upjohn Co.*, 72 A.D.2d 59, 61 (4th Dep't 1979), *aff'd*, 52 N.Y.2d 768 (1980)

Prescribing physicians intervene as *"the 'informed intermediary' between the manufacturer and the patient"* to make decisions about medical treatment, *"evaluating the patient's needs, assessing the risks and benefits of available drugs, and prescribing and supervising their use."*

*See also Martin v. Hacker*, 83 N.Y.2d 1, 9 (1993); *Glucksman v. Halsey Drug Co.*, 160 A.D.2d 305, 307 (1st Dep't 1990)

Doctors have available many sources of information about the risks of opioids, including Purdue's:

- FDA-approved labeling disclosing the risks that Purdue supposedly concealed
- Medical journals and treatises
- Government agencies, including the FDA, CDC, DEA, and SAMHSA (the Substance Abuse & Mental Health Services Administration)
- FDA REMS (Risk Evaluation and Mitigation Strategies) communicating the risks of opioids
- Grand rounds, medical meetings, continuing medical education, discussions with colleagues

# The Learned Intermediary Doctrine Breaks The Causal Chain

*Ironworkers Local Union No. 68 v. AstraZeneca Pharm. LP*,  
585 F. Supp. 2d 1339, 1344 (M.D. Fla. 2008)

Dismissing RICO, consumer protection, fraud, negligent misrepresentation and unjust enrichment claims against drug manufacturer and medical marketing firm for lack of proximate cause: **it “would require an inquiry into the specifics of each doctor-patient relationship implicated by the lawsuit.”**

*Sidney Hillman Health Center of Rochester v. Abbott Labs*,  
873 F.3d 574, 577 (7th Cir. 2017)

Affirming dismissal of insurers’ RICO claims against drug manufacturers based on alleged off-label promotion, for failure to plead proximate causation, as **insurers were several steps removed in causal chain between alleged illegal marketing and paying for improper prescriptions, including numerous independent decisions by physicians and patients**

*In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*,  
2010 WL 3119499, at \*7-9 (S.D. Ill. Aug 5, 2010)

Dismissing claims where court would **“have to delve into the specifics of each physician patient relationship to determine what damages were caused by [the] alleged fraudulent conduct, as opposed to what damages were caused by the physician’s independent medical judgment”**

## The Learned Intermediary Doctrine Breaks The Causal Chain

- Doctors make individual prescribing decisions
- The FDA-approved label provides prominent warnings about the risks of addiction, overdose, and death
- Purdue's marketing material was reviewed by the FDA and consistent with the FDA-approved label — as it was required by law to be

## Learned Intermediary Doctrine Breaks The Causal Chain

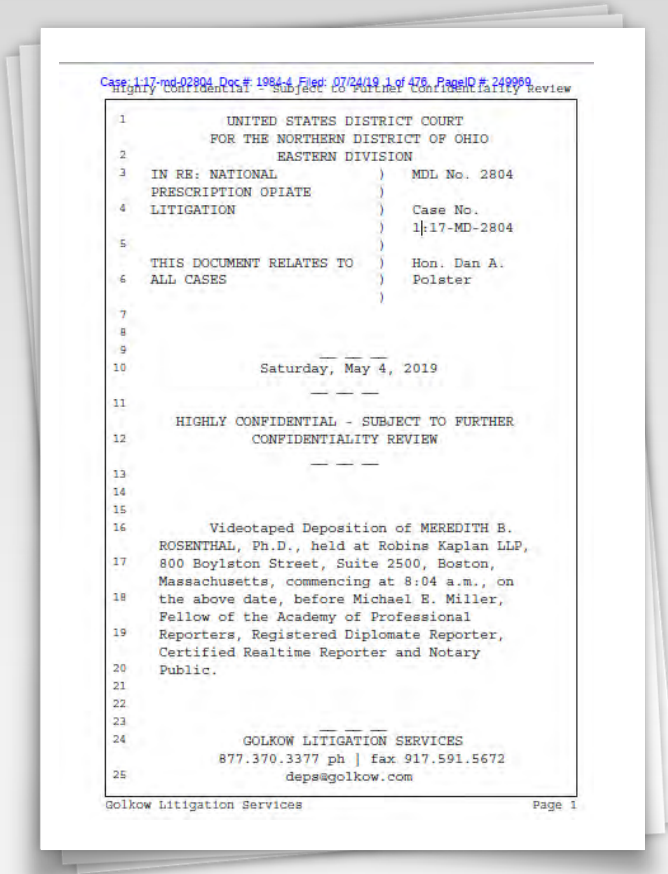
N.Y. PUB. HEALTH LAW §§ 3331(1)-(2), (5)-(7), 3343-a(2);  
10 N.Y.C.R.R. 80.63(c)(1), 80.64

New York strictly limits opioid prescribing and requires doctors to closely monitor patients taking such medicines, referencing the State's opioid prescription monitoring database before each prescription is written.

# Claimants Cannot Identify Prescriptions Written Because Of The Alleged Misconduct

Plaintiffs' economic expert in the MDL (Meredith Rosenthal) conceded she **could not identify which, if any, opioid prescriptions were medically improper and would not have been written but for the allegedly wrongful conduct** at issue in this case.

5/4/2019 Rosenthal Dep. Tr. 150:8-153:5 (MDL Dkt. #1984-4)



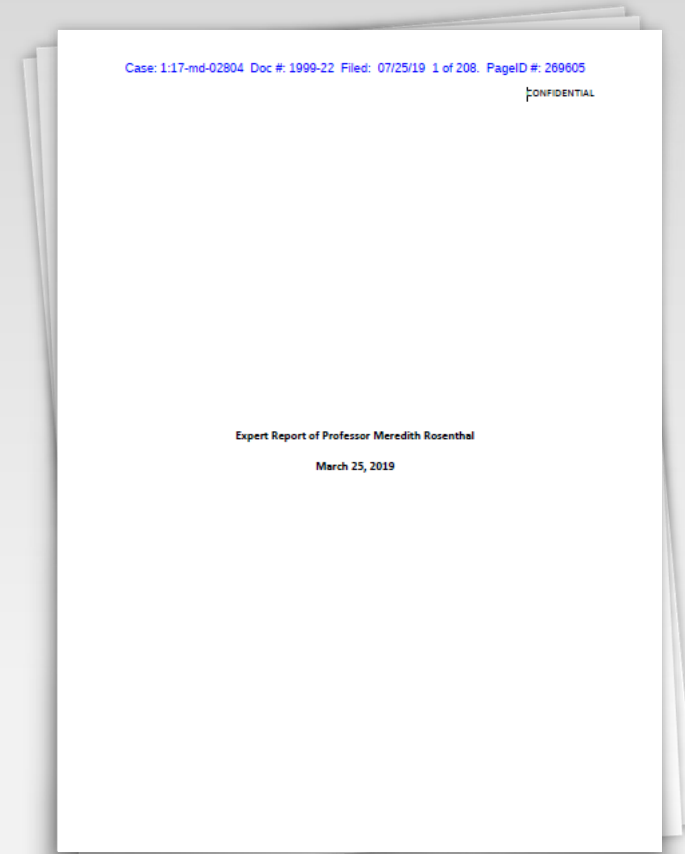


# Claimants' Statistical Models Fail To Establish Causation

In the MDL, **Plaintiffs' experts have relied solely on statistical analyses.**

Plaintiffs' expert Meredith Rosenthal prepared a **regression model** to measure the **aggregate effect of all prescription opioid promotion on all prescription opioid sales nationwide.**

The model compared all “detailing” contacts by manufacturer sales representatives to the number of milligrams of morphine equivalent (MME) sales for all opioids at issue — in the aggregate, **without differentiating among manufacturers**



Expert Report of Meredith Rosenthal, PhD ¶¶58-60 (MDL Dkt. # 1999-22)

# Claimants' Statistical Models Fail To Establish Causation

## Correlation is not causation

- The proffered opinions do not account for the many other causes of increased opioid prescribing.
- They do not connect Purdue's marketing to prescriptions or decisions by particular doctors or to any resulting harm, as required

*UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 135 (2d Cir. 2010)

*"General [aggregate] proof of but-for causation is impossible" because "at least some doctors were not misled by [Defendant's] alleged misrepresentations, and thus would not have written 'excess' prescriptions as identified by the plaintiffs."*

# Claimants' Statistical Models Fail To Establish Causation

Ms. Rosenthal **assumed that all opioid detailing** from manufacturers' sales representatives to prescribers **was unlawful**.

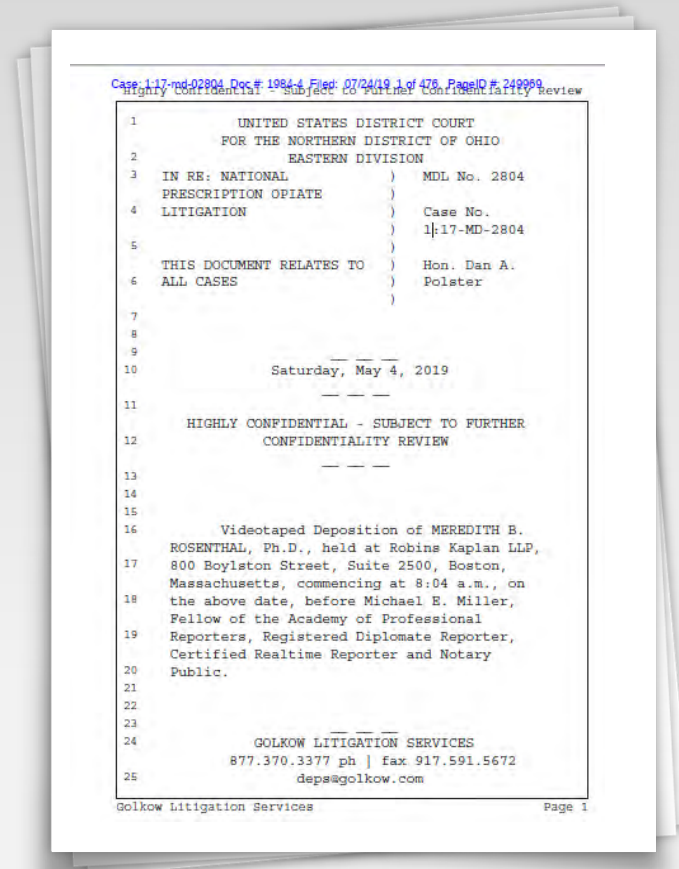
Rosenthal Report ¶ 75 (MDL Dkt. #1999-22); Rosenthal Dep. Tr. 149:24–150:7 (MDL Dkt. #1984-4)

Detailing and other promotions consistent with a medication's FDA-approved label **are lawful and appropriate**.

Detailing may help increase sales. **There is nothing wrong with increasing sales through lawful promotion.**

*See, e.g., Sorrell v. IMS Health Inc., 564 U.S. 552, 557 (2011)*

*"Speech in aid of pharmaceutical marketing ... is a form of expression protected by the Free Speech Clause of the First Amendment."*



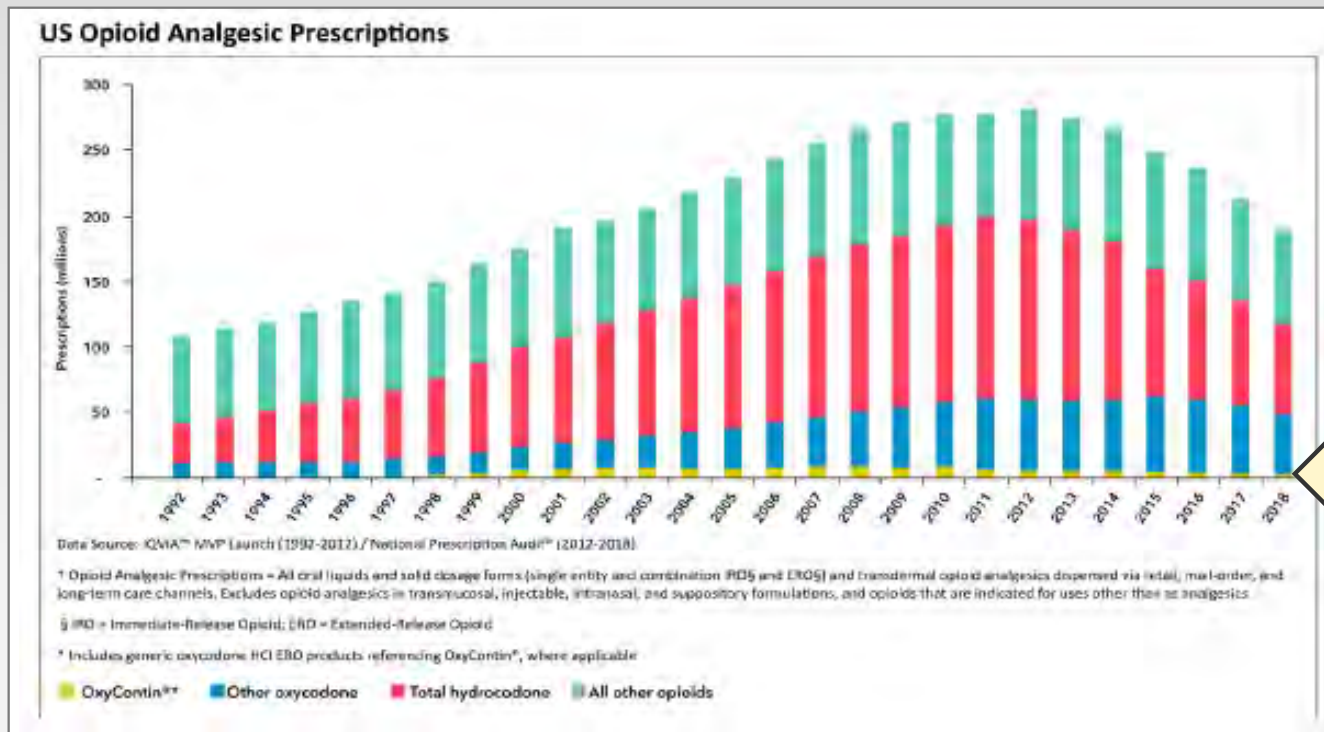
*Problem #2:*

*OxyContin Has Always Had A Small Market Share, And It Has Declined Since 2003*

---

## Purdue/OxyContin's Small And Flat/Declining Market Share

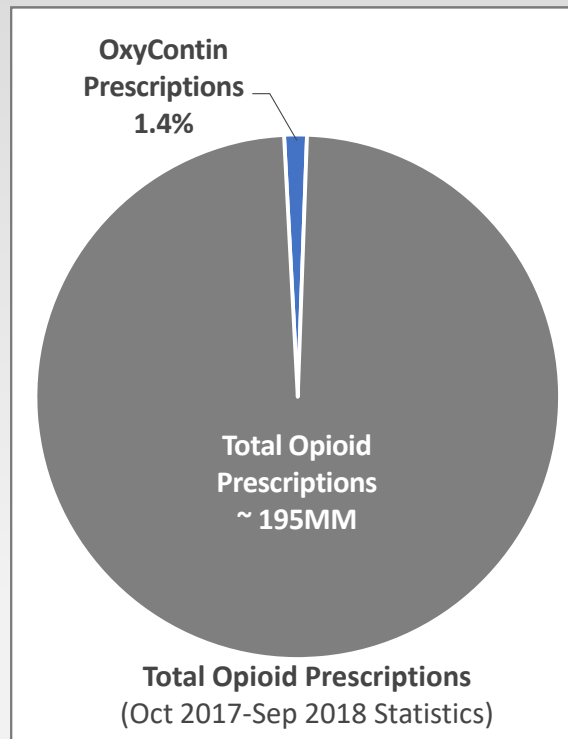
OxyContin is less than 2% of the total prescription opioid market and has never been more than 4% of the market



OxyContin is the yellow sliver at the very bottom of the bars

## Purdue/OxyContin's Small And Flat/Declining Market Share

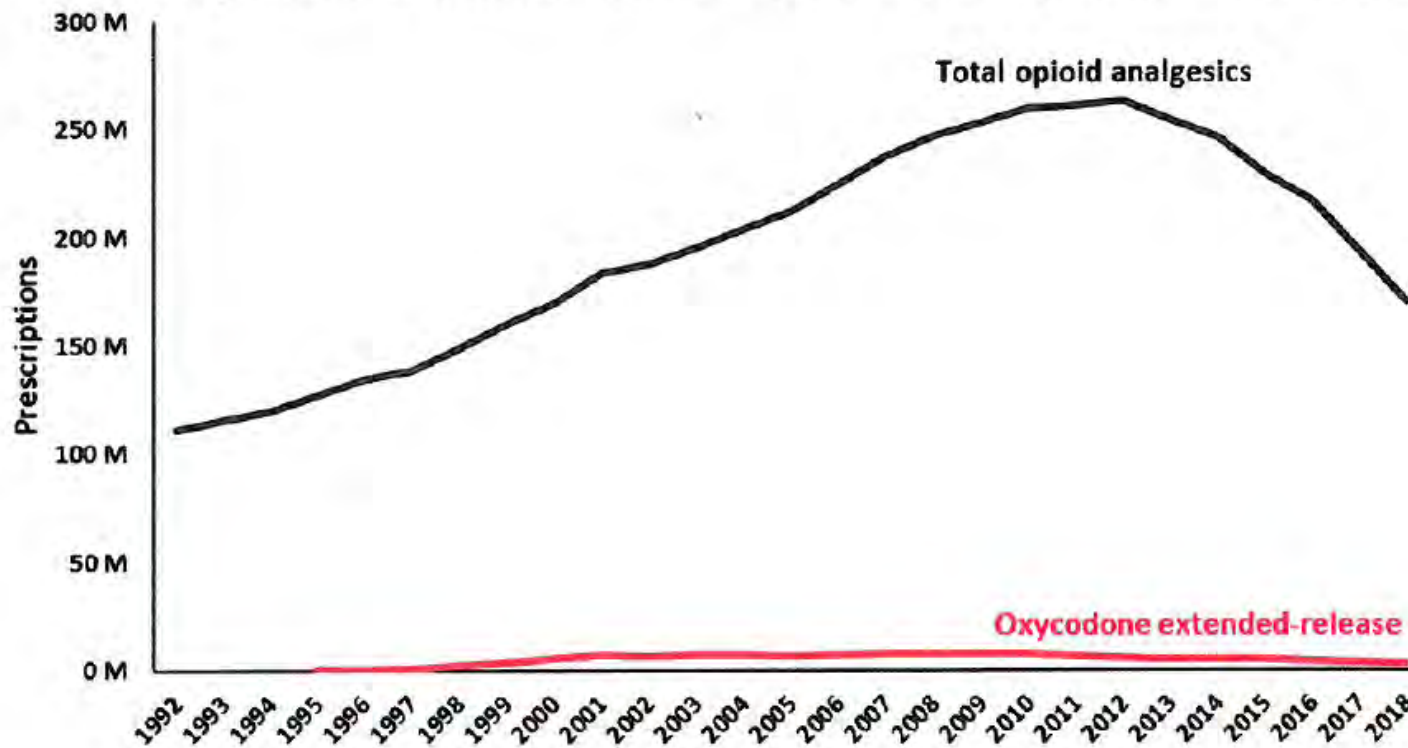
OxyContin was 1.4% of the prescription opioid market in the year ending Sept. 2018



Source: IQVIA NPA Data; <http://web.archive.org/web/20190910153705/https://www.purduepharma.com/news-media/common-myths-about-oxycotin/>

# Extend-Release Opioids — Including OxyContin and Its Competitors — Form A Sliver of Total Opioids Sold

**Figure 1. Estimated Number of Prescriptions Dispensed for Opioid Analgesics vs. Oxycodone Extended-Release<sup>1</sup> from U.S. Outpatient Pharmacies<sup>2</sup>**

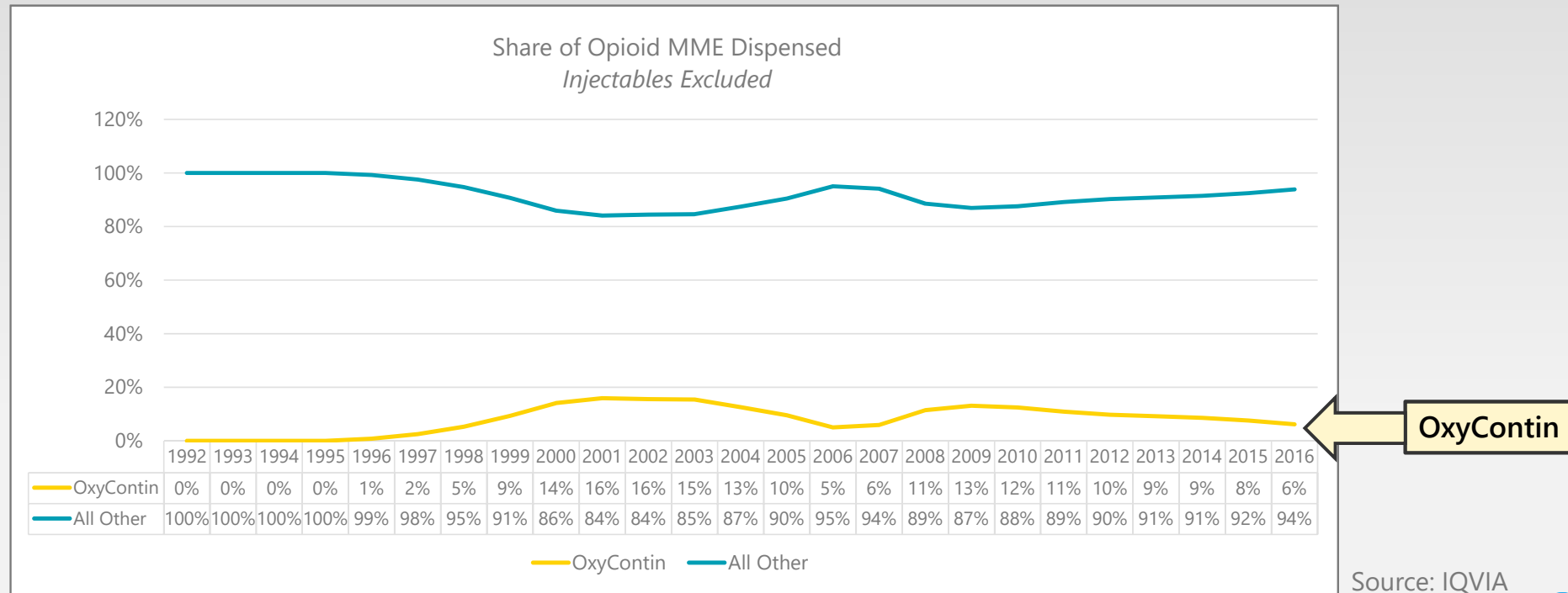


2020 FDA Letter to Senator Maggie Hassan:  
<https://www.hassan.senate.gov/imo/media/doc/FDA%20RESPONSE%20HASSAN%201.21.20.pdf>

OxyContin and all other EROs

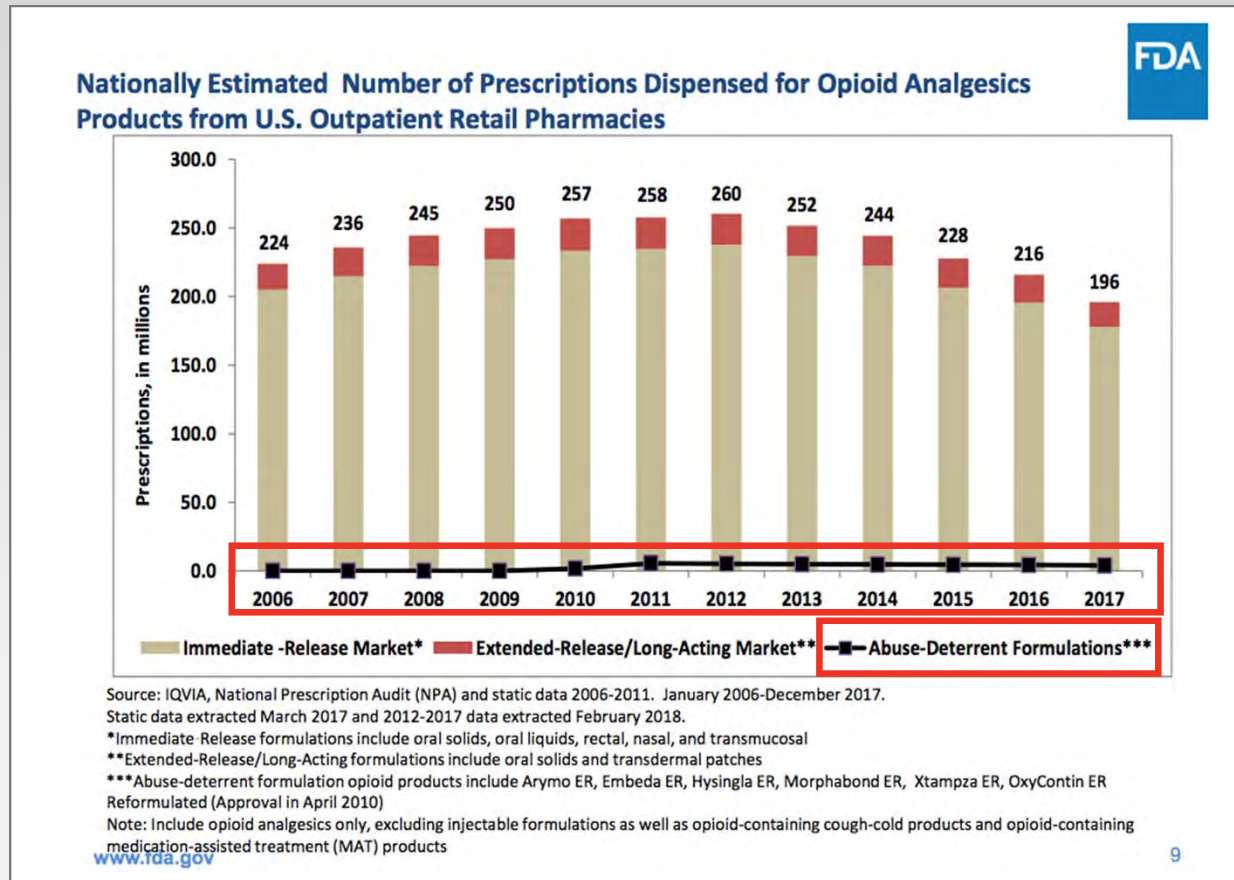
## OxyContin's Small And Flat/Declining Market Share

Measured by milligrams of morphine equivalent (MME), OxyContin declined from 13% of the total prescription opioid market in 2009 to 6% in 2016





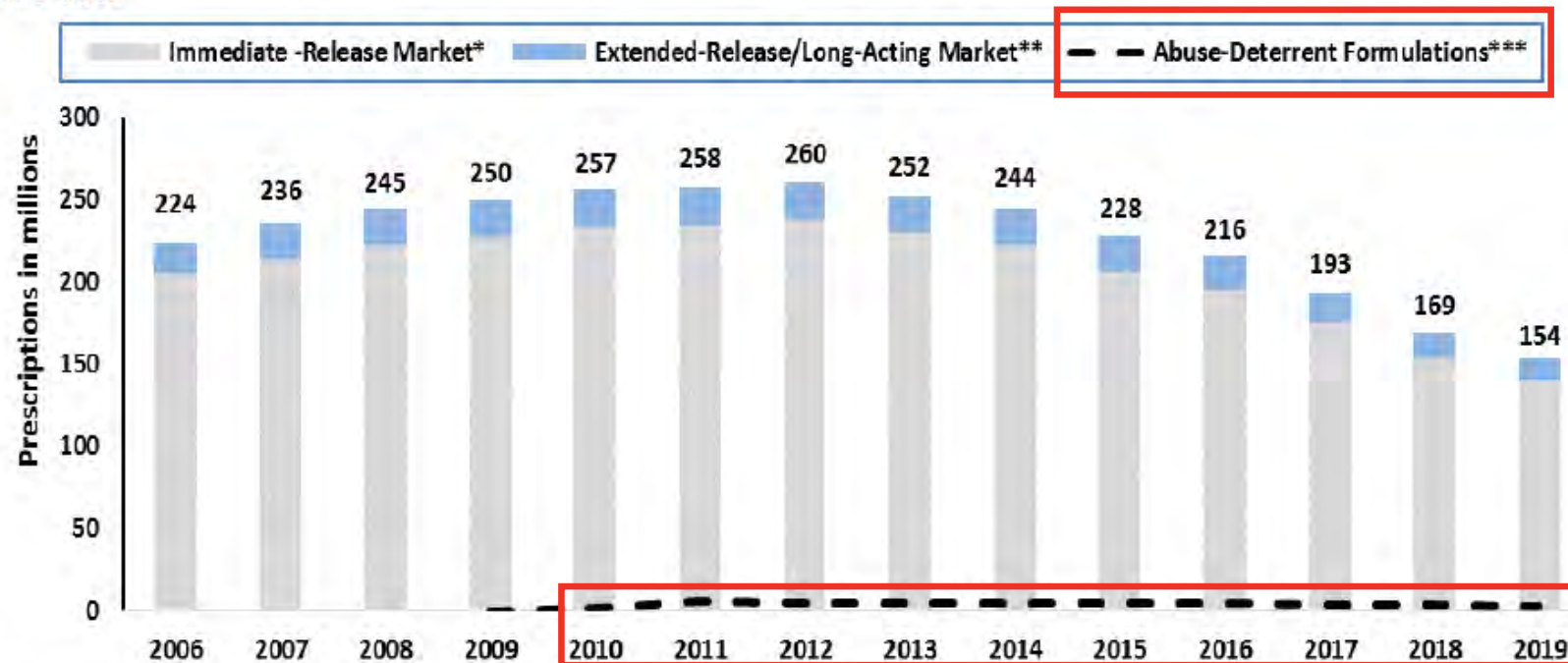
# Immediate-Release Prescription Opioids Have Always Dominated The Market



<https://www.fda.gov/media/112084/download>, Slide 9

# Immediate-Release Prescription Opioids Have Always Dominated The Market

Estimated number of prescriptions dispensed for all opioid analgesics from U.S. outpatient retail pharmacies, 2006-2019



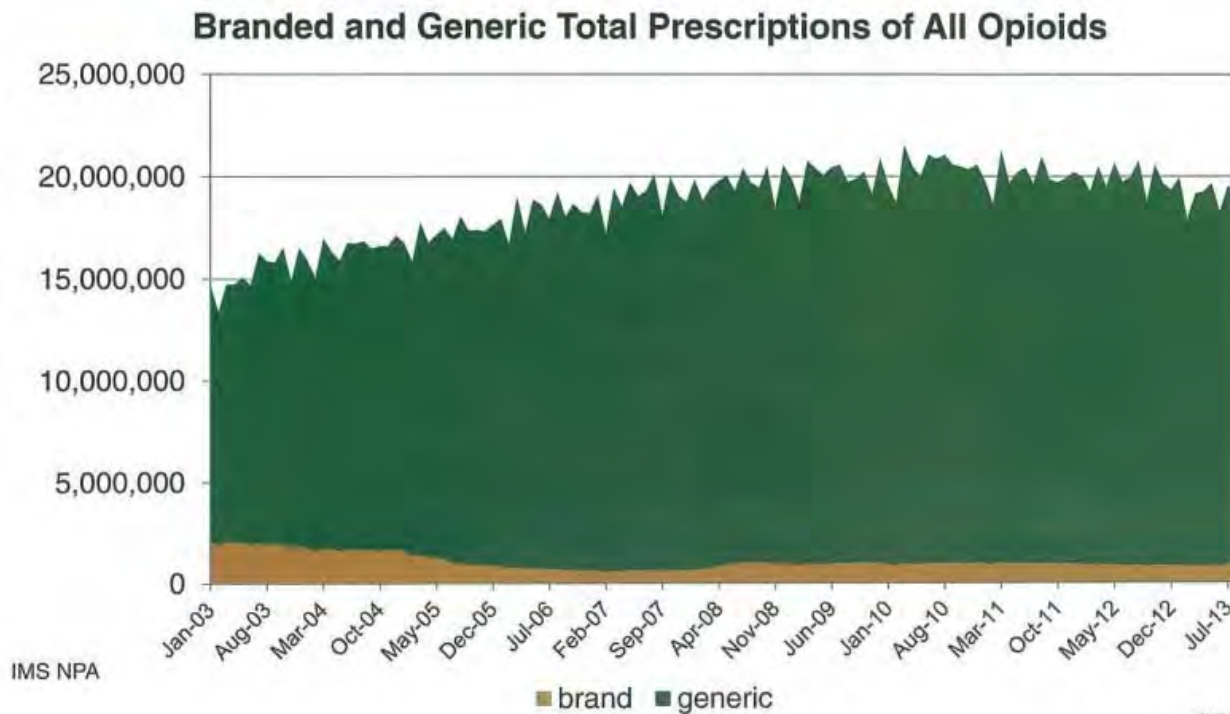
Source: IQVIA, National Prescription Audit (NPA) and static data 2006-2011. January 2006-December 2019. Static data extracted March 2017, 2012-2017 data extracted February 2018, 2018 data extracted March 2019, 2019 data extracted Jan 24, 2020

Source: FDA Briefing Book for Sept. 10-11, 2020, Joint Meeting of DSaRM and AADPAC Advisory Committees, at p. 10, <https://www.fda.gov/media/141914/download>

Note: Abuse-deterrent formulations include Arymo ER, Embeda ER, Hysingla ER, Morphabond ER, Xtampza ER, OxyContin ER Reformulated (Approval in April 2010), RoxyBond IR. *Id.* at 10

## Generic Prescription Opioids Have Always Dominated The Market

**More Than 95% of All Opioid Prescriptions  
Are Currently Dispensed As A Generic**



22

Source: Leventhal Supp. Ex. 51  
at page 22, Nov. 2013 Year End  
Budget Book (PPLP004410008)

# ERO Prescriptions Have Represented “A Very Small And Decreasing Fraction” of Opioid Prescriptions since 2010

## 2020 FDA Letter to Senator Maggie Hassan:

- “For at least 4 years after the [2001 OxyContin] labeling change — at a time when prescription opioid use was rising — the number of prescriptions dispensed for oxycodone ER was generally flat, with the number of oxycodone ER prescriptions making up a very small and decreasing fraction of prescriptions since 2010.”  
(Page 5)



<https://www.hassan.senate.gov/imo/media/doc/FDA%20RESPONSE%20HASSAN%201.21.20.pdf>

## There Is Widespread Confusion between Immediate-Release Oxycodone and OxyContin

### ***Drug Overdose Deaths Hit 'Alarming' New Record in U.S., CDC Says***

By Maggie Fox (December 18, 2015), NBC News:

“The CDC . . . proposed new draft guidelines this month that include using every other possible approach to managing pain before giving someone an opioid such as fentanyl or oxycontin to control pain.”

- There is no reference to OxyContin in the linked CDC webpage (<https://www.cdc.gov/drugoverdose/prescribing/guideline.html>)
- All references are to oxycodone

<https://www.nbcnews.com/health/health-news/drug-overdose-deaths-hit-new-record-u-s-cdc-says-n482746>



## There Is Widespread Confusion Between Immediate-Release Oxycodone and OxyContin

March 16, 2011 Testimony of DEA Administrator Michele Leonhart before House Appropriations Subcommittee on Commerce, Justice, Science & Related Agencies (Rep. Frank Wolf, Chair):

Mr. Wolf. Now the company that manufactures the pills, what company? I mean there was a successful case in the Western District of Virginia, is it the same company?

Ms. Leonhart. It is a little bit different than the OxyContin problem, and a lot of people think that the drug that is the number one drug out of the pill mills in Florida is OxyContin, and that is not correct.

Mr. Wolf. What is it?

Ms. Leonhart. It is the generic form, it is Oxycodone.

<https://www.govinfo.gov/content/pkg/CHRG-112hhr67259/html/CHRG-112hhr67259.htm>

# There Is Widespread Confusion Between Immediate-Release Oxycodone and OxyContin

## OxyContin

**PR02** Please look at the names and pictures of the pain relievers shown below.



In the **past 12 months**, which, if any, of these pain relievers have you used?

## Generic Oxycodone

**PR03** Please look at the names and pictures of the pain relievers shown below.



In the **past 12 months**, which, if any, of these pain relievers have you used?

Substance Abuse and Mental Health Services Administration, 2015 National Survey on Drug Use and Health: Prescription Drug Images for the 2015 Questionnaire (Sept. 2016), at pages 8-9. <https://www.samhsa.gov/data/sites/default/files/NSDUH-PillImages-2015.pdf>.  
See also <https://www.samhsa.gov/data/sites/default/files/NSDUH-PillImages-2016.pdf> at pages 8-9 (for 2016 survey);  
<https://www.samhsa.gov/data/sites/default/files/NSDUH-PillImages-2017.pdf> at pages 8-9 (for 2017 survey).

# The Introduction Of OxyContin Did Not Trigger The Opioid Crisis

2002 Congressional testimony of Dr. H. Westley Clark  
(Director, SAMHSA Center for Substance Abuse Treatment):

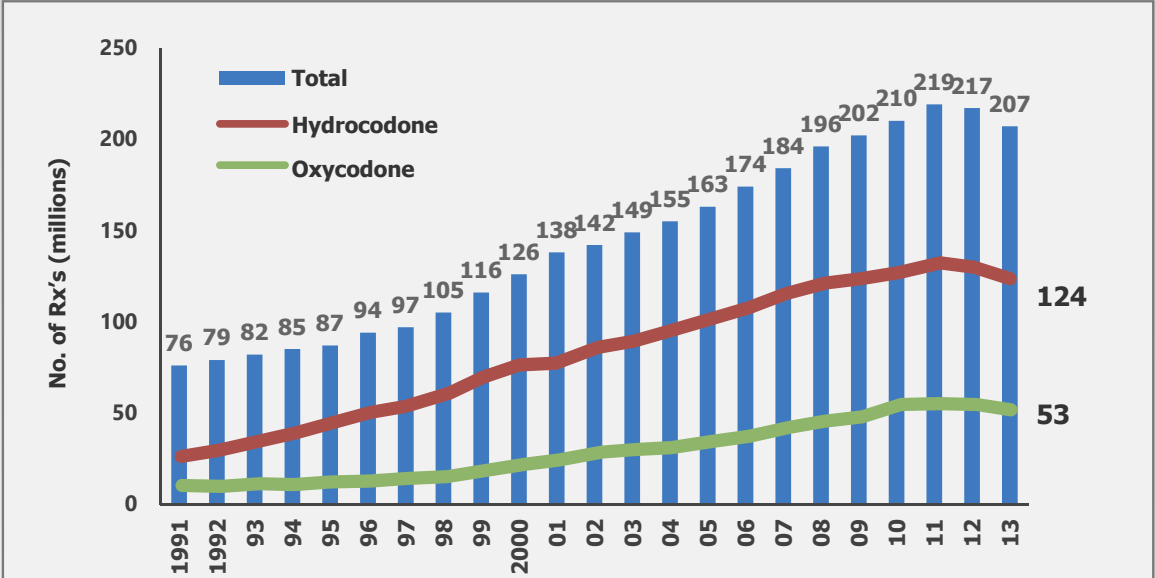
*"This is merely the newest part of a prescription opioid diversion and abuse problem that has been rising since the mid-1980s. ... [T]he incidence of new prescription opioid abuse and the number of new prescription opioid abusers has been rising steadily since well before the introduction of OxyContin."*

<https://www.govinfo.gov/content/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm>



# Opioid Prescriptions, Opioid Abuse And Opioid-Related Deaths Were Rising Before The Launch Of OxyContin In 1996

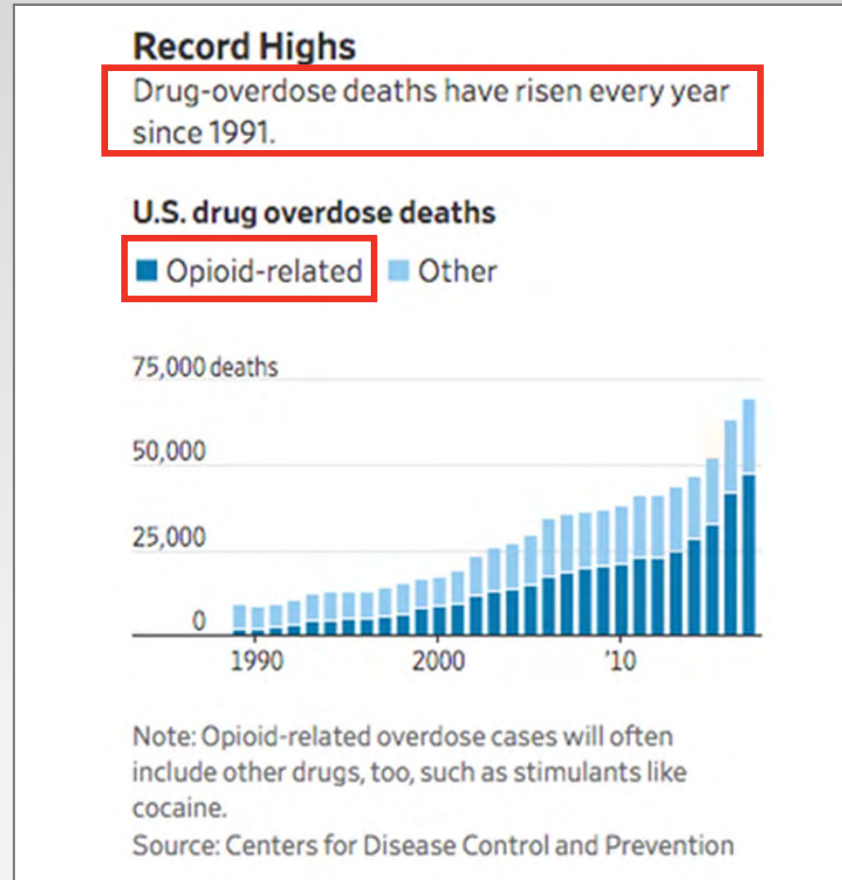
## Opioid Prescriptions (1991-2013)



**Figure 1 - Opioid Prescriptions Dispensed by US Retail Pharmacies** IMS Health, Vector One: National, years 1991-1996, Data Extracted 2011. IMS Health, National Prescription Audit, years 1997-2013, Data Extracted 2014.

# Opioid Prescriptions, Opioid Abuse And Opioid-Related Deaths Were Rising Before The Launch Of OxyContin In 1996

## Opioid-Related Overdose Deaths (1990-2017)



<https://www.wsj.com/articles/overdose-deaths-likely-to-fall-for-first-time-since-1990-11561541406>

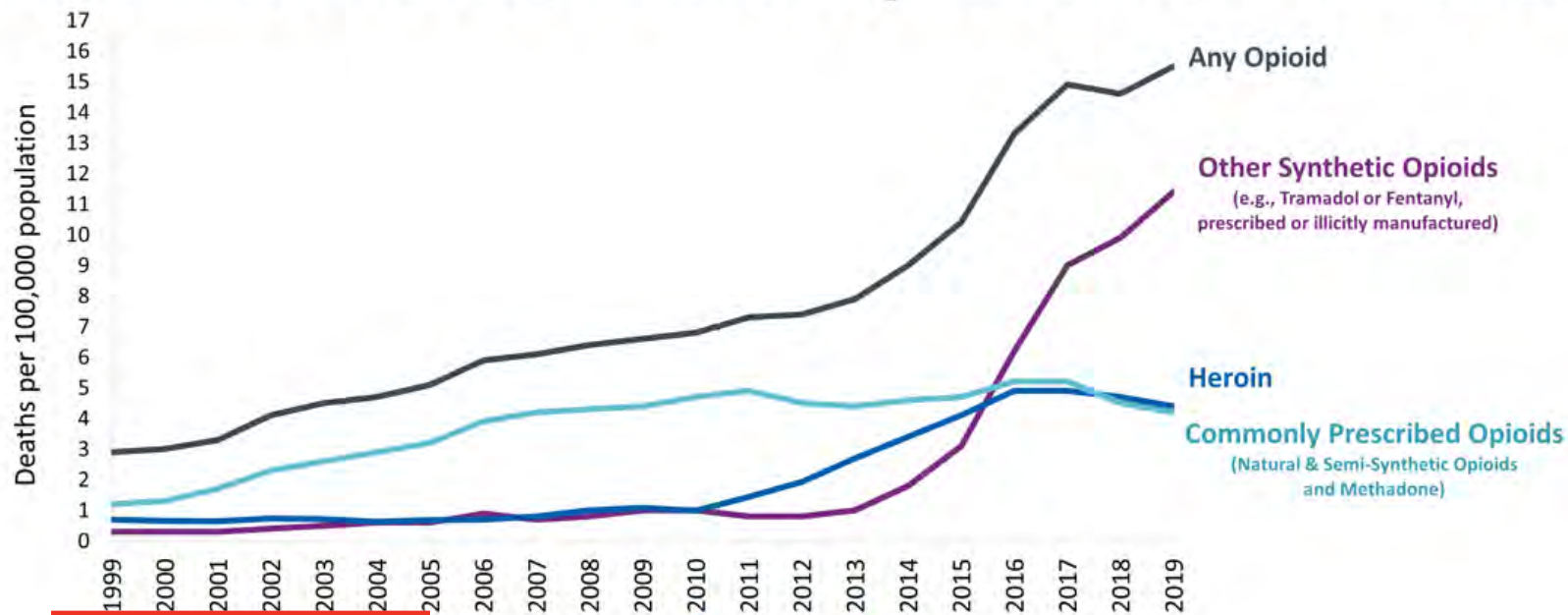
### ***Problem #3:***

***For Several Years, The Opioid Crisis Has Been Driven By Heroin, Street Fentanyl And Other Illegal Drugs, Not Prescription Opioids***

---

# Three Waves Of The Rise Of Opioid Overdose Deaths

## Three Waves of the Rise in Opioid Overdose Deaths



Wave 1: Rise in Prescription Opioid Overdose Deaths Started in 1999

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.

- Deaths from **Synthetic Opioids** increased by more than 1000% from 2011-2019
- Prescription Opioids** were involved in fewer than 25% of opioid deaths in 2019

<https://www.cdc.gov/drugoverdose/images/3-waves-2019.PNG>

## Illicit Fentanyl And Heroin Are Driving Today's Opioid Crisis

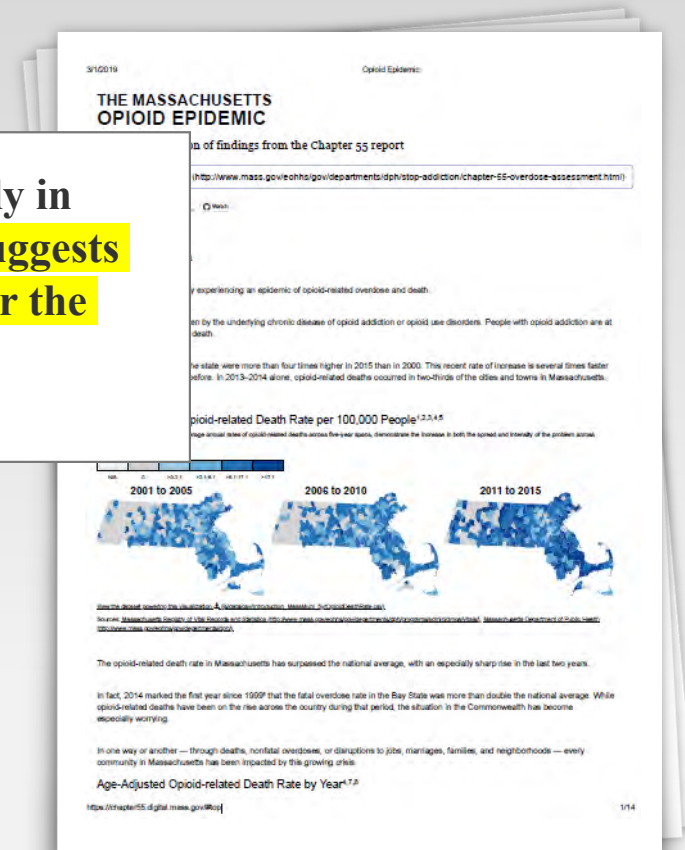
- Since 2013, the opioid crisis has rapidly worsened because of street drugs, like fentanyl and heroin smuggled from China and Mexico
- Between 2013 and 2016, fentanyl-related deaths approximately doubled each year
- Of the 47,600 opioid-related overdose deaths in 2017, 28,466 involved synthetic opioids, an increase of 45% between 2016 and 2017 and a ten-fold increase in the prior five years

<https://www.cdc.gov/drugoverdose/epidemic/index.html>  
[https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68\\_03-508.pdf](https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_03-508.pdf)  
[https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s\\_cid=mm675152e1\\_w](https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w)

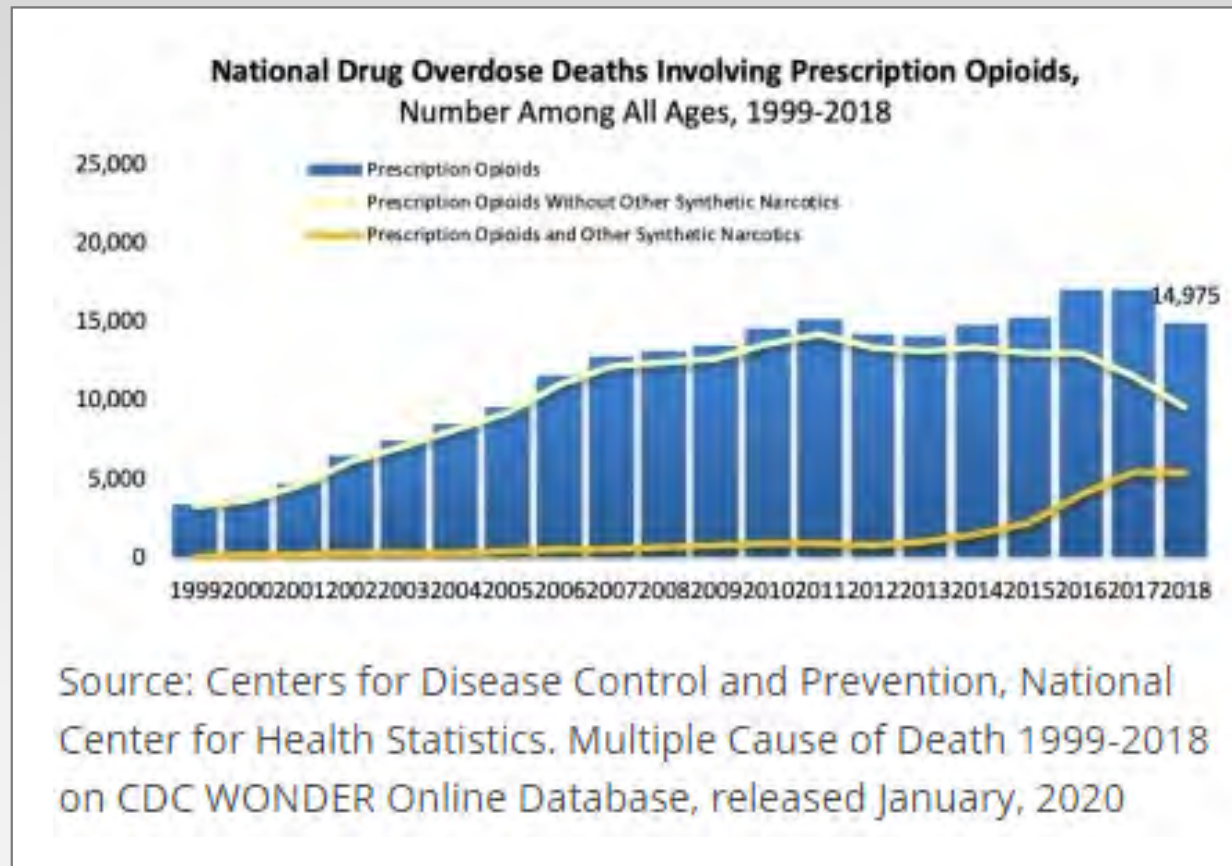
# Massachusetts Department of Public Health (2019): No Single Substance Or Practice Caused the Opioid Crisis

“It should be noted that opioid-related deaths began increasing sharply in 2012, no similar increase in opioid prescriptions was recorded. **This suggests that no single substance or health care practice is solely responsible for the current opioid crisis. Rather, it’s a complex issue with a number of contributing factors.**”

Massachusetts Chapter 55 Report (3/1/2019),  
<https://chapter55.digital.mass.gov/#top>



# Overdose Deaths Involving Prescription Opioids Alone Peaked In 2011



National Institutes of Health, National Institute on Drug Abuse,  
<https://web.archive.org/web/20210127234432/https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates>

# A 2021 Study Found No Direct Association Between Legally-Obtained Prescription Opioids And Injury-Related Mortality between 2006-2017

- “We hypothesized that prescription opioid use would be positively associated with injury-related deaths in the U.S.
- “For each state, we analyzed mortality data from the US CDC and prescription opioid data from the US Department of Justice from 2006–2017.
- “There was no relationship between amounts of opioids and injury-related mortality, including unintentional deaths, suicides, and homicides.”

\*\*\*

“Our inability to detect a relationship between legal prescription opioid use and injury mortality points to the fact that many factors influence trauma mortality.”

E.I. Truong, S.K. Kishawi, V.P. Ho et al., *Opioids and Injury Deaths: A Population-Based Analysis of the United States from 2006 to 2017*, *Injury*



[https://www.injuryjournal.com/article/S0020-1383\(21\)00233-3/fulltext](https://www.injuryjournal.com/article/S0020-1383(21)00233-3/fulltext)



***Problem #4:***

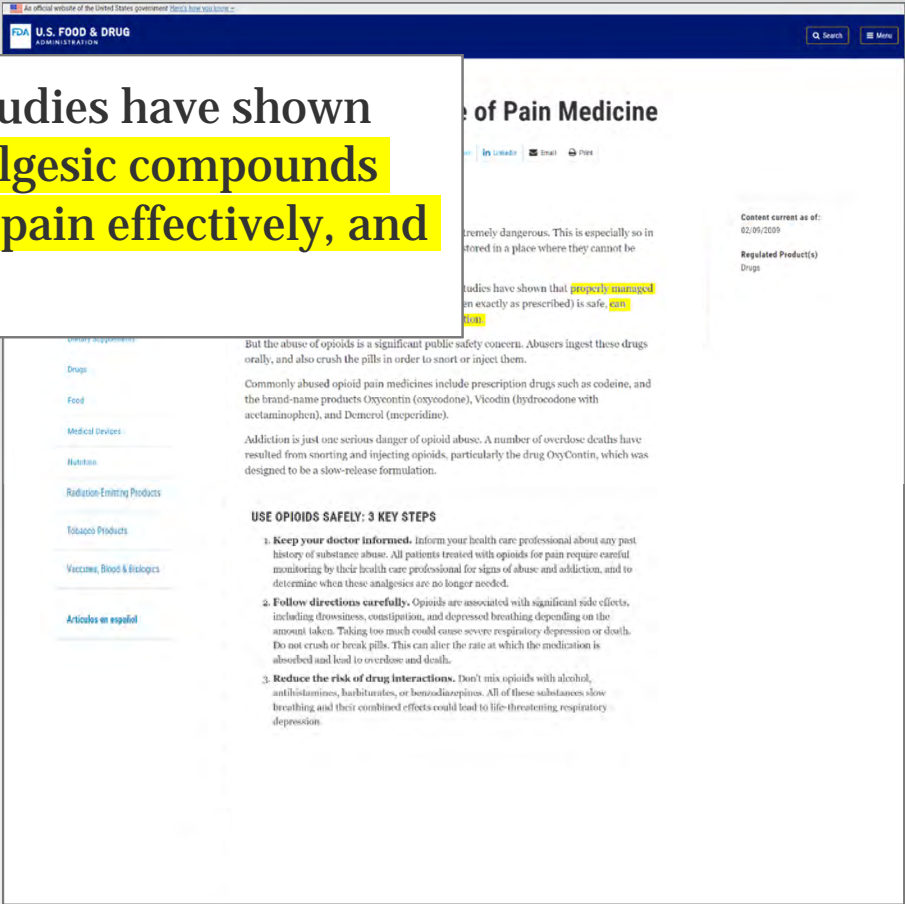
***The Risk of Addiction From Medically  
Prescribed Opioid Use Is Demonstrably Low***

---

# FDA: Medically-Managed Use of Opioids “Rarely Causes Addiction”

According to the National Institutes of Health, studies have shown that properly managed medical use of opioid analgesic compounds (taken exactly as prescribed) is safe, can manage pain effectively, and rarely causes addiction.

<https://www.fda.gov/consumers/consumer-updates/guide-safe-use-pain-medicine>  
(last visited March 30, 2021)



# A 2016 Study Confirmed The Low Risk of Addiction from Medically Prescribed Opioid Use

Unlike tolerance and physical dependence, addiction is not a predictable result of opioid prescribing. Addiction occurs in only a small percentage of persons who are exposed to opioids — even among those with preexisting vulnerabilities.

Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain--Misconceptions and Mitigation Strategies*, 384 New Eng. J. Med.1253, 1256 (2016)

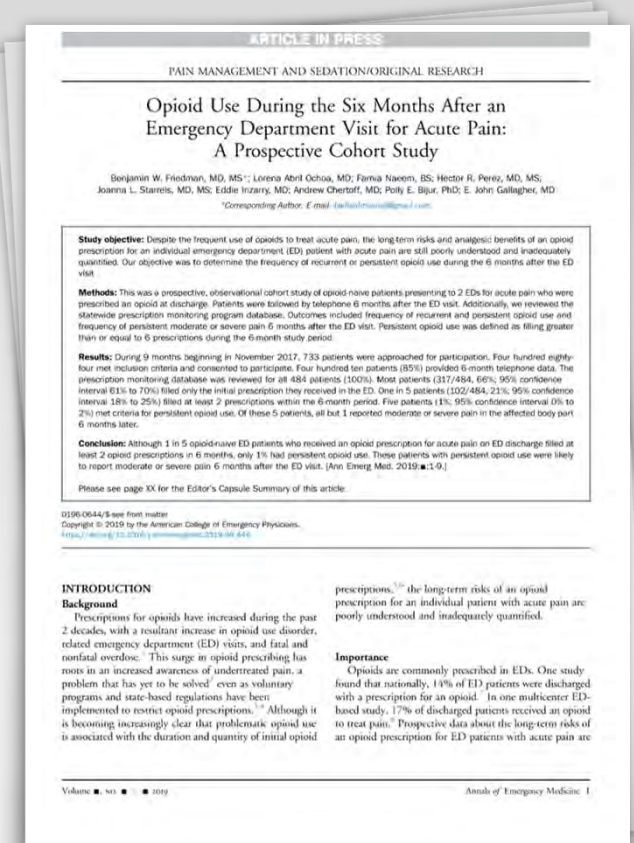


<https://www.nejm.org/doi/pdf/10.1056/NEJMr1507771?articleTools=true>

# A 2019 Study Showed Only 1% Of ER Patients with No Opioid Use in Past 6 Months Who Were Prescribed Opioids Developed Persistent Opioid Use

- A study published in the *Annals of Emergency Medicine* in late 2019 followed 484 opioid-naïve patients who visited the emergency room between November 2017 and August 2018 and were prescribed opioids on discharge
- Six months later, only 5 of those patients — or 1% — had developed persistent opioid use

Benjamin W. Friedman, MD, MS, et al., *Opioid Use During the Six Months After an Emergency Department Visit for Acute Pain: A Prospective Cohort Study*, *Annals of Emergency Medicine* (2019) [https://www.annemergmed.com/article/S0196-0644\(19\)31134-5/pdf](https://www.annemergmed.com/article/S0196-0644(19)31134-5/pdf)



## 2007 Study: Only a Small Percentage of Patients Entering Addiction Treatment Used OxyContin — And Most of Those Were Illicit Users

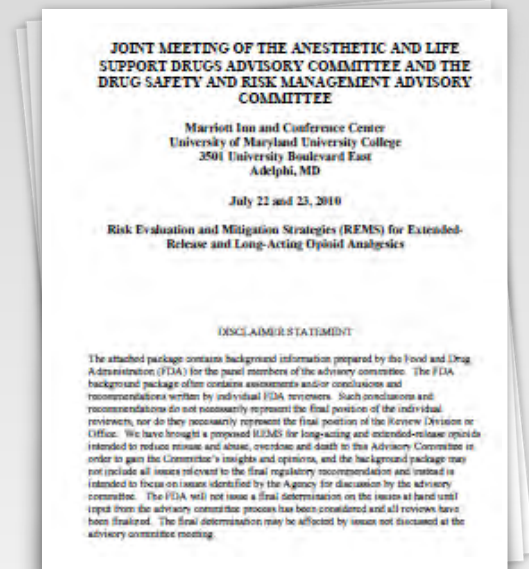
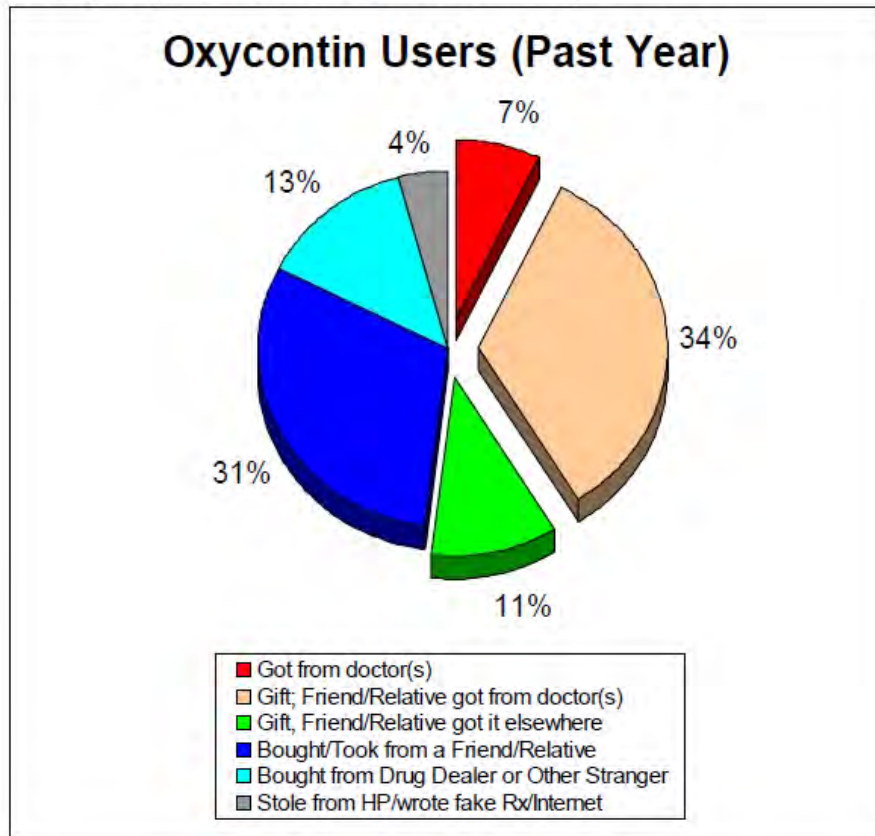
- A 2007 study found that 5% of 27,816 subjects admitted to 157 addiction treatment programs reported prior use of OxyContin.
- 78% of them also reported that OxyContin had not been prescribed to them for any medical reason.

Source: Deni Carise, Ph.D., et al., *Prescription OxyContin Abuse Among Patients Entering Addiction Treatment*, American Journal of Psychiatry, Nov. 2007; 164(11):1750-1756

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2785002/>

# 2008 SAMHSA Survey: Only 7% of OxyContin Abusers Obtained Their Drugs from A Doctor

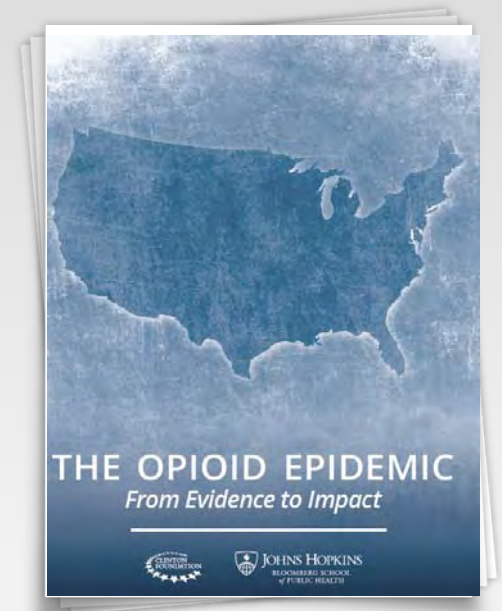
**Figure 1:** Sources of OxyContin for recent non-medical use among OxyContin users, NSDUH Survey 2008



July 22-23, 2010 Joint Meeting of the FDA Anesthetic and Life Support Drugs Advisory Committee and Drug Safety and Risk Mgmt. Advisory Committee , *Risk Evaluation and Mitigation Strategies (REMS) for Extended-Release and Long-Acting Opioid Analgesics* (PPLP003366082, at -089)

# 2016 Johns Hopkins/Clinton Foundation Report: 70% of Abusers Illegally Obtain Opioids From Friends And Family

Most patients fail to store opioid products in locked locations, including patients with children and adolescents who are particularly vulnerable to risks of opioid misuse and overdose. Many patients also retain unused opioids instead of disposing with them.... Collectively, these practices create household reservoirs of opioids that facilitate misuse and diversion all across America. In some cases, prescription opioids are diverted intentionally, while in other cases, they are used without the knowledge of the person for whom they were prescribed. Approximately 70 percent of people who report non-medical use of prescription opioids state their most recently used drug came from a friend or family member.



<https://www.jhsph.edu/events/2017/americas-opioid-epidemic/report/2017-JohnsHopkins-Opioid-digital.pdf>



***Problem #5:***

***Claimants Ignore Numerous Other Factors Causing Their Claimed Injuries***

---



# Claimants Ignore Numerous Other Factors Causing Their Claimed Injuries

## 2020 FDA Letter to Senator Maggie Hassan:

**"Multiple patient factors that have an association with opioid overdose (e.g., mental health diagnoses, family history of substance use disorder) may have as strong or stronger association that the magnitude of association for a higher-dose vs. lower-dose opioid analgesic prescription."** (Page 13)



<https://www.hassan.senate.gov/imo/media/doc/FDA%20RESPONSE%20HASSAN%201.21.20.pdf>

# Claimants Ignore Numerous Other Factors Causing Their Claimed Injuries

Among many other factors Claimants ignore:

- Family members and other unauthorized users unlawfully accessing lawfully-prescribed pills
- Individual patients' responses to opioids
- Patients not taking the drugs as prescribed
- Rogue doctors overprescribing for personal financial gain
- Illegal diversion and sale on the black market
- Socioeconomic factors

# Claimants Ignore Numerous Other Factors Causing Their Claimed Injuries

## Socioeconomic factors:

1. Diminishing job opportunities for the least educated
2. The dissolution of stable family structures
3. Lack of access to proper physical and mental healthcare
4. The growing isolation of many individuals from the broader community

See, e.g., NAT'L INST. ON MINORITY HEALTH AND HEALTH DISPARITIES, *The Drug Overdose Epidemic Affects All Communities*, NIH.GOV (Oct. 25, 2019), <https://nimhd.nih.gov/news-events/features/community-health/overdose-epidemic.html> ("**the opioid crisis may be part of a larger, longer-term process. Economic, sociological, and psychological factors, such as despair, loss of purpose, and dissolution of communities, may be at work to accelerate the crisis.**"); Jalal, *et al.*, *Changing dynamics of the drug overdose epidemic in the United States from 1979 through 2016*, 361 SCIENCE 1218 (Sep. 21, 2018) ("**Sociological and psychological 'pull' forces may be operative to accelerate demand, such as despair, loss of purpose, and dissolution of communities.**").

***Problem #6:***

***Claimants Cannot Establish Their Injuries Were Caused By  
Purdue Opioids, As Opposed To Other Manufacturers'***

---

# Claimants Impermissibly Lump Together All Opioid Manufacturers

Claimants' experts in the MDL did not attempt to analyze the impact of any individual opioid manufacturer's alleged unlawful conduct:

## Rosenthal

"My model ... is not designed to assign liability to individual manufacturers ..."

Rosenthal Dep. Tr. 164:4-9 (MDL Dkt. #1984-4)

## Cutler

"[My model] is attributing the harm to the defendants as a whole. It is not attributing it to any specific defendant."

Cutler Dep. Tr. 68:14-69:3 (MDL Dkt. # 1976-9)

"I made no attempt to calculate the proportion of fault due to any individual defendant."

*Id.* at 57:12-16

# Claimants Impermissibly Lump Together All Opioid Manufacturers

Claimants must show that the specific conduct of each opioid manufacturer proximately caused each of their injuries.

## RESTATEMENT (SECOND) TORTS §432(2)

Where there is concurrent conduct by more than one actor, to show the conduct of each was independently sufficient to cause “*the harm*,” there needs to be sufficient evidence that each actor’s conduct would have ***by itself*** constituted a ***substantial factor*** in bringing about “*the harm*”

## *Cresser v. Am. Tobacco Co.*, 174 Misc.2d 1, 4 (Sup. Ct. Kings Cty. 1997)

Dismissing complaints naming multiple cigarette manufacturers as defendants in products liability actions that did not specify the brand or brands of cigarettes that were smoked

## *Pang v. Minch*, 559 N.E.2d 1313, 1324 (Ohio 1990)

“The burden of proof is upon the plaintiff to demonstrate that the conduct of ***each defendant*** was a substantial factor in producing the harm”

# Claimants Impermissibly Lump Together All Opioid Manufacturers

1. Claimants have no evidence that would allow a fact-finder to determine that alleged wrongful conduct by Purdue — let alone the Individuals — was a substantial factor in bringing about their alleged harm
2. The Manufacturer Defendants' products are not interchangeable
  - They vary widely in their approved indications, formulation, and potency
  - They are distinctly labeled and easily traceable
  - OxyContin's extended-release abuse-deterrent formulation distinguishes it from most opioids on the market
3. The Manufacturer Defendants are competitors who employed differing marketing strategies over different periods for their different opioid products

# Claimants Impermissibly Lump Together All Opioid Manufacturers

**Claimants never analyzed the effect of each manufacturer's allegedly wrongful conduct.**

- Rosenthal's model *"is intended to, and does, capture the **average effect of all detailing**"* — across Defendants and non-defendants, and without regard to whether any fraud occurred in a particular interaction.

See Rosenthal Daubert Opp'n at 11 (MDL Dkt. # 2176)

At most the model is capable of measuring the total effect of all the detailing by all manufacturers, whether or not Plaintiffs sued them — not the contribution of Purdue's detailing.

- Plaintiffs' expert Cutler also admitted that he had *"not done anything with respect to any specific defendant."*

4/26/2019 Cutler Dep. Tr. 68:12-13 (MDL Dkt. # 1961-9/1976-9)





# Market Share Theory Of Causation Fails On The Facts

This “*extraordinary*” doctrine requires fungibility and equal degrees of risk

*See Hamilton v. Beretta U.S.A. Corp.*, 96 N.Y.2d 222, 240 (2001)

***“[C]ourts in New York and other jurisdictions have refused to extend the market share theory where [1] products were not fungible and [2] differing degrees of risk were created.”***

*Hamilton* refused to apply the market share theory because [1] guns are not “fungible,” since “it is often possible to identify the caliber and manufacturer of the handgun that caused injury to a particular plaintiff,” and [2] “[e]ach manufacturer engaged in different marketing activities that allegedly contributed to the illegal handgun market in different ways and to different extents.”

*Id.* at 242; 240-41

## Market Share Theory Of Causation Fails On The Facts

1. The Manufacturer Defendants' products are not interchangeable
  - They vary widely in their approved indications, formulation, and potency
  - They are distinctly labeled and easily traceable to a manufacturer
  - OxyContin's extended-release abuse-deterrent formulation distinguishes it from most opioids on the market
2. The Manufacturer Defendants are competitors and employed different marketing strategies over different periods to promote different opioids

***Problem #7:***

***States, Municipalities And Other Claimants Continue To Approve And Reimburse Opioid Prescriptions***

---

## This Precludes Any Claim That Purdue's Alleged Misrepresentations Were Material To Claimants' Reimbursement Decisions

*Teamsters Local 237 Welfare Fund v. AstraZeneca Pharm. LP*,  
136 A3d 688, 696 (Del. 2016) (analyzing New York law)

*"[Third-party payors] who continue to pay or reimburse for [a medication], while claiming they were harmed by allegedly false advertising, are neither 'victims' of the allegedly false advertising nor were they injured by reason of or as a result of it. They were injured by their own conduct."*

*See also Clearmont Prop., LLC v. Eisner*, 58 A.D.3d 1052, 1056 (3rd Dept. 2009); *Barrett v. Huff*, 6 A.D.3d 1164, 1167 (4th Dep't 2004)

***Problem #8:***

***Individuals Did Not Make Or Participate In Making Any Of The  
Purported Misstatements Allegedly Causing Claimants' Losses***

---

# Directors Are Not Liable For A Tort Committed By Their Company Unless They Personally Participated In It

*Lloyd v. Moore*,  
115 A.D.3d 1309, 1310 (N.Y. App. Div., 4th Dept 2014)

Defendant “cannot be held individually liable to plaintiff” if he “did not personally participate in malfeasance or misfeasance constituting an affirmative tortious act.”

*Bernstein v. Starrett City, Inc.*,  
303 A.D.2d 530, 532 (N.Y. App. Div., 2d Dept 2003)

“[A] corporate officer may not be held liable for the negligence of the corporation merely because of his or her official relationship to it.”

*MLM LLC v. Karamouzis*,  
2 A.D.3d 161, 161-62 (N.Y. App. Div., 1st Dept 2003)

Challenged “conduct amounts, at most, to nonfeasance, for which defendant is not liable.”

*Wesolek v. Jumping Cow Enters., Inc.*,  
51 A.D.3d 1376, 1379 (N.Y. App. Div., 4th Dept 2008)

Sole shareholder and director not liable for company’s alleged negligence “as a matter of law.”

3A FLETCHER, CYCLOPEDIA OF THE LAW OF CORPORATIONS  
§1137 (2019)

Corporate director “is not personally liable for torts of the corporation . . . merely by virtue of holding corporate office, but can only incur personal liability by participating in the wrongful activity.”

## The Individuals Did Not Make Or Participate In Any Of The Purported Misstatements That Allegedly Caused Claimants' Losses

The Individuals did not participate in any allegedly misleading marketing during the relevant post-2007 period

- They did not personally participate in drafting or approving the content of any marketing or advertising material
- They did not approve any allegedly deceptive marketing statements made to prescribers
- They reasonably relied on management reports, advice of outside compliance counsel, internal corporate reviews and audits, compliance monitoring, and assurances from a federal monitor in coming to the understanding that Purdue's marketing was in compliance with law
- This is demonstrated in detail in **Defense Presentation Part 2: Marketing Claims**

***Problem #9:***  
***Diversion Control Claims***

---



# Claimants Claim Defendants Flooded The Market With Opioids

Defendants Flooded Plaintiff Counties with Suspiciously Large Amounts of Opioids

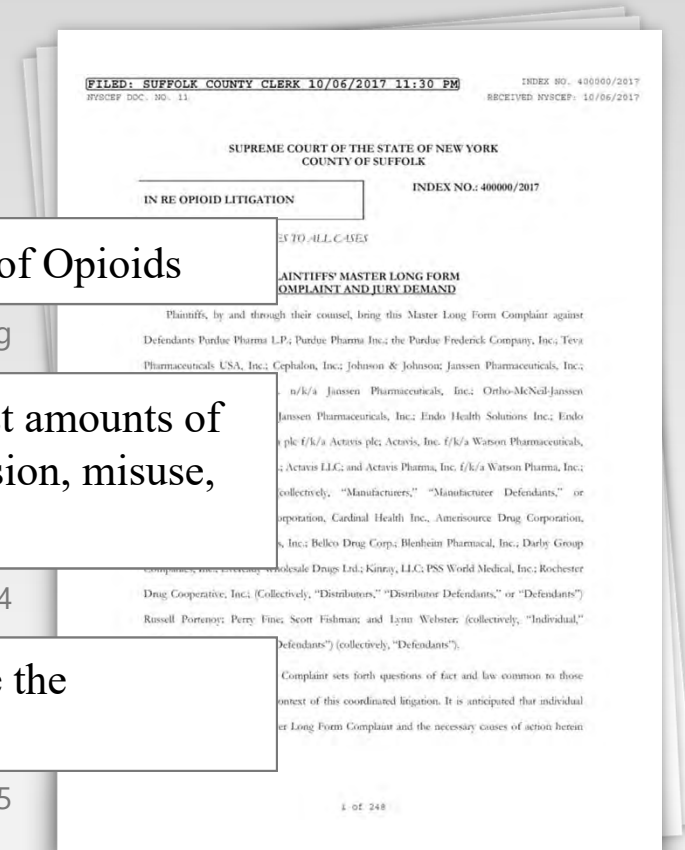
MLFC pp. 219-220, Facts Sub-heading

The Defendants knew or should have known that they were supplying vast amounts of dangerous drugs Plaintiffs' counties that were already facing abuse, diversion, misuse, and other problems associated with the opioid epidemic.

MLFC ¶744

The Defendants failed in their duty to take any action to prevent or reduce the distribution of these drugs.

MLFC ¶745

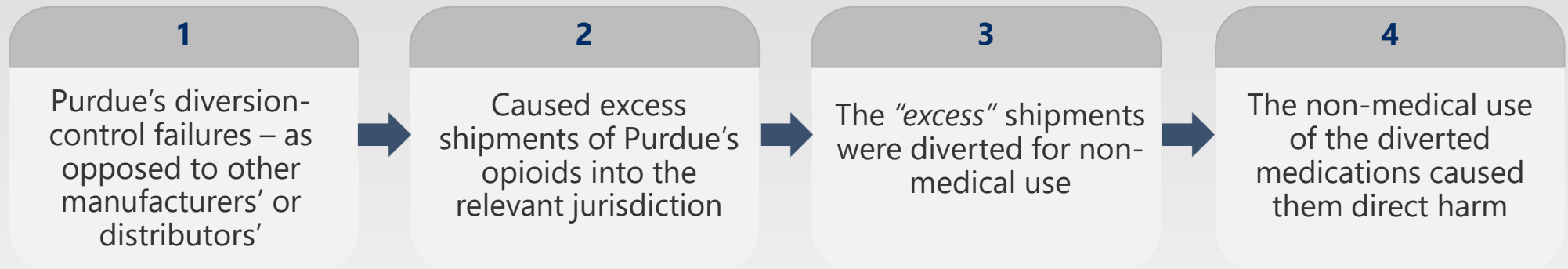


## Purdue's 2020 Guilty Plea And Civil Settlement Do Not Establish Diversion-Control Failures As Against The Individuals

- Purdue's plea and settlement have no collateral estoppel effect against former directors who had no control over Purdue when it agreed to enter into them  
*Stichting Ter Behartiging Van de Belangen Van Oudaandeelhouders In Het Kapitaal Van Saybolt Int'l B.V. v. Schreiber*, 327 F.3d 173, 184, 186 (2d Cir. 2003)
- None of the facts Purdue pled to was litigated, and Purdue denied all other facts alleged in its civil settlement. Those are inadmissible under Fed. R. Evid. 408
- In approving Purdue's entry into the plea agreement and civil settlement, the Bankruptcy Court did not find that any of the allegations admitted or denied by Purdue was true — the merits of DOJ's claims were not litigated
- Neither the plea nor the settlement is even final — both are conditioned on the Plan's providing that Purdue will emerge as a public benefit company
- Claimants must prove their claims of diversion-control failure against the family

## Claimants' Diversion Control Claims Causation Burden

To establish proximate cause for their diversion-control claims,  
Claimants must prove:



- Claimants must then prove the Individuals personally participated in the diversion control failures

## Diversion Control Claims Fail For Lack Of Causation

- Claimants cannot prove:
  - That any failure by Purdue to control the distribution of prescription opioids caused excess shipments of Purdue opioids into the relevant jurisdiction
  - That these excess shipments were used diverted for non-medical use
  - That these diverted medications caused them harm and
  - That this harm occurred during the relevant limitations period

# Claimants Cannot Prove They Were Harmed By Any Allegedly “Excess” Shipments Diverted For Non-Medical Use

**The volume of prescription opioids diverted annually for non-medical use is extremely difficult to estimate.**

Institute for Clinical and Economic Review, *Abuse-Deterrent Formulations of Opioids: Effectiveness and Value: Final Evidence Report* (Aug. 8, 2017), available at [www.https://necepac\\_adf\\_final\\_report\\_08\\_08\\_17.pdf](http://www.https://necepac_adf_final_report_08_08_17.pdf)



## Abuse-Deterrent Formulations of Opioids: Effectiveness and Value

Final Evidence Report

August 8, 2017

Prepared for:



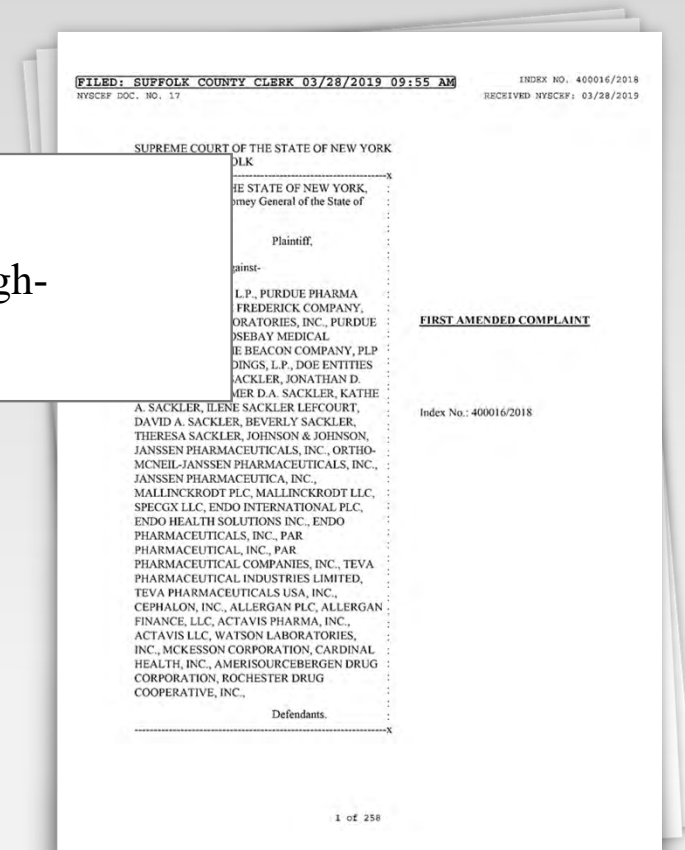
©Institute for Clinical and Economic Review, 2017

# Diversion Control Claims Against The Individuals Fail For Lack Of Personal Participation

## New York AG FAC ¶388:

388. For example, the Sacklers oversaw: . . .

- Purdue's improper response to signs of 'abuse and diversion' by high-prescribing doctors.



NY AG FAC ¶388

## Diversion Control Claims Against The Individuals Fail For Lack Of Personal Participation

- Claimants have no evidence tying any Individual to any alleged diversion-control failure
- The Individuals did not personally participate in Purdue's anti-diversion activities
- They responsibly monitored the anti-diversion activities, relying on extensive information provided by management and corporate systems in place at Purdue to prevent diversion
- This is demonstrated in detail in **Defense Presentation Part 3: Negligent Diversion Claims**

***Problem #10:***

***Municipal Cost Recovery Rule Bars Lawsuits For Local Government Expenditures In Many Jurisdictions***

---



## The Municipal Cost Recovery (Free Public Services) Rule

Many jurisdictions recognize the municipal cost recovery rule, which bars local government entities from bringing lawsuits to recover for their expenditure on government services

### New York:

*County of Erie v. Colgan Air, Inc.*, 711 F.3d 147, 150–51 (2d Cir. 2013)

Municipal cost recovery *“doctrine plainly bars the County’s claims to recover public expenditures.”*

*Matter of James AA*, 188 A.D.2d 60, 63–64 (3d Dep’t 1993)

Rule is *“longstanding and still applicable.”*

*Koch v. Consol. Edison Co. of N.Y.*, 62 N.Y.2d 548, 560 (1984)

Rule prevented New York City from recovering *“expenditures made in the performance of governmental functions”* during the blackout of 1977.

# The Municipal Cost Recovery Rule

## Massachusetts:

*Town of Freetown v. New Bedford Wholesale Tire*,  
384 Mass. 60, 61 (1981)

Free public services rule barred town's attempt to recover costs of its expenses arising from defendants' "*negligently dump[ing]*" used tires on town land "*creating a nuisance*"

# The Municipal Cost Recovery Rule

*County of Erie v. Colgan Air, Inc.*, 711 F.3d 147 (2d Cir. 2013)

*County of Erie* held there “**could not, strictly speaking, be a general public nuisance exception**” to the municipal cost recovery rule “**because it would be the exception that swallows the rule, since many expenditures for public services could be re-characterized by skillful litigants as expenses incurred in abating a public nuisance.**”

*Id.* at 153

*County of Erie* recognized that municipalities have a statutory right to recover the costs for abating certain public nuisances under N.Y. PUB. HEALTH LAW §1306, when they are recovering the costs of performing a third-party’s (normally the property owner’s) costs. *Id.* at 153

But N.Y. PUB. HEALTH LAW §1306 does not apply because the New York municipalities are trying to recover **the costs of performing government services.**

***Problem #11:***

***Derivative-Injury Rule Bars Claimants' Third Party Payer Claims***

---

## Derivative-Injury Rule Bars Claimants' Third-Party Payer Claims

*Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris USA Inc.*,  
3 N.Y.3d 200, 206 (2004)

"[A]n insurer or other third-party payer of medical expenditures may not recover derivatively for injuries suffered by its insured." Its "sole remedy is in equitable subrogation...."

- Claimants have made no subrogation claims.
- This bars, at a minimum, the claims for recoupment of medical and drug costs incurred by the Claimants' employees and Medicaid beneficiaries.

# ***Statutory Consumer Fraud Claims***

---

## Statutory Marketing Claims: 7 Principal Problems

1. Extraterritoriality
2. Statutes of Limitations Barring Recovery for Pre-2007 Conduct
3. No Personal Participation in Post-2007 Conduct
4. Purdue's Post-2007 Marketing Was Not Deceptive
5. Preemption
6. No Scierter
7. First Amendment

***Problem #1:***  
***Extraterritoriality***

---



# States Cannot Enforce Their Laws Extraterritorially

*Watson v. Emp'rs Liab. Assurance Corp.*,  
348 U.S. 66, 70 (1954)

"[A] state is without power to exercise 'extraterritorial jurisdiction,' that is, to regulate and control activities wholly beyond its boundaries."

*BMW of North America, Inc. v. Gore*,  
517 U.S. 559, 585 (1996)

A single State may not "impos[e] its regulatory policies on the entire Nation."

*Shaffer v. Heitner*,  
433 U.S. 186, 197 (1977)

"Any attempt 'directly' to assert extraterritorial jurisdiction over persons or property would offend sister States and exceed the inherent limits of the State's power."

*Bristol-Myers Squibb Co. v. Superior Court of Cal.*,  
137 S. Ct. 1773, 1780 (2017)

The due-process limits on "the coercive power of a State" over non-resident litigants are "a consequence of territorial limitations on the power of the respective States."

# Each State Must Establish Personal Jurisdiction Over Each Defendant

*Bristol-Myers Squibb Co. v. Superior Court of Cal.*,  
137 S. Ct. 1773, 1781–82 (2017)

No personal jurisdiction over manufacturer that operated laboratories and had hundreds of employees in state where plaintiffs' claims did not arise out of or relate to manufacturer's contacts with state

*BNSF Ry. Co. v. Tyrrell*,  
137 S. Ct. 1549, 1554 (2017)

No personal jurisdiction over railroad with over 2,000 miles of track in state because claims were unrelated to any activity occurring within the state

*Walden v. Fiore*,  
571 U.S. 277, 291 (2014)

No personal jurisdiction over defendant whose conduct was not in or directed at the forum state, even though the foreseeable effects of defendant's conduct were felt in the forum state

*Daimler AG v. Bauman*,  
571 U.S. 117, 136–39 (2014)

No personal jurisdiction over parent auto manufacturer with wholly-owned subsidiary that was the largest supplier of luxury vehicles in state because claims did not arise from parent's contacts with state

*Goodyear Dunlop Tires Operations, S.A. v. Brown*,  
564 U.S. 915, 930 (2011)

No personal jurisdiction over company that regularly sold products in state because claims did not arise from those sales

*J. McIntyre Mach., Ltd. v. Nicastro*,  
564 U.S. 873, 886–87 (2011)

No personal jurisdiction over manufacturer of a product sold by a different company to a customer in the state, where manufacturer targeted the United States market as a whole but not the specific state

## Personal Jurisdiction Requires Purposeful Availment

Each State must show both that:

1. Each individual defendant “purposefully reached out beyond [his or her] State and into another,” and  
*(Walden v. Fiore, 571 U.S. at 285)*
2. The claim against the individual “arise[s] out of or relate[s] to the defendant’s contacts with the forum”  
*(Bristol-Myers Squibb, 137 S. Ct. at 1780; Ford Motor Co. v. Mont. 8th Judicial Dist. Court, 141 S.Ct. 1017, 1025 (2021))*

## Five Threshold Personal Jurisdiction Problems

1. No personal jurisdiction over a director or shareholder based on conduct of the corporation

*Keeton v. Hustler Magazine, Inc.*,  
465 U.S. 770, 781 n.13 (1984)

*"[J]urisdiction over an employee does not automatically follow from jurisdiction over the corporation which employs him ...."*

## 5 Threshold Personal Jurisdiction Problems

### 2. No personal jurisdiction over a director in any particular state based on corporation's nationwide marketing

*Shuker v. Smith & Nephew, PLC*,  
885 F.3d 760, 780 (3d Cir. 2018)

"What is necessary is a deliberate targeting of the forum, so efforts to exploit a national market that necessarily included [the state] are insufficient" to establish jurisdiction in the state

*Mouzon v. Radiance, Inc.*,  
85 F. Supp. 3d 361, 372 (D.D.C. 2015)

No personal jurisdiction over a CEO "[e]ven if [he] played a central and dominant part" in the campaign and "directly profited" from it because plaintiffs "ha[d] not alleged that [he] himself targeted" the marketing campaign to the forum (D.C.)

*Fasugbe v. Willms*,  
2011 WL 3667440, at \*3-4 (E.D. Cal. Aug. 22, 2011)

Allegations that CEO was the "guiding spirit" behind corporation's alleged false advertising insufficient to establish personal jurisdiction

*Delman v. J. Crew Grp., Inc.*,  
2017 WL 3048657, at \*2 (C.D. Cal. May 15, 2017)

No personal jurisdiction over CEO whom plaintiffs alleged was "hands-on micro-manager of the [corporation]", "acutely aware of pricing and marketing policy" and "only one of two [executives] having any operational responsibility"

*Federated Rural Elec. Ins. Corp. v. Kootenai Elec. Coop.*,  
17 F.3d 1302, 1305 (10th Cir. 1994)

Advertising "in nationally distributed papers or journals does not rise to the level of purposeful contact with a forum required by the Constitution in order to exercise personal jurisdiction over the advertiser"

## 5 Threshold Personal Jurisdiction Problems

### 3. Corporate officers and employees are agents of the Company, not agents of the directors or owners

3A FLETCHER, CYCLOPEDIA OF THE LAW OF CORPORATIONS §1066 (2019)

*"[O]fficers and agents are not agents of the directors but are agents of the corporation."*

*Karabu Corp v. Gitner*,  
16 F. Supp. 2d 319, 324–25 (S.D.N.Y. 1998) (Sotomayor, D.J.)

*Under an agency analysis, allegations that corporate officers "directed" corporate conduct were insufficient to establish personal jurisdiction*

*Gerstle v. Nat'l Credit Adjusters*,  
76 F. Supp. 3d 503, 510 (S.D.N.Y. 2015)

*Under an agency analysis, "generalizations that [corporate officers] 'oversaw' or 'authorized' 'illegal policies' not described in any factual detail" insufficient*

## 5 Threshold Personal Jurisdiction Problems

### 4. The corporation is not the agent of the directors — the directors are agents of the corporation

*In re Banco Santander Sec.-Optimal Litig.*,  
732 F. Supp. 2d 1305, 1326 (S.D. Fla. 2010), *aff'd*, 439 F. App'x 840 (11th Cir. 2011)

No personal jurisdiction over corporate directors on an agency theory where plaintiffs “do not specify any actions that the directors took that would alter the standard legal presumption that directors and officers are agents of the corporation, not the other way around”

*Twin-Lick Oil Co. v. Marbury*,  
91 U.S. 587, 589 (1875)

“The directors are the officers or agents of the corporation”

*Crowell v. Randell*,  
35 U.S. 368, 382 (1836)

Directors “are but agents of the corporation”

*Topik v. Catalyst Research Corp.*,  
339 F. Supp. 1102, 1106 (D. Md. 1972), *aff'd*, 473 F.2d 907 (4th Cir. 1973)

“[C]orporate employees who acted in [the state] were agents of the corporation and not agents of the individual directors”

*Wilby v. Savoie*,  
86 A.3d 362, 375-76 (R.I. 2014)

Individuals, “as officers and directors [of a corporation] ... were agents of [the corporation]”

*Pritchard v. Myers*,  
174 Md. 66, 76 (1938)

“[T]he relation between a corporation and its directors is generally that of principal and agent.”

*Newman v. Forward Lands, Inc.*,  
418 F. Supp. 134, 136 (E.D. Pa. 1976)

Directors “were merely agents of the corporation.”

## 5 Threshold Personal Jurisdiction Problems

### 5. Receipt of a board report Is not conduct aimed at a particular State

*Stewart v. Am Ass'n of Physician Specialists, Inc.*,  
2014 WL 2011799, at \*4-5 (C.D. Cal. May 15, 2014)

"Mere knowledge" of wrongdoing by others in forum does not support jurisdiction.

*Ontel Prod., Inc. v. Project Strategies Corp.*,  
899 F. Supp. 1144, 1149 (S.D.N.Y. 1995)

"It is not enough that [the defendant] likely possessed authority to direct all the activities that gave rise to this suit. If that were the case, the President of every company would be subject to jurisdiction in New York based on activities with which he or she had no personal involvement and over which he or she exercised no decision making authority."

*Lavastone Capital LLC v. Coventry First LLC*,  
2015 WL 4940471, at \*8 (S.D.N.Y. July 30, 2015)

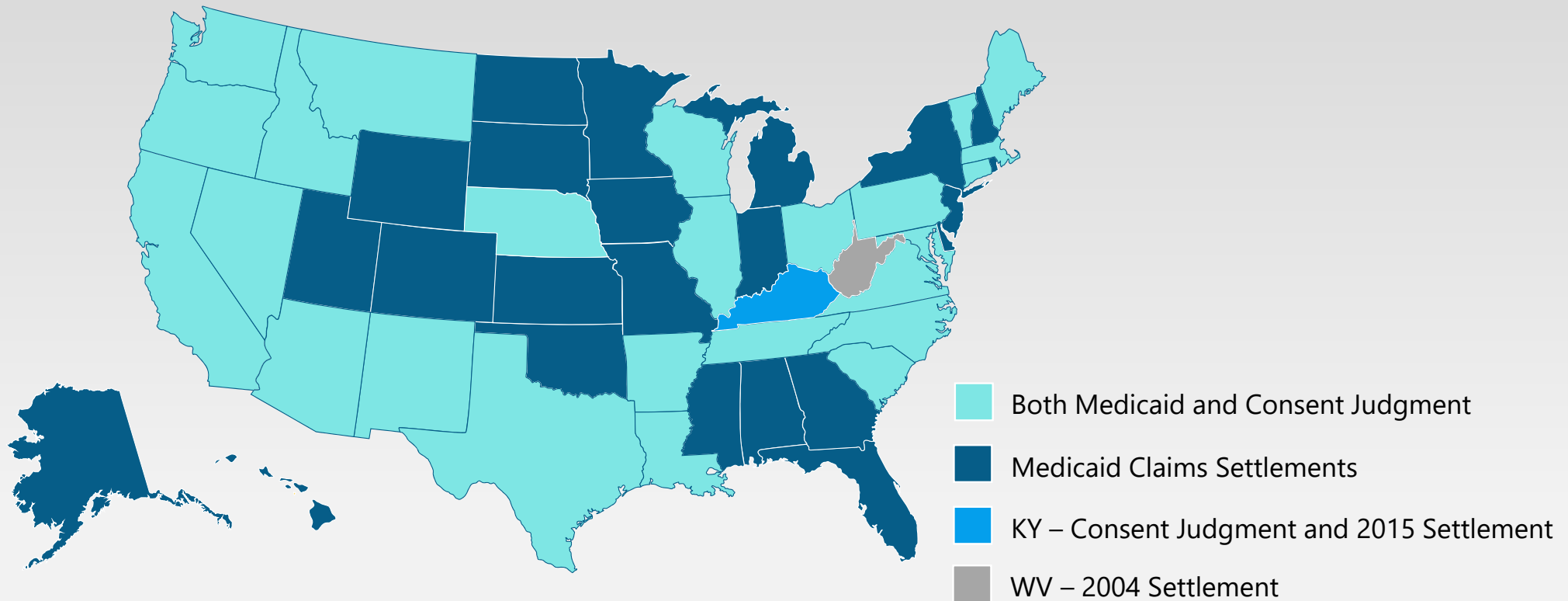
"The fact that [the officer] had authority to approve ... transactions is not sufficient without evidence that she actually exercised that authority with respect to transactions that are relevant to the claims at issue here."



***Problem #2:***  
***Statutes Of Limitations***

---

## 2007 Settling Jurisdictions — Claims Before 2007 Have Been Released



## State Statutes Of Limitations Limit Claimants' Ability To Recover

- *E.g.*, The New York's GBL §§349 and 350 claims have 3-year statute of limitations
- *E.g.*, Massachusetts' claims have 3- and 4-year statutes of limitations
- No tolling doctrines apply
  - All States and the District of Columbia were aware by 2007 of issues relating to Purdue's opioid issues — they had settled claims for alleged Purdue misconduct
  - All States and the District of Columbia had contractual rights to demand additional information from Purdue at any time
  - Intense media coverage of Purdue's marketing and diversion issues dates to the turn of the century and has escalated exponentially over the years
  - There was nothing concealed about Purdue's marketing — it was sent to third parties

***Problem #3:***  
***No Personal Participation Post-2007***

---

# Directors Are Not Liable For Torts Committed By Their Company Unless They Personally Participated In It

3A FLETCHER, CYCLOPEDIA OF THE LAW OF CORPORATIONS  
§1137 (2019)

Corporate director “is not personally liable for torts of the corporation . . . merely by virtue of holding corporate office, but can only incur personal liability by participating in the wrongful activity.”

*Lloyd v. Moore*,  
115 A.D.3d 1309, 1310 (N.Y. App. Div., 4th Dept 2014)

Corporate officer “cannot be held individually liable to plaintiff” if he “did not personally participate in malfeasance or misfeasance constituting an affirmative tortious act.”

*Bernstein v. Starrett City, Inc.*,  
303 A.D.2d 530, 532 (N.Y. App. Div., 2d Dept 2003)

“[A] corporate officer may not be held liable for the negligence of the corporation merely because of his or her official relationship to it.”

*MLM LLC v. Karamouzis*,  
2 A.D.3d 161, 161-62 (N.Y. App. Div., 1st Dept 2003)

Challenged “conduct amounts, at most, to nonfeasance, for which defendant is not liable.”

*Wesolek v. Jumping Cow Enters., Inc.*,  
51 A.D.3d 1376, 1379 (N.Y. App. Div., 4th Dept 2008)

Sole shareholder and director not liable for company’s alleged negligence “as a matter of law.”

# Awareness Of Misconduct Does Not Create Individual Liability

*Reynolds v. Lifewatch, Inc.*,  
136 F. Supp. 3d 503, 526 (S.D.N.Y. 2015)

*"In cases where courts have found individual defendants to have participated in the misrepresentations at issue, the complaints specifically alleged personal participation, rather than mere awareness or control."*

*Lloyd v. Moore*,  
115 A.D.3d 1309, 1310 (N.Y. App. Div., 4th Dep't 2014)

*"Plaintiff . . . submitted no evidence that defendant affirmatively created the dangerous . . . condition at the property or did anything to make it worse; at most, defendant merely failed to remedy the condition."*

## No Personal Participation In Any Alleged Post-2007 Mismarketing

- No participation in or approval of the content of marketing materials
- No participation in or approval of content of sales reps' presentations
- Directors reasonably relied on review of all marketing material reviewed by Legal, Medical Services and Regulatory Affairs
- Directors reasonably relied on audits of compliance program by outside counsel and by management
- Directors reasonably relied on reports from management that marketing was in compliance with all applicable state and federal law — and for 5 years, on a federal monitor's confirmation of Purdue's compliance with its Corporate Integrity Agreement

***Problem #4:***

***Purdue's Post-2007 Marketing Was Not Deceptive***

---

See Defense Presentation Part 2



## ***Problem #5: Preemption***

---

See Defense Presentation Part 5

***Problem #6:***

***No Scier (No Intent to Deceive, Manipulate Or Defraud)***

---

See Defense Presentation Parts 1, 2 and 3

## Problem #6 – Claimants Cannot Show That The Individuals Acted With An Intent To Deceive

Many statutes require the State to prove scienter or provide a good faith defense

- Mass. Gen. Laws Ann. ch. 93A, §4 permits civil penalties only “If the court finds that a person has employed any method, act or practice which he knew or should have known to be in violation of said section two.”
- Utah’s Consumer Sales Protection Act §13-11-4(2) requires a showing of an intent to deceive.
  - “[A] supplier commits a deceptive act or practice if the supplier knowingly or intentionally . . .”

## Claimants Cannot Show That The Individuals Acted With An Intent To Deceive

- The evidence proving the good faith of the Individuals is set forth in detail in Defense Presentation Parts 1 (Generally), 2 (Marketing) and 3 (Diversion)
- Purdue's marketing:
  - Is literally true
  - Is consistent with the FDA-approved label
  - Was reviewed by Medical, Legal and Regulatory Affairs and
  - Was submitted to the FDA for review before use

*United States ex rel. Berg v. Honeywell Int'l*,  
740 F. App'x 535, 539 (9th Cir. 2018)

The fact that defendant showed the challenged calculations to the relevant government regulator "*negates scienter*."

## Claimants Cannot Show That The Individuals Acted With An Intent To Deceive

- Purdue had an extensive compliance program
- The Board relied on Purdue's management to determine what marketing materials would say and to ensure that the marketing messages were:
  1. Consistent with FDA and other legal requirements, and
  2. Accurate and supported by appropriate science
- The Board was consistently informed, in quarterly compliance reports, that Purdue was in compliance with all state and federal laws
- For 5 years, the Board was informed that a federal monitor found Purdue in compliance with its Corporate Integrity Agreement, which was designed to ensure compliance with federal healthcare law

See Defense Presentation Part 1

***Problem #7:***  
***First Amendment***

---

# First Amendment

*Sorrell v. IMS Health, Inc.*,  
564 U.S. 552 (2011)

***"Speech in aid of pharmaceutical marketing . . . is a form of expression protected by the . . . First Amendment. . . . [The] creation and dissemination of information are speech within the meaning of the [Constitution]."***

*Miller v. California*,  
413 U.S. 15, 34 (1973)

Including speech with *"serious . . . scientific value."*

# First Amendment

*Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*,  
447 U.S. 557, 564 (1980)

First Amendment protection applies to commercial speech, as long as it is "*neither misleading nor related to unlawful activity.*"

*United States v. Caronia*,  
703 F.3d 149, 164 (2d Cir. 2012)

Government prohibition on accurate speech regarding "*off-label*" drug uses violated the First Amendment.



# *Public Nuisance*

---

# Public Nuisance: 7 Principal Problems

<b><i>Problem #1:</i></b>	Novel and Legally Flawed Theory
<b><i>Problem #2:</i></b>	Articulation of What the Nuisance Is
<b><i>Problem #3:</i></b>	Preemption
<b><i>Problem #4:</i></b>	Purdue's Marketing Was Not Deceptive
<b><i>Problem #5:</i></b>	Causation
<b><i>Problem #6:</i></b>	Claimants Cannot Establish that Purdue—Let Alone the Individuals—Played a Substantial Role in Creating a Nuisance
<b><i>Problem #7:</i></b>	Claims Against Purdue Do Not Create Claims Against Former Directors

***Problem #1:***  
***Novel And Legally Flawed Theory***

---

# Public Nuisance Claims Must Be Based On Interference With A Public Right

## RESTATEMENT (SECOND) OF TORTS §821B (1979)

*"A public nuisance is an unreasonable interference with **a right common to the general public.**"*

RESTATEMENT (SECOND) OF TORTS §821B (1979)

*"**A public right is one common to all members of the general public. It is collective in nature** and not like the individual right that everyone has not to be assaulted or defamed or defrauded or negligently injured."*

*Id., cmt. g*

# Public Nuisance Claims Are Not Traditionally Based On Impact Of Lawful Products On Individual Users

Claimants' theory of the opioid crisis is that individuals became addicted to or abused opioids that:

- They should not have been prescribed because of improper marketing or
- They should not have received as a result of illegal diversion

That is harm to individuals, not harm to “a right common to the general public”

## These Public Nuisance Claims Are Novel And Legally Flawed

*Tioga Pub. Sch. Dist. No 15 v. U.S. Gypsum Co.*, 984 F.2d 915, 920 (8th Cir. 1993)

Extending public nuisance laws to make a company that sells a lawful product liable **for what others do with the product** would expand public nuisance far law beyond its traditional limits:

*"Nuisance thus would become a monster that would devour in one gulp the entire law of tort ..."* (reversing public nuisance claim arising from asbestos containing materials).

## Public Nuisance Law Does Not Reach What An Individual Does With A Lawful Product

*City of Chicago v. Beretta U.S.A. Corp.*, 213 Ill.2d 351, 381–82, 432 (2004)

Lawful sale of **firearms** does not constitute a public nuisance (Illinois law).

The court would not recognize novel public nuisance claims: *“Any change of this magnitude in the law affecting a highly regulated industry must be the work of the legislature, brought about by the political process, not the work of the courts.”*

*Camden Cty. Bd. of Chosen Freeholders v. Beretta, U.S.A. Corp.*, 273 F.3d 536, 540 (3d Cir. 2001)

Lawful sale of **firearms** does not constitute a public nuisance (New Jersey law).

## Public Nuisance Law Does Not Reach What An Individual Does With A Lawful Product

*State v. Lead Indus. Ass'n*, 951 A.2d 428, 456–57 (R.I. 2008)

**Lead paint** does not constitute a public nuisance.

*Indep. Cty. v. Pfizer, Inc.*, 534 F. Supp. 2d 882, 890 (E.D. Ark. 2008),  
*aff'd* 552 F.3d 659 (8th Cir. 2009)

Dismissing public nuisance claims based on use of **FDA-approved over-the-counter cold medicine**: *"Because Defendants are not landowners, Plaintiffs cannot succeed on their public nuisance claim."*



## Public Nuisance Law Does Not Reach What An Individual Does With A Lawful Product

*People ex rel. Spitzer v. Sturm, Ruger & Co.*, 309 A.D.2d 91, 96–97, 105 (1st Dep’t 2003)

Lawful sale of firearms does not constitute a public nuisance (New York law).  
Warning that allowing public nuisance to create an end-run on product liability law would “*open the courthouse doors*” to a “*flood*” of challenges to “*countless ... types of commercial enterprises*” marketing lawful, nondefective products.

*City of Philadelphia v. Beretta U.S.A. Corp.*, 277 F.3d 415, 421 (3d Cir. 2002)

Lawful sale of **firearms** does not constitute a public nuisance (Pennsylvania law).

*City of St. Louis v. Cernicek*, 2003 WL 22533578, at \*2 (Mo. Cir. Ct. Oct. 15, 2003)

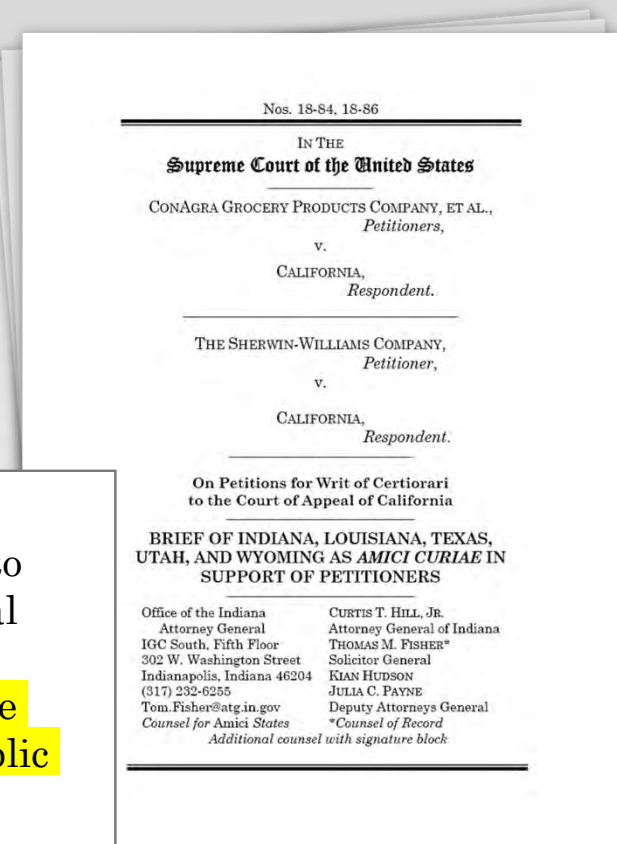
Lawful sale of **firearms** does not constitute a public nuisance (Missouri law).

# Five States Recently Argued In The Supreme Court That Nuisance Law Does Not Apply To Products Claims

In 2018, five states argued in the Supreme Court that public nuisance laws cannot be stretched to convert products liability suits—based on the collective effect of harms to individuals—into public nuisance liability

Amicus brief of **Indiana, Louisiana, Texas, Utah** and **Wyoming**, in *ConAgra Grocery Products Company v. California*, No. 18-84 (U.S. Aug. 16, 2018):

Public nuisance law is derived from hundreds of years of common law tradition. But in recent years, state and local governments have sought to use public nuisance lawsuits for a new purpose: to regulate broad societal problems through litigation or failing that, to enable mass transfers of wealth from industry to preferred groups. **These new regulatory nuisance lawsuits drift far afield of the original common law understanding of public nuisance doctrine.**



Amicus Brief of Indiana, Louisiana, Texas, Utah and Wyoming, in *ConAgra Grocery Products Company v. California*, No. 18-84 (U.S. Aug. 16, 2018)  
Available at <https://tinyurl.com/nuisanceamicus>.

## Courts Have Rejected Public Nuisance Claims Against Purdue

*State ex rel. Jennings v. Purdue Pharma L.P.*,  
2019 WL 446382, at \*12 (Del. Super. Ct. Feb. 4, 2019)

Dismissing nuisance claim brought by Delaware Attorney General—noting “*a clear national trend to limit public nuisance to land use.*”

*State ex rel. Stenehjem v. Purdue Pharma L.P.*,  
2019 WL 2245743, \*13 (D.N.D. May 10, 2019)

Dismissing public nuisance claim brought by North Dakota Attorney General—declining to “*extend[] the public nuisance statutes to cases involving the sale of goods,*” and holding that “*[t]he State does not have a cause of action for nuisance against Purdue since its nuisance claim arises from the ‘overprescribing and sale’ of opioids manufactured by Purdue.*”

# Courts Have Rejected Public Nuisance Claims Against Purdue

*City of New Haven v. Purdue Pharma, L.P.*, 2019 WL 423990, at \*4-6 (Conn. Super. Ct. Jan. 8, 2019)

Dismissing claims, including public nuisance claims, brought by local government under Connecticut law because the links between the alleged misconduct and the plaintiffs' expenditures are too attenuated.

*Grewal v. Purdue Pharma L.P.*, 2018 WL 4829660, at \*17-18 (N.J. Super. Oct. 2, 2018)

Dismissing New Jersey's public nuisance claim *"with prejudice for failure to state a claim"* as barred by the New Jersey Products Liability Act.

*City of Everett v. Purdue Pharma L.P.*, 2017 WL 4236062, at \*9 (W.D. Wash. Sept. 25, 2017)

Dismissing public nuisance claims brought by local government under Washington law: *"[T]he Court agrees with Purdue and will dismiss Everett's public nuisance claim for failure to allege a connection to property."*

***Problem #2:***

***Because Claimants Do Not Allege A Conventional Public Nuisance, They Cannot Articulate What The Nuisance Is***

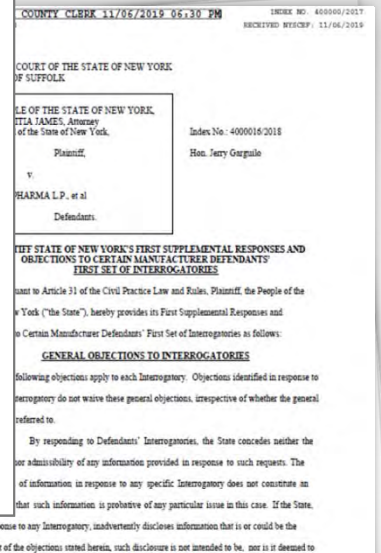
---

# What Is The Public Nuisance?

## New York AG:

As used in these paragraphs, 'public nuisance' refers to this recognized cause of action and Defendants' conduct and omissions that have **offended, interfered with, and/or caused damage to the public in the exercise of common rights, including, but not limited to, the health, safety, and comfort of a considerable number of people.** In particular, through these paragraphs, the State has alleged that Defendants' conduct has **caused and/or contributed to the current epidemic of opioid addiction in the State of New York.**

This epidemic is marked by, inter alia, **the following harms: the oversupply, overprescribing, and diversion of prescription opioids, inaccurate perceptions concerning the risks and benefits of opioids by both the public and the medical community, widespread prescription opioid misuse and opioid use disorder, neonatal-abstinence-syndrome births, opioid overdoses (both fatal and non-fatal), and increased rates of crime and incarceration.**



# What Is The Public Nuisance?

## Identified harms:

- “the oversupply, overprescribing, and diversion of prescription opioids”
- “inaccurate perceptions concerning the risks and benefits of opioids by both the public and the medical community”
- “widespread prescription opioid misuse”
- “opioid overdoses”
- “increased rates of crime and incarceration”



# “The Oversupply, Overprescribing, And Diversion Of Prescription Opioids”

## Oversupply

- The supply of prescription opioids is set by the Drug Enforcement Agency
- The DEA can increase the annual production quota only if it determines that there is a legitimate medical need for that amount of the drug (21 C.F.R. §1303.11)
- Claimants cannot rely on Purdue’s plea to prove fraud on the DEA or oversupply
- The plea and settlement have no collateral estoppel effect against former directors who had no control over Purdue when it agreed to enter into them  
(Defense Presentation Part 1)
- DOJ never alleged, and Purdue never admitted, that Purdue’s fraud on the DEA had any effect on any quota the DEA set  
(Defense Presentation Part 5)
- DEA was at all times well aware that OxyContin was abused and diverted and took that into account in setting Purdue’s opioid quota  
(Defense Presentation Part 5)



# “The Oversupply, Overprescribing, And Diversion Of Prescription Opioids”

## Overprescribing

Each prescription of opioids is given by a licensed doctor based on a determination that prescription opioids are appropriate for an individual patient.

- The former Purdue Directors were not involved in this decision
- The prescribing doctors are all aware that prescription opioids have a high potential for addiction
- Under the learned intermediary doctrine, that severs the chain of causation.

*Bodie v. Purdue Pharma Co.*, 236 F. App'x 511, 521 (11th Cir. 2007)

*“Because the evidence suggests that the learned intermediary, Dr. Mangieri, prescribed OxyContin **based on his independent knowledge of the drug and its high potential for addiction**, we cannot conclude that the allegedly inadequate warning (that is, the claimed defect) proximately caused Bodie’s injury of addiction.”*

*Bodie v. Purdue Pharma Co.*, 236 F. App'x 511, 521 (11th Cir. 2007)

# “The Oversupply, Overprescribing, And Diversion Of Prescription Opioids”

## Diversion

- Diversion of prescription opioids is a crime — the result of third-party criminal activity
- To avert diversion, Purdue implemented a Suspicious Order Monitoring (SOM) system in addition to its ADD Program and other anti-diversion programs
- The Board understood that Purdue vigorously implemented the SOM system, the ADD Program and all of its anti-diversion programs

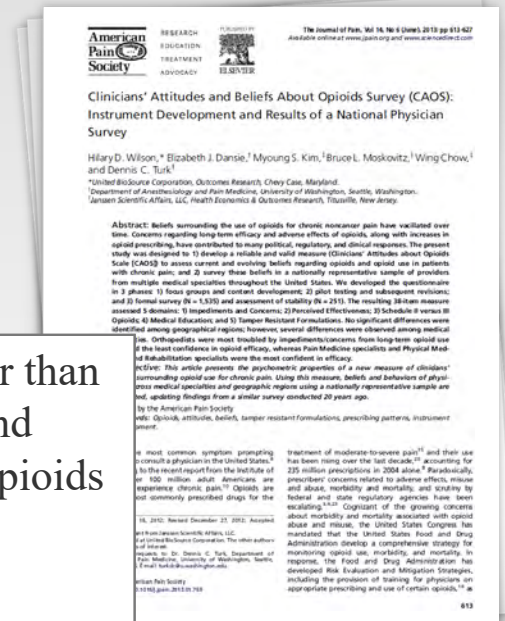
March 2017 Ethics And Compliance Report at 49, 50, 53 (PPLP004413913);  
*see generally* Defense Presentation Part 3

# “Inaccurate Perceptions” About Opioids

## “Inaccurate Perceptions Concerning the Risks and Benefits of Opioids by Both the Public and the Medical Community”

- The New York AG’s position is that ideas it disagrees with are a public nuisance
- No case holds that ideas can constitute a public nuisance
- The CDC 2016 Guidelines – which the New York AG relies on – cites studies showing that the medical community is aware of the risk of addiction and abuse associated with opioids

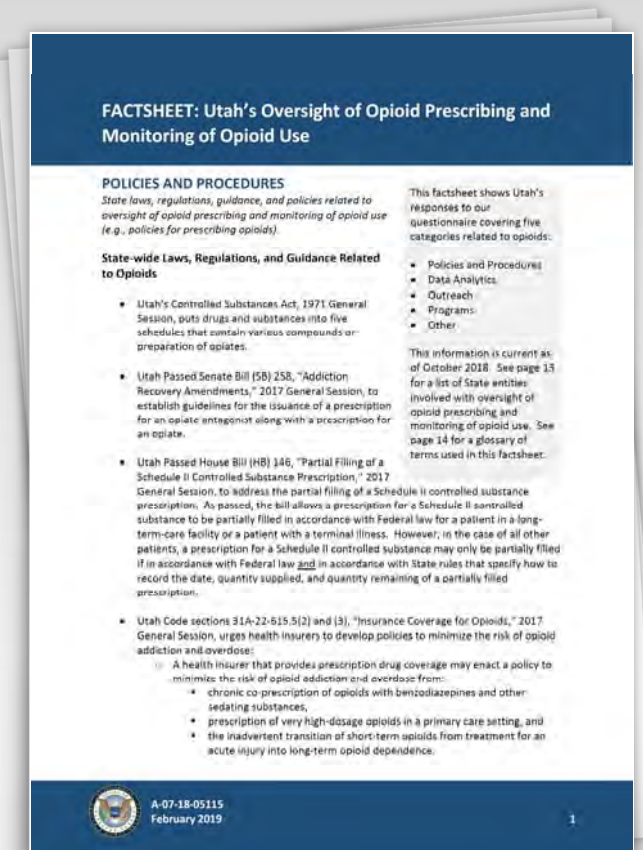
Physicians strongly agreed that patients “sometimes take opioids for reasons other than pain” (mean = 7.42, SD = 2.24) and that “addiction” (mean = 7.43, SD = 2.16) and “physical dependence” (mean = 7.35, SD = 2.06) were “impediments to taking opioids for long periods of time.” Moreover, physicians also strongly disagreed with the statement “Patients rarely misuse/abuse opioids” (mean = 3.37, SD = 2.36).



Hilary D. Wilson et al., *Clinicians' Attitudes and Beliefs about Opioids Survey*, 14 J. OF PAIN 613, 616 (2013).

# No Need for Nuisance Remedy

- Governments can educate prescribers about opioids
  - *E.g.*, 2016 CDC Guidelines.
- States have mandatory education for prescribers
- The media has widely reported on abuse of and addiction
- Purdue does not control what highly educated and regulated prescribers know about prescription opioids
- The Individuals have no control over this
- The FDA-approved label provides all warnings deemed appropriate by the federal regulator charged with making that determination



[https://oig.hhs.gov/oas/reports/region7/71805115\\_Factsheet.pdf](https://oig.hhs.gov/oas/reports/region7/71805115_Factsheet.pdf)

## “Widespread Prescription Opioid Misuse”

- Misuse of prescription opioids is a crime and severs causation

*People ex rel. Spitzer v. Sturm, Ruger & Co.*, 309 A.D.2d 91, 99 (1st Dep’t 2003)

Dismissing public nuisance claims against gun manufacturers because the “*indisputable intervention of unlawful ... acts of criminals*” severs the chain of proximate causation.

*In re Opioid Litigation*, 2018 WL 3115102, at \*21–22 (Sup. Ct. Suffolk Cnty. June 18, 2018)

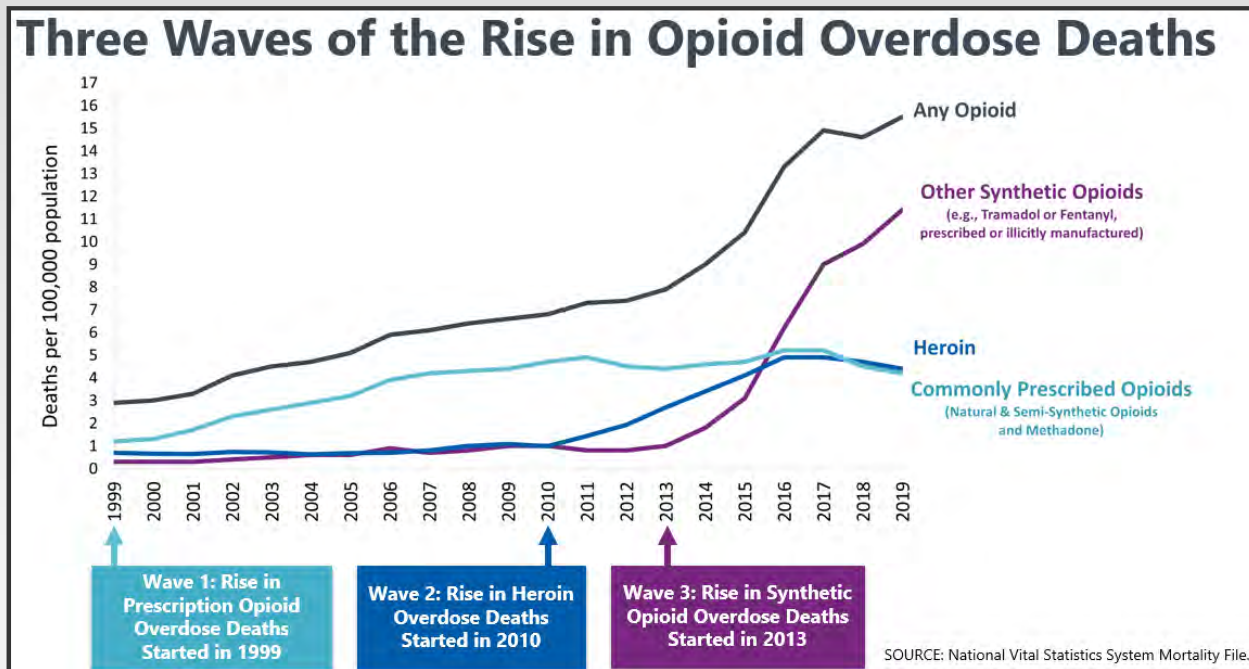
In the New York Counties lawsuit, Justice Garguilo indicated the plaintiff counties must show injury from the “*legal use*” of opioids.

## **“Increased Rates of Crime and Incarceration”**

- **Neither Purdue nor the Individuals are responsible for crimes committed by third parties**
- **High rates of incarceration are the result of years of government policy**

# “Opioid Overdoses”

There have been three waves of the opioid crisis



The data show the rise in overdose deaths for several years has largely been a crisis of **illegal opioids** (heroin and illicit fentanyl)

<https://www.cdc.gov/drugoverdose/epidemic/index.html>

## *Problem #3:*

### *Preemption*

---



# The Claim That An FDA-Approved Drug Is A Nuisance Is Preempted

- The essence of the Claimants' claim is that FDA-approved drugs are a public nuisance
- That second-guesses the FDA's judgment that these drugs should be available
- State laws cannot make the sale of FDA-approved medicine unlawful or automatically tortious

**See Defense Presentation Part 5**

# The Claim An FDA-Approved Drug Is A Nuisance Is Preempted

*Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 489 (2013)

If a state law makes it inherently tortious for the manufacturer of an FDA-approved medicine to sell FDA-approved medicine, then the state law is preempted.

*Zogenix, Inc. v. Patrick*, 2014 WL 1454696, at \*2 (D. Mass. Apr. 15, 2014)

*"The FDA has the authority to approve for sale to the public a range of safe and effective prescription drugs—here, opioid analgesics. If the Commonwealth were able to countermand the FDA's determinations and substitute its own requirements, it would undermine the FDA's ability to make drugs available to promote and protect the public health."*

*Zogenix, Inc. v. Patrick*, 2014 WL 3339610, at \*4 (D. Mass. July 8, 2014)

Enjoining amended regulations adopted by Massachusetts aimed at making an FDA-approved opioid less available because it interfered with the federal scheme.

## The Claim An FDA-Approved Drug Is A Nuisance Is Preempted

Claimants argue their claims are not about the distribution of FDA-approved drugs

- They claim the public nuisance does not arise from the distribution of the FDA-approved drugs, but from the impact of misleading marketing.

Claimants are forced to disclaim any argument that FDA-approved labels were deceptive

- They claim that the marketing was deceptive because it differed from the label.

There is no evidence to support this supposed distinction

*Wos v. E.M.A. ex rel. Johnson*, 568 U.S. 627, 636-37 (2013)

*"Pre-emption is not a matter of semantics.... In a preemption case, a proper analysis requires consideration of what the state law in fact does, not how the litigant might choose to describe it."*

***Problem #4:***

***Purdue's Post-2007 Marketing Was Not Deceptive***

---

See Defense Presentation Part 2

## Purdue's Post-2007 Marketing Was Not Deceptive

- The risk of addiction and abuse was always prominently disclosed
- The risk of addiction and abuse was well-understood by prescribers
- All marketing material was reviewed by the FDA and consistent with the FDA-approved label
- Purdue had a rigorous compliance program to avoid misleading marketing:
  - To ensure everything said was true and consistent with FDA-approved labels
  - To retrain and remediate employee errors or misconduct in marketing, including by termination of employment

*Problem #5:*  
*Causation*

---

# Proximate Causation Is Required to Recover Damages on a Public Nuisance Claim

*People ex rel. Spitzer v. Sturm, Ruger & Co.*, 309 A.D.2d 91, 105 (1st Dep't 2003)

Plaintiff in a public nuisance suit must establish both that defendants caused or contributed to the nuisance and that their conduct was a "*proximate cause*" of plaintiff's injury (dismissing claim based on remoteness of causation).

*City of Chicago v. Beretta U.S.A. Corp.*, 2013 Ill.2d 351, 412 (2004)

Affirming dismissal of public nuisance claims against firearms distributors for lack of proximate cause because their illegal use was "*several times removed from the initial sale of individual weapons by these defendants.*"

- See Slides 3-71, above (no causation in fact)

***Problem #6:***

***Claimants Cannot Establish That Purdue — Or The Individuals — Played A Substantial Role In Creating A Nuisance***

---



## Neither Purdue Nor The Individuals Had Any Control Over The Nuisance Or Instrumentalities Creating It

*City of Bloomington v. Westinghouse Elec. Corp.*, 891 F.2d 611, 614 (7th Cir. 1989)

Manufacturer of PCBs not liable for public nuisance caused by another company's use of PCBs; ***the manufacturer did not have "control of the product" after the other company purchased it and therefore did not "participate[] in carrying on the nuisance."***

*State v. Lead Indus., Ass'n*, 951 A.2d 428, 449 (R.I. 2008)

Plaintiff must show that the defendant ***"ha[d] control over the instrumentality causing the alleged nuisance at the time the damage occurs."***

## Neither Purdue Nor The Individuals Had Any Control Over The Nuisance Or Instrumentalities Creating It

*Henry v. St. Croix Alumina, LLC*, 2007 WL 6030275, at \*16 (D.V.I. Aug. 10, 2007)

*"[C]ourts that have interpreted nuisance law require that an entity can be liable based on a nuisance claim if that entity has **the ability or opportunity to abate the nuisance.**"*

Granting summary judgment for supplier because it did not have control over premises after a certain date and therefore *"had no opportunity, or authority to abate the storage or containment of the bauxite"* (collecting cases).

## Neither Purdue Nor The Individuals Had Any Control Over The Nuisance Or Instrumentalities Creating It

Widespread abuse of and addiction to opioids are far beyond Purdue's and any Individual's control

- Purdue and the Individuals **cannot control illegal opioids**
- Purdue and the Individuals cannot control **how doctors prescribe opioids**
- Purdue and the Individuals cannot control **what patients do with prescribed or illegal opioids**
- Purdue and the Individuals cannot control **doctors' understanding of the risks of opioids**

*State ex rel. Stenehjem v. Purdue Pharma L.P.,*  
2019 WL 2245743, \*13 (D.N.D. May 10, 2019)

Dismissed public nuisance claims on this ground: *"The reality is that **Purdue has no control over its product after it is sold to distributors, then to pharmacies, and then prescribed to consumers**, i.e. after it enters the market. Purdue cannot control how doctors prescribe its products and it certainly cannot control how individual patients use and respond to its products, regardless of any warning or instruction Purdue may give."*

# Purdue Did Not Substantially Participate In Creating The Opioid Crisis

## RESTATEMENT (SECOND) OF TORTS §834 (1979)

To prevail on a public nuisance claim, a plaintiff must also show that the defendant's participation was **"substantial participation"** in creating the nuisance.









RESTATEMENT (SECOND) OF TORTS §834 (1979)

*"When a person is **only one of several persons** participating in carrying on an activity, **his participation must be substantial** before he can be held liable for the harm resulting from it. This is true because to be a legal cause of harm a person's conduct must be a substantial factor in bringing it about."*

*Id., cmt. d*

# Purdue Did Not Substantially Participate In Creating The Opioid Crisis

Purdue was one small player in the distribution of opioids in the United States. Others include:

-  Other opioid manufacturers, who occupied 96% or more of the prescription opioid market
-  Drug distributors and pharmacies, which had control of any product that was diverted
-  Government regulators including:
  -  The CDC, which advises about public health issues
  -  The DEA, which decides how many opioids there will be
  -  The FDA, which approves the drugs and their labelling
  -  State licensing authorities
-  Criminals, who divert lawful opioids and distribute illegal ones like heroin and illicit fentanyl

***Problem #7:***

***Claims Against Purdue Do Not Create Claims Against  
Former Directors***

---

## Directors Are Not Liable For A Public Nuisance Created By Their Company Unless They Personally Participated In It

*Sahu v. Union Carbide Corp.*, 2012 WL 2422757, at \*11 (S.D.N.Y. June 26, 2012), *aff'd* 528 F. App'x 96 (2d Cir. 2013)

Personal participation in public nuisance required—approval of budget “*does not rise to the level of participation in the commission of a tort.*”

## None Of The Individuals Personally Participated In Creating The Alleged Nuisance

- None reviewed or approved the content of marketing material
- None made or approved allegedly deceptive marketing statements to HCPs
- None decided what Purdue's sales representatives would say to HCPs
- None personally participated in executing Purdue's anti-diversion programs

See Defense Presentations Nos. 2 and 3



## None Of The Individuals Personally Participated In Creating The Alleged Nuisance

Courts dismiss nuisance claims for violations of environmental statutes against senior corporate officers absent personal participation

*Estate of Goldberg v. Goss-Jewett Co.*, 2019 WL 4221398, at \*3 (C.D. Cal. June 4, 2019)

Corporate president not personally liable under CERCLA. “[T]he normal relationship that the president of a corporation has with the corporation” does not support liability. It would be impermissible **“to hold [President] liable as an operator simply because, as president of Goss-Jewett, he was ultimately in charge of all aspects of the corporation.”**

## Directors Are Not Liable For The Torts Of Their Companies Unless They Personally Participated In Them

*T.V. Spano Bldg. Corp. v. Dep't of Nat. Res. & Env'tl. Control*, 628 A.2d 53, 62 (Del. 1993)

*"[C]orporate officer who had broad, general authority for the Raintree project and direct knowledge of the disposal trenches" not liable, for violations of public nuisance law, where "he did not direct, control, approve, consent to, or ratify the decision to dispose of the construction waste."*

*People ex rel. Madigan v. Tang*, 346 Ill. App. 3d 277, 288 (2004)

Corporate CEO not liable for **environmental violations** under Illinois statute. **Plaintiff failed to show the defendant's "personal involvement or active participation in the acts resulting in liability."** General allegations that defendant had the power to control the company or general responsibility for supervising its conduct were not enough to support liability.

# *Claims By Opioid Users And Their Families*

---

## Types of Claims Brought

- Strict products liability
- Failure to warn
- Breach of implied warranty
- Breach of express warranty
- Fraud
- Negligent marketing

## Claims Have Historically Been Unsuccessful

Opioid users and family members have been unable show causation because of:

- Prescribing physicians' awareness of the risks of opioids
- The absence of evidence that a physician's decision to write a prescription was caused by deceptive marketing
- Patients' misuse of OxyContin contrary to label warnings
- Patients' concurrent use of multiple opioids
- Warnings on the OxyContin label
- The learned intermediary doctrine

## Claims Have Historically Been Unsuccessful

- Doctors testified they were aware of the risks of opioids
- No evidence the prescriber would have acted differently with different warning
- Intentional misuse of medication, breaking the chain of causation
- Patient taking multiple opioids

*United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569, 575 (W.D. Va. 2007)

"As to any individuals injured by the use of OxyContin, the difficulties of establishing causation are demonstrated by numerous civil suits that have been filed by such persons against Purdue.... **Courts have consistently found that despite extensive discovery, plaintiffs were unable to show that Purdue's misbranding [from 1995 to 2001] proximately caused their injuries.**"

## Cases in 2003–08 Found No Causation in Patient/Survivor Claims

*Bodie v. Purdue Pharma Co.*, 236 Fed. App'x 511 (11th Cir. 2007)

No proof of causation because **patient's doctor testified he was aware of the risks of opioids, and prescribing decision unaffected by Purdue promotional literature**

*Foister v. Purdue Pharma, L.P.*, 295 F. Supp. 2d 693 (E.D. Ky. 2003)

No causation where **patients misused OxyContin contrary to label warnings** and warning to doctors was adequate

*Labzda v. Purdue Pharma, L.P.*, 292 F. Supp. 2d 1346 (S.D. Fla. 2003)

**Manufacturers not obligated to police prescribers; patient's intentional misuse broke causal chain**

*Koenig v. Purdue Pharma Co.*, 435 F. Supp. 2d 551 (N.D. Tex. 2006)

**Plaintiff failed to show OxyContin marketing caused doctors to prescribe it to him**

*McCauley v. Purdue Pharma, L.P.*, 331 F. Supp. 2d 449 (W.D. Va. 2004)

Failure to establish causation against Purdue where **patients took multiple opioids concurrently**

*Boysaw v. Purdue Pharma*, 2008 WL 4452650 (W.D. Va. Sept. 30, 2008), *aff'd*, 320 F. App'x 178 (4th Cir. 2009)

No proof of causation against Purdue because patient was taking **multiple opioids** in addition to OxyContin

*Timmons v. Purdue Pharma Co.*, 2006 U.S. Dist. LEXIS 3965, (M.D. Fla. Feb. 2, 2006)

Failure to show causation where **prescribers were aware of risks and were not influenced by Purdue marketing**

*Cornelius v. Cain*, 2004 WL 48102 (Fl. Cir. Ct. Jan. 5, 2004)

OxyContin **label warnings were adequate, doctors were aware of risks, and learned intermediary doctrine broke chain of causation**

*Harris v. Purdue Pharma, L.P.*, 218 F.R.D. 590 (S.D. Ohio 2003)

Finding lack of commonality in class action based on learned intermediary doctrine; **plaintiffs would have to show that each plaintiff's doctor was deceived**

## *In re Purdue Pharma LP, et al.*

---

Joseph Hage Aaronson LLC

Counsel to Raymond Sackler Family ("Side B")

**Defense Presentation Part 6: Causation, Statutory Consumer Fraud, Public Nuisance, Claims By Opioid Users And Their Families**

April 27, 2021