

# Lawsuits Against Drug Companies for Their Role in the Opioid Crisis

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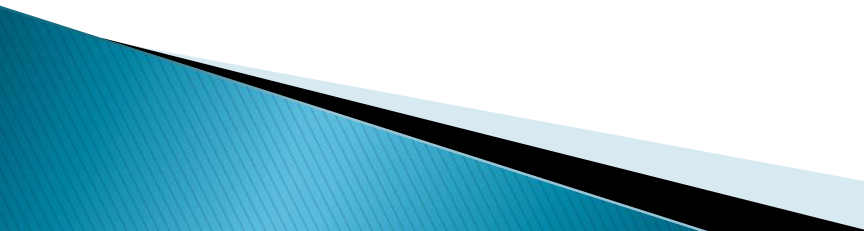
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# What is the precedent?

## ▶ Tobacco Litigation

- 1998: settled with 46 states, 6 other jurisdictions
  - Annual payments forever for public health programs
- Basis: They were responsible for healthcare costs
- Resulted in immunity from further lawsuits
  
- NOTE:
  - Users were using their product as directed
  - Consumers were the target of their ad campaigns

# Bases for Suits vs. Drug Companies May Include:

- ▶ Their drugs are responsible for enormous costs to state and local jurisdictions due to addiction/overdose
  - ▶ False advertising, indicating drugs are safer and more effective than they are
  - ▶ Know drugs are being funneled to black market but have done nothing to stop it
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# Are these claims true?

## Opioid costs

- ▶ Opioids are in fact responsible for enormous costs to state/local jurisdictions
  - EMTs/firemen called to sites of overdoses
  - Police called to sites of illegal activity
  - Crime associated with drug addiction
  - Medicaid costs due to drug addiction, its consequences, and its treatment
  - Public funding for drug control programs, take-back days, etc.
  - Incarceration and drug-court costs

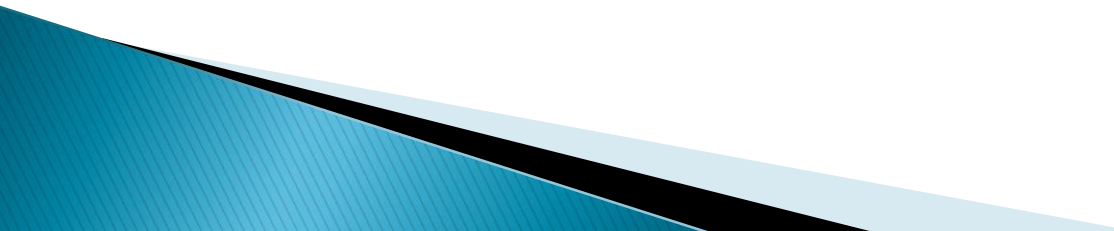
# Are these claims true?

## False advertising

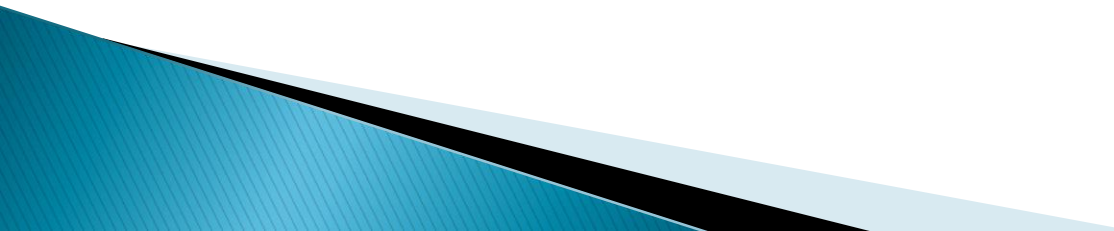
- ▶ Purdue Pharma, in particular, claimed that Oxycontin was “less prone to abuse” due to long-acting effect, also quoted “Porter & Jick”
- ▶ Also claimed 12-hr. effect when they knew it was shorter (allegedly promoting abuse)
- ▶ Several companies under investigation for promoting their opioids for uses not approved by FDA
- ▶ One company (Insys) set up a “reimbursement unit” allegedly defrauding insurers by saying use was for cancer when it wasn’t

# Are these claims true?

## Funneling drugs to black market

- ▶ This is extremely difficult to prove
  - ▶ In some cases, highly disproportionate # of pills are going to low-population areas
  - ▶ Making case that this is the companies' responsibility to police is extremely difficult
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# Problems with Suing Drug Companies, distributors, etc.

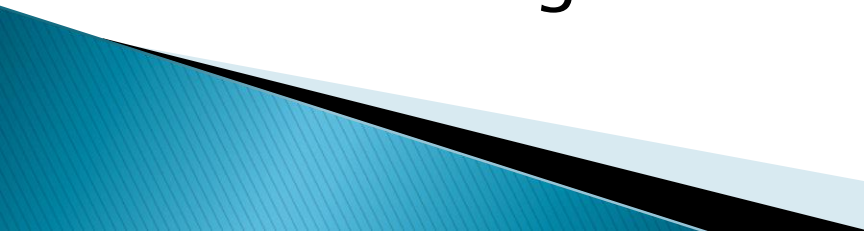
- ▶ The patients are abusing the drugs, not taking them as recommended.
  - ▶ Courts tend to consider patients as responsible for their own addiction (though this is highly suspect)
  - ▶ Advertising was directed at doctors, not the patients
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# Problems with Suing Drug Companies, distributors, etc.

- ▶ There's a lot of blame to go around
  - The scientific community accepted opioids as “safe and effective” based on very dubious evidence and overlooked growing evidence to the contrary
  - JCAHO and CMS adopted “5<sup>th</sup> Vital Sign” and required caregivers to aggressively treat pain, with severe punishment for not doing so
  - Pharmacies and distributors failed to report suspicious prescriptions, orders, etc.
  - The FDA continued to allow additional opioids to come out despite little evidence of long-term benefit
  - Some doctors continued to prescribe despite little evidence of benefit and often didn't screen for developing evidence of addiction (though most were just doing what they'd been taught by scientific community)



# Drug Companies' Defense Stance

- ▶ Our drugs were approved by the FDA.
  - ▶ They weren't taken as prescribed.
  - ▶ Doctors are responsible for how many are used.
  - ▶ Pharmacists are responsible for determining if a prescription is appropriate.
  - ▶ We have worked with the FDA in developing Risk Evaluation and Mitigation Strategy training for prescribers in safe use.
  - ▶ Purdue has already been sued for misleading advertising from 1995–2001 and settled.
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# Companies Sued

## Company

## Drug(s) Involved

Purdue Pharma

OxyContin (oxycodone)

MSContin (morphine)

Butrans (buprenorphine patch)

Hyslingla (hydrocodone)

Targiniq (oxycodone/naloxone)

Abbot

OxyContin (oxycodone) *they co-marketed it with Purdue*

Janssen (Johnson & Johnson)

Duragesic (fentanyl patch)

Nucynta (tapentadol)

Cephalon (Teva)

Actiq (fentanyl sucker)

Fentora (fentanyl oral patch)

Endo

Percocet (oxycodone/acetaminophen)

Percodan (oxycodone/aspirin)

Opana (oxymorphone)

Zydone (hydrocodone/acetaminophen)

Allergan

Kadian (morphine)

several generic opioids

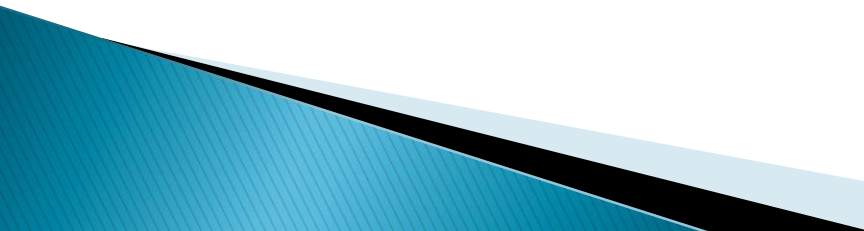
Insys

Sybsys (fentanyl sublingual spray)

# Lawsuits

- ▶ 2001 Purdue settled with WV \$10 million for creating a “public nuisance” with marketing
- ▶ 2007 Purdue
  - \$19.5 million to 26 states and DC for encouraging overprescribing
- ▶ 2007 Purdue
  - \$600 million in fines and payments to federal and state agencies for misleading advertising
  - \$130 million to resolve civil lawsuits


# Lawsuits

- ▶ 2015 Judge halts lawsuits by Orange and Santa Clara counties in CA to allow FDA to finish studies on long-term effectiveness
  - ▶ 2015 Kentucky settles with Purdue for misleading the public about addictiveness of OxyContin
  - ▶ 2015 Oregon settles w/ Subsyst for off-label promotion
  - ▶ 2016 Judge allows IL lawsuit similar to those from CA to proceed
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# Lawsuits

- ▶ 2016 IL sues Insys for promoting Subsys for non-cancer pain (not approved by FDA)
- ▶ 2016 Suffolk County, NY sues 11 drug companies for misleading public and doctors about addictiveness of opioids
- ▶ 2016 St. Clair County, IL sues Abbot and Purdue for OxyContin marketing
- ▶ 2017 New Hampshire settles w/ Insys for \$2.9 million for off-label marketing
- ▶ 2017 Shareholders of Insys sue for violating securities laws

# Lawsuits

- ▶ 2017 Everett, WA sues Purdue for allowing OxyContin to be funneled into black market
  - ▶ 2017 Cherokee Nation sues distributors and pharmacies in tribal court over opioid epidemic
  - ▶ 2017 Ohio sues Purdue, Teva, and J&J for misleading risks and benefits of opioids
  - ▶ 2017 Mississippi sues opioid makers for misrepresenting dangers of opioids
  - ▶ 2017 Missouri sues Endo, Purdue, and Janssen for lying about risks of opioids
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# Lawsuits

- ▶ 2017 BatesCarey LLP, a natl. insurance coverage law firm, opens “Opioid Coverage Task Force” to monitor opioid litigation risk