

# Opioid Crisis: Lawsuits and Solutions

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This article deals with opioid actions against manufacturers, distributors and healthcare providers. And it reviews some solutions to the current opioid crises by federal, state and local governments, medical organizations, consumer advocates and the public.

## ***1. Opioid actions against manufacturers and distributors***

Like Big Tobacco, states and cities have recently begun fighting the worst opioid epidemic in U.S. history by suing the multibillion-dollar drug companies, including both the manufacturers and distributors that market and distribute dangerous opioid medications for pain. About two-thirds of the 64,000 people that died of drug overdoses in 2016 were linked to legally prescribed opioids.

Hundreds of lawsuits have already been filed across the U.S. against opioid makers and distributors. For example, in 2007, Purdue Pharma paid a penalty more than \$630 million for misleading marketing.

In 2017, McKesson agreed to pay a \$150 million settlement to the Department of Justice for failing to report suspicious orders of pharmaceutical drugs, particularly opioids. In 2008, McKesson paid an over \$13 million fine for similar violations.

Mississippi, Oklahoma, Missouri, New Hampshire, and other states as well as local jurisdictions filed lawsuits. Kentucky previously settled with Purdue (for \$24 million) and Janssen (for nearly \$16 million) in cases alleging misleading marketing.

In May 2017, the Ohio Attorney General<sup>1</sup> filed a lawsuit against Purdue Pharma L.P., The Frederick Company, Inc., Teva Pharmaceutical Industries, Ltd., Cephalon, Inc., Johnson & Johnson, and several other companies, alleging that defendants:

- (a) Used Multiple Avenues To Disseminate False And Deceptive Statements About Opioids;
- (b) Marketing Scheme Misrepresented The Risks And Benefits Of Opioids;
- (c) Targeted Susceptible Prescribers And Vulnerable Patient Populations;
- (d) Knew That Their Marketing Of Opioids Was False And Deceptive, They Fraudulently Concealed Their Misconduct;
- (e) Deceptive Marketing Scheme Has Fueled The Opioid Epidemic And Devastated Ohio Communities;
- (f) Unlawful Opioid Promotion And Scheme Has Caused Substantial Economic Injury To State Agencies; and

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(g) Their Fraudulent Marketing Has Led To Record Profits.

In January, 2018, Mayor Bill de Blasio announced that New York City is suing manufacturers and distributors of opioids in an effort to recoup some of the costs associated with the deadly epidemic.

In May 2018, U.S. state attorneys general of Nevada, Texas, Florida, North Carolina, North Dakota and Tennessee alleged that Purdue Pharma LP, maker of OxyContin, violated state consumer protection laws by falsely denying or downplaying the addiction risk while overstating the benefits of opioids. The company was accused of fueling a national opioid epidemic by deceptively marketing its opioids to generate billions of dollars in income. It encouraged doctors to overprescribe the pills and persuaded patients to think the pills were safe and effective.

In May 2018, Florida sued Endo Pharmaceuticals Inc, Allergan, units of Johnson & Johnson and Teva Pharmaceutical Industries, and Mallinckrodt, as well as drug distributors AmerisourceBergen Corp, Cardinal Health Inc and McKesson Corp. Opioid distributors supplied an inordinate amount of opioids, even when they should have known they were going to people who were misusing the drugs. They allegedly violated the law by letting opioids proliferate.

Manufacturers and distributors argue in defense that they merely manufacture and sell opioids, respectively. They have no direct contact with patients and their opioids cause mainly pseudo-addiction and not addiction. Furthermore, pharmacists dispense the opioids. The latter are legally prescribed by doctors who are considered "Learned Intermediaries". Pharmacists and doctors have always known that opioids are addictive and have numerous side effects which may lead to overdose and death. For centuries, it has been commonly known by the public that opiates/opioids are addictive. Finally, the manufacturers and distributors argue that patients receive informed consent from the doctors and enter into treatment agreements for opioids in an attempt to prevent catastrophic outcomes. And, many individuals resort to illicit and highly addictive opioid drugs which lead to overdose and death.

## 2. *Liability of Healthcare Providers*

Physicians who *under-prescribe* pain medications may confront monetary, licensure and privileges risks. Those who *overprescribe* may additionally face criminal liability.<sup>2</sup>

### (a) *Liability for Under-prescribing*

- **Negligence (Malpractice).** In 1991, a 74-year-old man suffering from pain due to metastatic prostate cancer was admitted to a nursing home in North Carolina. His pain opioid treatment was reduced and substituted with headache medication and placebos despite multiple protests. The original prescriber of the opioid had followed established WHO guideline. The nursing home was found guilty of negligence for failure to provide proper pain treatment. The plaintiffs were awarded \$15 million.<sup>3</sup>

- **Elder Abuse.** In 2001, an 85 year old male was hospitalized in California with terminal lung cancer, respiratory disease, and suspected metastatic back pain. The family requested continuous administration of IV Demerol, whether the patient was awake or not. The physician refused and prescribed the opioid on an as needed basis, due to the risk of respiratory depression and death. After the patient died, the family sued the physician. All expert witnesses and the California Medical Board agreed that the physician met the standard of medical care owed to the patient. However, the plaintiff's attorney used elder abuse statutes arguing that the physician violated those statutes by not prescribing IV Demerol on a continuous basis. The plaintiffs were successful, and were awarded \$1.5 million by a jury.<sup>4</sup> Of note, elder abuse may not be covered by malpractice insurance.
- **State Board Disciplining.** Patients may file complaints to the State medical boards against physicians who under-prescribe, which may result in disciplining physicians with fines, suspension of licensure, and remedial class work. For example, in 1999, the Oregon Board of Medical Examiners disciplined a doctor for under-prescribing narcotics for six patients.<sup>5</sup> One patient was an 82-year-old male with CHF who wanted narcotics because "he could not breathe". Another 35-year-old female patient was on a ventilator and wanted pain medicine and anxiolytics for "wheezing." The physician was disciplined and ordered by the Board to complete (1) communication training, (2) a physician education program, and (3) a psychiatric evaluation as part of his retraining process.
- **Quality of Care.** Some patients may equate good medical care with more pain medications. Others may develop behavioral issues upon tapering their medication is tapered and may request to revert back to the previous dose of opioids. Such patients may accuse the physician of a lack of empathy and poor quality of pain treatment resulting in complaints to hospital administrators.<sup>6</sup> That may result in peer review and limitation or loss of privileges. Lawsuits may also be filed due to a patient's misconceptions of proper care which do not match the physician's.<sup>7</sup>

**(b) Liability for Overprescribing**

- **Addiction.** In a landmark case, in 2015, the West Virginia Supreme Court<sup>8</sup> held for the first time that physicians may be liable for 'causing' addiction. Twenty-nine admitted drug addicts and criminals sued four physicians and three pharmacies for their addiction to controlled substances. The Court ruled that patients who become addicted are able to sue doctors and pharmacies for addiction related damages despite evidence that the plaintiffs were using the medications themselves illegally.
- **Overdose.** Physicians have been sued or prosecuted for their negligence concerning overdose of prescribed opioids. For example, in Maine, in 2012, a woman sustained during sleep temporary respiratory depression from opioids which led to brain damage. She sued her family physician who was found liable; \$1.9 million dollars were awarded in damages. In Alabama, in 2012, a male patient overdosed on opioids and died. His wife sued his physician. The jury found the physician liable, and awarded the decedent's

wife \$500,000 in damages.<sup>9</sup>

- ***Third party liability and Duty to Warn.*** Overprescribing may cause injury to a third party. Prescribing and dispensing opioids should be accompanied by documented warnings of impairment when driving. Physicians can be liable if the drugs or combinations of drugs they prescribe are inappropriate or if they do not warn of possible side effects. For example, in 2007 in Massachusetts, a physician prescribed oxycodone to a 75 year-old male with metastatic lung cancer. While driving, the patient fell asleep at the wheel and struck a pedestrian. The third party pedestrian sued the physician for negligently prescribing narcotics without warning of possible sedative side effects. The Court found that physicians do have a duty of reasonable care to everyone foreseeably put at risk by the medications prescribed.<sup>10</sup>
- ***Criminal liability.*** From 2004 to 2016, over 240 criminal cases have involved convicted physicians.<sup>11</sup> This is compounded by risks of civil lawsuits and loss of licensure. For example, in 2015, criminal charges were brought against a California physician who was accused of negligence due to ignoring numerous ‘red flags’, resulting in some 8 opioid overdose deaths and over a dozen illegal prescription counts. She was sentenced to 30 years in prison for second-degree murder.<sup>12</sup>
- ***Federal DEA license Revocation.*** Controlled substances can only be prescribed by DEA licensed physicians “for a legitimate medical purpose” and “within the usual course of professional practice”. In 2015, the largest DEA initiative was conducted under the name ***Operation Pilluted*** in Arkansas, Alabama, Louisiana, and Mississippi.<sup>13</sup> It lasted 15 months and involved over 1000 federal agents. Search warrants were issued based on phone calls and complaints about exceedingly easy access to oxycodone, xanax and Percocet. The operation resulted in 280 arrests including 22 doctors. In Delaware, 2 undercover agents were able to receive controlled substances without having any examinations or tests performed and providing no medical history, resulting in prison sentences.<sup>14</sup> Other examples of physicians receiving varying prison sentences have occurred in Florida, Alabama, Utah, California, and Kansas.
- ***State Board Disciplining.*** Overprescribing can lead to censure, fines, and restrictions on licenses to practice medicine. For example, a physician who is found to prescribe controlled substances without a physical examination or indication that the drugs were therapeutically required may be guilty of unprofessional conduct warranting the revocation of his/her license.<sup>15</sup> Physician may be fined, placed on probation for 1-2 years, sent to remedial CME courses for prescribing excessive amounts of opioids, restricted from prescribing narcotics, and subjected to frequent medical board monitoring.

### 3. Solutions

The role of clinicians in solving the current opioid crisis is pivotal. Why? Because almost 80 percent of heroin addicts begin with prescription pain medications, and 75 percent of opioid misuse starts with people taking medications that were intended for others.<sup>16</sup>

- **Solution #1: Utilize the *Prescription Drug Monitoring Program (PDMP)*<sup>17</sup>**

PDMPs are state-controlled. As of April 2018, 49 states have PDMPs; Missouri does not have a statewide PDMP but St. Louis County, Missouri has one. The PDMP is an electronic database which tracks controlled substance prescriptions in a state. It is one of the most promising state-level interventions to improve opioid prescribing, inform clinical practice and protect patients at risk.

The ***Oklahoma PDMP*** (aka **PMP**) was established in 1990 to monitor Schedules II, III, IV, and V drugs. It is overseen by the Oklahoma Bureau of Narcotics and Dangerous Drugs. Effective 2015, Oklahoma law states:

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- 'the PMP check has become mandatory for new patients or after 180 days elapsed since PMP check for patient prior to physician prescribing one of the following: opiates, synthetic opiates, semi-synthetic opiates, benzodiazepine, or carisoprodol (with exclusions for Hospice or end-of-life, or patients residing in nursing facility).
  - Physicians may designate a staff member to run the patient PMP on the physician's behalf.
  - Physicians may include a copy of the patient's PMP in the patient's medical record.
  - Under this act, access to the OBN PMP was granted to medical practitioners and their staff employed by federal agencies treating patients in the state of Oklahoma.'

As of 2016, eighteen states have authority to share data with other PDMPs, Oklahoma included.<sup>18</sup>

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- **Solution #2 - Implement CDC Guideline for Prescribing Opioids for Chronic Pain<sup>19</sup>**

In 2016, the *Centers for Disease Control and Prevention* (CDC) published Online its ***CDC Guideline for Prescribing Opioids for Chronic Pain*** to establish clinical standards for balancing the benefits and risks of chronic opioid treatment. According to the CDC guidelines:

"Improving the way opioids are prescribed through clinical practice guidelines can ensure patients have access to safer, more effective chronic pain treatment while reducing the risk of opioid use disorder, overdose, and death. More than 11.5 million Americans, aged 12 or older, reported misusing prescription opioids in 2016."

The CDC guidelines have been approved by the Federation for State Medical Boards and by several states and medical organizations. Failure to follow the CDC guideline may lead to civil liability, hospital peer review and actions by the State Medical Licensing Board.

- **Solution #3 - Use the *Opioid Overdose Prevention Toolkit, published Online*<sup>20</sup>**

In 2018, *The Substance Abuse and Mental Health Services Administration* (SAMHSA) published an update of the ***Opioid Overdose Prevention Toolkit***. The toolkit offers strategies to health care providers, communities, and local governments for developing practices and policies to help prevent opioid-related overdoses and deaths.<sup>21</sup> It includes:

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- a. [Opioid Use Disorder Facts](#)(PDF, 204 KB)

- b. [Five Essential Steps for First Responders](#)(PDF, 214 KB)
- c. [Information for Prescribers](#)(PDF, 210 KB)
- d. [Safety Advice for Patients & Family Members](#)(PDF, 144 KB)
- e. [Recovering From Opioid Overdose](#)(PDF, 187 KB)
- f. [Opioid Overdose Prevention Toolkit - Full Document](#)(PDF, 424 KB)

The Journal of the OSMA published the full toolkit document in the 2018 September-October issue. SAMHSA also observes annually a National Prevention Week (NPW)<sup>22</sup> dedicated to increasing public awareness of, and action around, mental and/or substance use disorders. The next NPW is scheduled on **May 12-18, 2019** to raise awareness about the importance of substance use prevention and positive mental health.

- **Solution #4 - Know the FDA Risk Evaluation and Mitigation Strategy (REMS).**

The FDA *Risk Evaluation and Mitigation Strategy* (REMS) was established under the *Food and Drug Administration Amendments Act* (FDAAA) of 2007. REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use.<sup>23</sup> On September 18, 2018, the FDA approved the *Opioid Analgesic REMS*,<sup>24</sup> in hopes of decreasing the risk of abuse, misuse, addiction, overdose, and deaths due to prescription opioid analgesics. The REMS program requires that training be made available to all health care providers (HCPs) who are involved in the management of patients with pain, including nurses and pharmacists.

- **Solution #5 - Drug Courts**

The Oklahoma "adult drug court programs provide eligible, non-violent, felony offenders the opportunity to participate in a highly structure, court supervised treatment program in lieu of incarceration. Since the inception of the first program in 1995, Oklahoma's adult drug court programs have expanded to 73 of the 77 counties in the state."<sup>25</sup> Locking up addicts in jail and prisons instead of providing the treatment they desperately need is the wrong way to deal with the addiction epidemic.<sup>26</sup> The drug courts are excellent alternatives to incarceration of individuals with substance abuse disorders; they provide treatment and rehabilitation with significant success and much less cost than imprisonment.

**Finally**, the medical school core curriculum should include managing pain effectively by utilizing multidisciplinary teams, without opioids whenever possible, and training the students to qualify for waivers to manage opioid use disorders after graduation. And postgraduate continued medical education of clinicians on pain management is paramount. Both the Oklahoma Medical Board (OMB) and the OSMA also provide timely continuing pain management educational programs. The OMB is an excellent resource for legal and medical guideline information about pain management.<sup>27</sup>

<sup>1</sup> <https://www.wsj.com/articles/ohio-sues-five-drug-firms-saying-they-fueled-opioid-crisis-1496248317>

<sup>2</sup> [https://www.huffingtonpost.com/entry/medical-legal-risks-of-prescribing-pain-medications\\_us\\_59c908cee4b0b7022a646c36](https://www.huffingtonpost.com/entry/medical-legal-risks-of-prescribing-pain-medications_us_59c908cee4b0b7022a646c36)

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- <sup>3</sup> Estate of Henry James v. Hillhaven Corp. In: CVS, North Carolina Supreme Court, 1991:64.
- <sup>4</sup> Bergman v. Wing Chin, MD and Eden Medical Center. In: California Supreme Court, 1999.
- <sup>5</sup> Oregon Board Disciplines Doctor for Not Treating Patients' Pain. In: The New York Times, 1999.
- <sup>6</sup> Group WSAMDs. Interagency Guideline on Opioid Dosing for Chronic Non cancer Pain. In: Washington State Agency Medical Director's Group, 2010:55.
- <sup>7</sup> Sohn DH. Negligence, genuine error, and litigation. Int J Gen Med 2013;6:49-56.
- <sup>8</sup> Tug Valley Pharmacy et al v All Plaintiffs. In: LEXIS, West Virginia Court of Appeals, 2015.
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- <sup>11</sup> Cases Against Doctors. In: U.S. Department of Justice DEA, ed. U.S. Department of Justice, Drug Enforcement Administration., 2016:101.
- <sup>12</sup> Gerber M, Girion L, Queally J. California doctor convicted of murder in overdose deaths of patients. In: Los Angeles Times, Los Angeles: Los Angeles Times, 2015.
- <sup>13</sup> Officer PI. DEA Announces Largest-Ever Prescription Drug Operation. 2015. Available from: <https://www.dea.gov/divisions/no/2015/no052015.shtml>. 2016.
- <sup>14</sup> Rose A. Delco doc convicted of 99 drug counts in pill mill case. In: Delaware County Daily Times, Delco County Daily Times.
- <sup>15</sup> Kolnick v. Board of Medical Quality Assurance. In: California Court of Appeals, 1980.
- <sup>16</sup> <https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.htm#summary>
- <sup>17</sup> [https://www.ok.gov/obnnd/Prescription\\_Monitoring\\_Program/PMP\\_Mandatory\\_Check.html](https://www.ok.gov/obnnd/Prescription_Monitoring_Program/PMP_Mandatory_Check.html)
- <sup>18</sup> <http://www.namsdl.org/library/8C2F8F5B-F426-FC5F-226056040DF15FD6/>
- <sup>19</sup> <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>
- <sup>20</sup> <https://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA18-4742>
- <sup>21</sup> Opioid Overdose Prevention Toolkit<https://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA18-4742>
- <sup>22</sup> <https://www.samhsa.gov/prevention-week>
- <sup>23</sup> <https://www.fda.gov/AboutFDA/Transparency/Basics/ucm325201.htm>
- <sup>24</sup> <https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm>
- <sup>25</sup> [https://ok.gov/odmhsas/Substance\\_Abuse/Oklahoma\\_Drug\\_and\\_Mental\\_Health\\_Courts/Adult\\_Drug\\_Court/index.html](https://ok.gov/odmhsas/Substance_Abuse/Oklahoma_Drug_and_Mental_Health_Courts/Adult_Drug_Court/index.html)
- <sup>26</sup> <http://www.foxnews.com/opinion/2018/07/07/dr-marc-siegel-opioid-crisis-has-solution-here-it-is.html>
- <sup>27</sup> <http://www.okmedicalboard.org/>