

NOTHING HEREIN SHOULD BE CONSTRUED AS LEGAL ADVICE

# The Opioid Crisis - Legal Issues and Recent Developments

Brad Honnold

Goza & Honnold, LLC

[bhonnold@gohonlaw.com](mailto:bhonnold@gohonlaw.com)



# THE OPIOID CRISIS

- Everyday, more than 90 Americans die from opioid overdose
- Misuse of and addiction to opioids - including prescription pain medications, heroin, and synthetic opioids such as fentanyl - is a serious public health crisis that threatens our social and economic welfare
- The CDC estimates the "economic burden" of prescription opioid misuse in the U.S. in \$75.5 billion, a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement
- How did this happen? In the late 1990's, pharmaceutical companies reassured the medical community that prescription opioid pain relievers were rarely addictive and prescriptions for these substances increased



# THE OPIOID CRISIS

- Over time, diversion and misuse of these medications became rampant before it became clear that these medications could be highly addictive
- Opioid overdose rates increased dramatically



# OPIOID CRISIS STATISTICS

- In 2015, more than 33,000 Americans died as a result of an opioid overdose, including prescription opioids, heroin, and illicit fentanyl
- In 2015, 2 million people in the U.S suffered from substance use disorder related to prescription opioid pain relievers, and 591,000 suffered from heroin use disorder
- 21 to 29 percent of patients prescribed opioids for chronic pain misuse them
- Between 8 and 12 percent develop an opioid use disorder
- An estimated 4 to 6 percent who misuse prescription opioids transition to heroin
- About 80 percent who use heroin first misused prescription opioids

Source: National Institute on Drug  
Abuse, June 2017



# MISSOURI AND KANSAS REGULATION OF CONTROLLED SUBSTANCES

- In Missouri, a controlled substance is a drug or other substance that comes under the jurisdiction of the Federal Controlled Substances Act of 1970
- Regulated substances include narcotics, depressants, stimulants, hallucinogens and anabolic steroids
- Schedules I thru V vary based upon potential for abuse and medical usefulness. Schedule I substances have a high potential for abuse and no accepted medical use in the U.S Schedules II-V have an FDA - approved therapeutic use and decreasing levels of abuse potential
- In Missouri, the Comprehensive Drug Control Act of 1989, administered by the Bureau of Narcotics and Dangerous Drugs in the Missouri Department of Health and Senior Services, closely parallels federal law
- The statutes are in Chapter 195 RSMO ; state regulations are in 19 CSR 30 - 1.00 through 1.078



# MISSOURI AND KANSAS REGULATION OF CONTROLLED SUBSTANCES

- Controlled substance list is at RSMO Sec. 195.017 and listed by schedule ; can also be found at [www.health.mo.gov/BNDD](http://www.health.mo.gov/BNDD)
- In Missouri, controlled substance offense statutes are in Chapter 579 RSMO
- In Kansas, the state controlled substances authority is the Kansas Board of Pharmacy . The Kansas controlled substance statute is at K.S.A 65 - 4101 et seq. and the controlled substance rules are at K.A.R 68-20-1 et seq.



# KANSAS CONTROLLED SUBSTANCE TRACKING

- Kansas does have a prescription drug monitoring program in operation since October 2010
- The Kansas prescription monitoring program statute is at K.S.A 65-1681 through 65-1694
- The program, called K - TRACS, also has a detailed website and dispenser's guide at [www.pharmace.ks.gov/k-tracs](http://www.pharmace.ks.gov/k-tracs)
- K-TRACS regulations are at K.A.R 68-21-1



# MISSOURI CONTROLLED SUBSTANCE TRACKING

- Missouri does not have a state-wide monitoring program. However, St. Louis county has adopted a prescription drug monitoring program, CPDMP, by ordinance. To date, 34 of Missouri's 114 counties have joined the program by adopting a similar ordinance
- The Missouri legislature has tried for years to pass a statewide PDMP



# THE WEST VIRGINIA LITIGATION

- Cabell County Commission v. AmerisourceBergen Drug Corporation, et al.
- U.S. District Court for the Southern District of West Virginia, Case 2:17 - cv - 11111 , filed March 9 , 2017
- Cabell County Commission is a public corporation and political subdivision ; not an agency or agent of the state
- Suit names ten defendants , collectively referred to as "Defendant Wholesale Distributors " that comprise the chain of distribution of prescription opiates, primarily hydrocodone and oxycodone , and known to have sold 40 million doses to Cabell County between 2007 and 2012
- Alleges a duty under 21 U.S.C. 823 to monitor , detect , refuse and report suspicious orders of prescription opiates
- Alleges foreseeable harm of breach of this duty is diversion of the prescription opiates for nonmedical purposes



# THE WEST VIRGINIA LITIGATION

- Claims damages in the form of significant rates of "drug poisoning", opiate abuse, addiction, morbidity and mortality that is a temporary public nuisance and hazard to public health and safety
- Seeks economic, noneconomic and punitive damages to eliminate the public health hazard and to abate the public nuisance caused by the opioid epidemic



# THE OHIO LITIGATION

- State of Ohio, ex rel . Mike DeWine, Ohio Attorney General v Purdue Pharma L.P. , et al
- In the common Pleas court of Ross County , Ohio , Civil Division
- Suit names 18 defendant pharmaceutical manufacturers including Purdue , Tera , Cephalon , Johnson & Johnson , Janssen , Endo , Allergan and Watson
- Complaint includes extensive factual allegations regarding defendants' marketing strategies , use of independent third parties including key opinion leaders and front groups
- Defendants alleged to have misrepresented risks and benefits of opioids , targeted vulnerable prescribers and patients and engaged in a false and deceptive marketing scheme



# THE OHIO LITIGATION

- Six specific causes of action

- Statutory Public Nuisance
- Common Law Public Nuisance
- Unlawful Consumer Sales Practices
- Medical Fraud
- Common Law Fraud
- Violations of Ohio Corrupt Practices Act ( Pattern of Racketeering Activity )

- Broad Damage Allegations

- State Medical and Bureau of Workers' Compensation suffered financial harm due to unnecessary opioid prescriptions
- Ohio consumers paid for unnecessary prescriptions
- seek abatement of public nuisance
- seeks compensatory, punitive, and treble damages and attorneys' fees



# THE MISSOURI LITIGATION

- The State of Missouri, ex rel. Joshua D. Hawley, in his official capacity as Missouri Attorney General v. Purdue Pharma, L.P., et al.
- Filed June 21, 2017 in the Circuit Court of St. Louis City
- Purdue, Endo, Janssen and Johnson & Johnson named as defendants
- "Missouri faces an urgent public health crisis."
- In 2014, nearly half of all opioid related hospitalizations and ER visits in Missouri occurred in the St. Louis area, and the State of Missouri paid for approximately one-third of those visits
- Court I - Violations of Missouri Merchandising Practices Act - Deception
- Court II - MMPA - Fraud and Fraudulent Misrepresentation
- Court III - MMPA - False Pretense
- Court IV - MMPA Misrepresentation



# THE MISSOURI LITIGATION

- Court V - MMPA - Lack of Reasonable Basis for claims of Performance
- Court VI - MMPA - Unfair Practices
- Court VII - MMPA - Concealment, Suppression, and Omission of Material Facts
- Court VIII - MMPA - Unlawful "Half-Truths"
- Court IX - Violations of Sec. 191.900 - 191.194 - False claims to Mo HealthNet Program



# IMPORTANT REGULATORY GUIDANCE AFFECTING CLINICAL PRACTICE

- CDC Guideline for Prescribed Opioids for Chronic Pain - United States , 2016
  - "This guideline provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care."
  - Also see CDC checklist for prescribing opioids for chronic pain as well as website ( <http://cdc.gov/drugoverdose/prescribingresources.html> )
- 35 page guideline with 223 references
- Represents a significant change in views regarding use of opioids for chronic pain



# KANSAS IMPORTANT REGULATORY GUIDANCE AFFECTING CLINICAL PRACTICE

- Joint Policy Statement of the Kansas Boards of Healing Arts, Nursing and Pharmacy on the use of controlled substances the the treatment of chronic pain
- Important principles for treating chronic pain:
  - Patient Assessment
  - Treatment Plan
  - Informed Consent and Agreement for Controlled Substance Treatment
  - Periodic Review
  - Consultation
  - Medical Records
  - Compliance with Controlled Substances Laws and Regulations
  - Important Definitions of Terms



# FDA POLICY INITIATIVES ON THE OPIOID EPIDEMIC

- See statement by FDA commissioner Scott Gottlieb, M.D. - FDA, taking new steps to help assess opioid drugs with abuse-deterrent properties
- FDA Opioid Action Plan
  - Expand use of advisory committees
  - Develop warnings and safety information for immediate release (IR) opioid labeling
  - Strengthen post market requirements
  - Update Risk Evaluation and Mitigation Strategies (REMS) Program
  - Expand access to abuse-deterrent formulations (ADFS) to discourage abuse
  - Support better treatment including access to Narcan (Naloxone)
  - Reassess the risk-benefit approval framework for opioid use



# FDA POLICY INITIATIVES ON THE OPIOID EPIDEMIC

- See. Califf , A Proactive Response to Prescription Opioid Abuse , N Eng J Med 2016 ; 374 : 1480 - 1485
- FDA on June 8 , 2017 request removal of Opana ER for risks related to abuse
- IMPORTANT - FDA Education Blueprint for Health Care Providers Involved in the Management or Support of Patients with Pain (May 2017)