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**Did you prescribe too many pain medications? The impact of the opioid crisis on the practicing physician.**

## I. How did we get here? (20 mins)

### Not a new issue

Morphine use was prevalent in the United States by 1900. However, modern pain management seems to parallel the availability of commercially made narcotics. In 1898, Bayer began producing heroin. It was marketed as a "wonder drug" but its addictive effects were quickly noted and heroin was declared illegal in 1924.

Injured soldiers from both World War I and World War II were among those to benefit from these drugs as well as suffer the consequences of addiction. In response to the need for pain management for soldiers returning from World War II, the first "nerve block clinic" was opened in the early 1950's.

A letter printed in the New England Journal of Medicine in January 1980 pushed back on the growing consensus that using opioids to treat chronic pain was risky. This letter noted that "the development of addiction is rare in medical patients with no history of addiction." This thinking was reinforced by a study done in 1986 which opined that opioid maintenance therapy "can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable or non-malignant pain and no history of drug abuse. "

### Purdue Pharma, Addiction, the FDA and Primary Care (The Cook, the Thief, His Wife and Her Lover)

OxyContin was introduced into the US market in 1996. At that time the FDA noted OxyContin "had a lower potential for abuse than other oxycodone products." Also helping Oxy's marketplace presence was a very aggressive campaign by Purdue Pharma. As part of their 1998 marketing campaign the company produced a video called "I Got My Life Back." This was distributed to be used by physicians (many in primary care) as an educational tool. Reportedly 15,000 copies of the video were distributed. Opioid prescriptions increased by 11 million the following year.

**Opioids for Chronic Pain**

In the same general time frame, personal injury plaintiffs and claimants with chronic pain were being referred to pain management doctors who were treating with refillable prescriptions for narcotic medications with expectations of perpetual renewals. This reality allowed for life care planners to use the expected future costs to bolster large expected future economic damages.

Unfortunately, the cure became worse than the disease. The mortality rate for individuals prescribed narcotic pain medication began to rise at an alarming rate and the death rate went under-reported for a period of time. Some of the under-reporting was due to the contributing cause being masked by trauma such as in a death from a industrial or motor vehicle accidents As of the year 2010, death was the most common outcome in medication management claims (57%) versus 9% in other chronic pain claims. Most such claims involved patients who did not cooperate in their care or who were inappropriately managed by their physicians.

The side effects alone of opioids are a functional concern as there is clear evidence of cognitive/psychomotor functional impairment associated with opiate use. Tolerance does develop in some people on stable long-term doses. While evidence of slightly slowed reactions and increased errors are noted, the significance is unclear.

The most commonly prescribed opioid medications in 1997, in order, were codeine, hydrocodone, morphine, meperidine (pethidine), oxycodone, methadone and fentanyl. By 2006, the largest by far was oxycodone with a 732% increase to 37,034,220 retail sales. The largest gains by percentage of change was methadone (used to treat addiction) and its sales increased 1,177% during that decade.

## II. Current Litigation and Its Effect (20 mins)

**Verdicts and Settlements**

Several verdicts have changed the way defense counsel, insurance companies and insured physicians and corporations look at this issue. In particular, a recent $17.6M verdict was rendered against a physician and hospital in St. Louis, MO. The appellate court confirmed the verdict which included $15M in punitive damages. Many carriers do not cover for punitive damages and the result can be devastating to the defendants, both economically and emotionally.

The majority of cases being brought, as with all medical malpractice filings, are either settled or dismissed. However, when a case is tried, the excess exposure can be daunting. The opioid epidemic is being cited in the press/media at an increasing rate. The CDC came out with guidelines, including 12 recommendations that address various aspects of opioid pain management. These guidelines have become a focal point in plaintiff cases and have become the “standard of care” for physicians. If physicians do not follow these guidelines then they will be defending their actions from a national perspective and plaintiffs will find an expert to

expound on this failure which caused damages to the patient. Given the preponderance of media coverage, a jury is already swayed toward the patient and fighting this is already formed opinion/thought process is an uphill battle for the defense bar.

**Effects on Current Prescribing Practices**

Media coverage, hospital policy and fear of litigation are changing the way physicians prescribe medications. The CDC guidelines are no longer just a guideline but are becoming the standard of care. Following these guidelines is paramount to the defense of a litigated case. The CDC guidelines put the onus of prescribing narcotics onto the primary care physician and yet do not offer strategies for managing these patients. Further assistance from the CDC does not appear to be forthcoming and so the plaintiff bar is using these guidelines as evidence of malpractice against the medical community. As a result, physicians are becoming much more cautious when prescribing narcotics. However, there are those physicians still out there overprescribing opioids.

Between 1999 and 2016 there have been over 200,000 deaths in the US from opioid overdose. The death rate from opioid overdose was 5 times higher in 2016 than in 1999. In 2012, 259 million prescriptions for opioids were written. In 2016 the number had dropped to approximately 215 million. In 2016 2 million people had a substance abuse disorder involving pain medications. The result of the opioid epidemic has resulted in the majority of physicians either not prescribing narcotics or prescribing in a very limited dose. Physicians need to be extra careful to go over the risks and benefits of opioid medications and document that discussion in their record. A physician has to seriously consider if the use of narcotics will truly benefit the patient. If the answer is no or equivocal, they need to assess if they could consider prescribing nonopioid pharmacological therapy, including, non-narcotic pain relievers and physical therapy.

Pain management physicians are in the cross hairs for becoming involved in litigation since that is their focus of practice. It is essential that they take a thorough history of the patient and document this history, as well as, properly evaluating if their pain can be controlled only through the use of narcotics. Clearly, this epidemic is not going away and the past culture from the big pharma companies is no longer tolerated by the public. Given the constant media attention on the opioid epidemic, clinicians must be cautious in the prescriptions of these medications. Continuous assessment of the patient and documentation of the treatment plan is essential to the defense of these cases, more so now than ever before.

**III The Future of Litigation (20 Minutes)**

**Changing Strategies**

Defending inappropriate prescribing vs. Defending appropriate prescribing

There are approximately 115 opioid deaths per day. As a result, significant focus is on the whether or not opioids are being appropriately prescribed by physicians and extended care providers. The plaintiff bar use to appear to be focusing on addictions to narcotics and not necessarily death cases. However many of the lawsuits being filed are for opioid overdose/unintentional death and we have seen an upswing in the filing of these actions since 2017.

States have passed laws to restrict duration of use and limiting dosage amounts. As a result, physicians and other medical providers must be aware of any laws in their state. States require medical providers to address when prescribing narcotics a discussion on informed consent including the risk/benefits of use and are establishing guidelines which are improperly being used against medical providers as the "standard of care". Unfortunately these guidelines are contradictory from state to state. For example 38 states require referral to a pain management specialist if a patient requires opioids. The rest of the states continue to allow any physician to prescribe narcotics. As a result, there truly is no standard when it comes to the prescription of narcotics in the medical community.

The CDC has established 12 guidelines for prescribing opioids. While these are merely guidelines, the plaintiff's bar is attempting to use these guidelines to prove deviations from the standard of care. These cases are being pursued as not a case about reasonable care but one of perfect care. Living up to these expectations is difficult at best and hard to achieve for medical providers. It is important for our physicians and extended care providers to realize and try to achieve to do everything reasonable NOT everything possible. There is a difference and being held to unreasonable levels is the main driving force of today's filings by the plaintiff's bar. In addition, guidelines change over time. It is essential to have access to the guidelines in question at the time of the treatment. They can vary significantly with each new version of the new guidelines.

There are several areas by which to attack these claims. The main component is a causation defense. What was the patient's past medical history? Did they have prior issues related to addiction? Did they move from medical practice to medical practice? Did they leave out significant medical history at these medical practices? Next you need to attack the damages claim. What are their pre-existing conditions? Do they have significant co-morbidities? Would any of these issues contribute to the cause of death? When defending these cases you have to think outside the box and create a strategy from when the claim comes in the door. Explore every aspect of the patient's life. This may end up helping establish a long history of dependency that was not shared from practice to practice or that the patients underlying medical issues contributed toward the deterioration in their health or death.

**Regulatory "Help"**
The Joint Commission Standards 2018

**On January 1, 2018, The Joint Commission implemented new and revised pain assessment and management standards for accredited hospitals.**

The new and revised pain assessment and management standards are reflected in the Leadership; Medical Staff; Provision of Care, Treatment, and Services; and Performance Improvement chapters of The Joint Commission hospital accreditation manual.

The standards require a Joint Commission accredited hospital to establish policies and procedures that address comprehensive clinical assessment of pain; treatment or referral for treatment; and reassessment for patients as it designates, based on patient population and scope of services provided.

The additions and revisions require hospitals to:

- Establish a clinical leadership team
- Actively engage medical staff and hospital leadership in improving pain assessment and management, including strategies to decrease opioid use and minimize risks associated with opioid use
- Provide at least one non-pharmacological pain treatment modality
- Facilitate access to prescription drug monitoring programs
- Improve pain assessment by concentrating more on how pain is affecting patients' physical function
- Engage patients in treatment decisions about their pain management
- Address patient education and engagement, including storage and disposal of opioids to prevent these medications from being stolen or misused by others
- Facilitate referral of patients addicted to opioids to treatment programs

Recent US Attorney for Massachusetts warning letter:

The letters issued by the US Attorney for Massachusetts reminded doctors that prescribing opioids without a legitimate medical purpose or in excessive amounts is illegal.

"While the amount of opioids prescribed and sold in the U.S. has quadrupled since 1999, the overall amount of pain reported by Americans during this period has not changed," the statement says. "The opioid epidemic was caused, in part, by the widespread overprescription of opioid-based medications."

The letters reflect a heightened focus on doctors' prescription practices by federal prosecutors around the country, although they do not appear to be directly connected to any coordinated effort by the US Department of Justice. The DOJ created a team last year, the Opioid Fraud and Abuse Detection Unit, to analyze data and identify doctors who may be breaking the law.

Nearly 2,000 Massachusetts residents died of opioid-related overdoses in 2017, according to the state's Department of Public Health. The share of opioid-related deaths in which prescription drugs were present has declined somewhat in recent years.

Board of Medical Practice Issues

State's Board of Medical Practice bodies are certainly not immune to the media coverage. While these bodies have always been aware of "pill mills," they are now also taking a closer look what has traditionally been considered appropriate pain management. Past infractions may be used by plaintiff's counsel as proof of prescribing too many meds.

**The current state of addiction treatment**
Opioid addition treatment centers and new emergency room resources and interventions

Addiction treatment is expensive and complicated to administer. Locating the appropriate physician, paying for treatment and following addicts throughout recovery is proving to be a complicated task for those policy makers interested in tackling this project.

As an example, a 2015 study published in JAMA followed 329 opioid addicted patients in an urban teaching hospital between April 7, 2009 and June 25, 2013. The study suggested that addicted patients who were given buprenorphine in the emergency room setting were twice as likely to be in treatment a month later than those who were simply handed an informational pamphlet.

This study and others like it have led to the creation of education and resources available to those addicted to prescription narcotics. Currently such programs are available only in large urban areas.

## V. Ending thoughts?

The opioid crisis impacts practicing physicians. Claims involving opioid prescribing practices are increasing. However, there are things we can do to protect our client physicians. First, we need to be prepared to explain to juries that physicians deal with patients in pain on an ongoing basis. They are the best suited to decide on a day to day basis what is best for that patient. In addition, prescribing practices are dependent on educational resources. Physician practice patters have been influenced by education and marketing and will continue to be influenced as new data is developed.

There has been in increase in the frequency of opioid litigation claims. Indemnity and associated costs have yet to level out. As these cases increase defense counsel will need to be aware of media coverage and how it may affect the jury pool in their respective jurisdictions.

Finally, federal and state governments continue to play a role in this issue. Close behind are guidelines by The Joint Commission and the respective boards of medical practice. The defense team needs to be aware of how current policy may be used by plaintiff's counsel.