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Opioid Lawsuits: Where Are They Going in 2019?

I. The Opioid Cases Are Coming – What do they look like?

Opioids, like Oxycodone, OxyContin and Hydrocodone, are prescription pain drugs that are essentially synthetic versions of opium. These drugs work by preventing the brain from perceiving pain in the same way as heroin, often producing not only pain relief but also euphoric effects. Although these drugs are commonly prescribed by medical professionals for pain relief, they also have significant risks such as growing tolerance, dependency, addiction, overdose and death. Patients who take these prescriptions, much like heroin, commonly require more of the drug to achieve the same effects of previous, smaller doses. This tolerance and dependency can lead to addiction, progression to cheaper street drugs, and death.

Almost all experts agree that opioids are dangerous substances that should only be prescribed for pain with a severity that is not adequately relieved by other non-narcotic pain relievers. Even when opioids are used, the lowest dosage possible should be used and elevations in dosages should only be used when absolutely necessary. Once the condition necessitating the medication is complete, the medication should be stopped as soon as possible. Should cessation of the medication not be possible, a referral to a pain specialist is often preferred. So what happens when a medical provider has a patient

that becomes addicted to opioids, elevates to street drugs like heroin, or even dies? A lawsuit may soon follow.

In late February of 2008, a worker for a large mid-western city went to his family medicine physician complaining of back pain after throwing it out while drying off after a shower. He claimed his pain was impacting his ability to do his job. The worker had been a patient of the family physician since 2001 so the physician was a natural option for further treatment after chiropractic treatment failed to alleviate the pain. The physician initially prescribed a muscle relaxer and ibuprofen after x-rays did not show any obvious abnormality. The worker called the doctor after a few days and complained that the ibuprofen didn't help on some days and asked if he could prescribe him some pain medications. The doctor wrote a prescription for 30 days of hydrocodone (Vicodin/Lortab) with one refill to be taken as needed every six hours. The physician seemed to recall a discussion with the worker about the risks and benefits of opioid medications, but did not document the details of any such conversation in the chart.

Less than a month later, the worker contacted the family physician requesting a refill while stating that he was taking double the amount of the prescribed medications. The doctor obliged. The pattern continued. The worker would complain of continued pain, stating that he was having to take more than the prescribed medication for relief and the doctor would increase the dosage. The worker attempted to cut back his opioid intake but could not tolerate withdrawal symptoms and quickly restarted the medications. Eventually another physician added a longer acting opioid, OxyContin, to the worker's regiment but the worker claimed that it wore off quicker than he would like. The family physician continued the hydrocodone prescription that was then taken in conjunction with the OxyContin. By 2012 the worker was taking 31 times the amount of opioid medications that he was taking in 2008 when the family physician first began treating him for back pain. Many of these prescriptions were written without an examination or a discussion with the patient. Eventually the worker was diagnosed with having a severe opioid use disorder and had to be admitted to a rehabilitation program.

The family physician and his employer, a large university based medical provider, were sued on four grounds: 1) failing to weigh the risks and benefits of prescribing opioids to the worker, 2) overprescribing him opioids, 3) failing to monitor him, and 4) failure to assess him for dependency. A jury returned a verdict for the worker and his wife on their claims for compensatory damages in the amounts of $938,000 for the worker and $804,000 for his wife. The family physician and his employer were found to be 67% at fault and the worker 33% at fault. The jury also awarded $15,000,000 in punitive damages.

Lawsuits are also being filed in cases nationwide on behalf of the estates of patients who overdose on opioid medications, or on heroin after becoming addicted to prescribed opioids and shifting the addiction to the less expensive and more potent street drug. One such case involved another family physician who was criminally charged with 34 counts of unlawful dispensing of drugs, health care fraud, and money laundering. Prosecutors in that case alleged that this physicians opioid prescriptions led to 68 overdose deaths. Subsequently over half of those deaths led to civil wrongful death cases against the physician and his clinic. Those cases were ultimately resolved for undisclosed amounts. There are similar cases resulting in Plaintiff's verdicts for creating an addiction, or for overdoses, in states throughout the country.

In these cases you can not only expect compensatory damages for addiction treatment, lost wages, loss of consortium, pain and suffering and other related medical treatment but also a great likelihood of punitive damages. That punitive damage exposure in those cases is exacerbated by what could not be considered "shock value damages." Much of the 15 million dollar punitive damages case involving the city worker centered around admission of opioid epidemic evidence. This arguably irrelevant yet highly prejudicial evidence took that case out of the realm of the single Plaintiff and into an arena where the Defendants were essentially held accountable for the harm caused by opioids to hundreds of thousands of non-parties around the country. Every day in America ninety-one people die of opioid overdoses. These deaths and addictions are at their highest levels ever. Certainly nearly every juror has

a friend or family member who has struggled with opioid addiction. In 2014, almost 1.3 million people required hospital care for opioid related conditions. This is a high publicity issue, and one which many jurors will want to "send a message" to the health care industry.

II. Regulatory and Criminal Issues – The First Wave

Nearly every state has enacted a number of laws impacting various areas of opioid prescriptions, usage, dosage and record keeping. These laws often limit the number of pills a health care provider can initially prescribe and how those prescriptions must be entered into a database. Many states have created electronic databases of opioid prescriptions so that patient's usage, especially from multiple medical providers, can be tracked. Failure to use these systems is often a reason for disciplinary action from the state medical board. Although many states have ruled that a physician need not abide by every state and federal rule to comply with the standard of care, it is easy to see how state and federal rules can create a theory of malpractice for a Plaintiff and their expert to create an expansive standard of care that must be followed by the medical professional. These states are also beginning to track data of the highest volume prescribers and automatically investigating a certain threshold, like the top 1%. This information will certainly be sought after by Plaintiff's attorneys in pursuing their civil cases.

The Federation of State Medical Boards has published an expansive guideline for the chronic use of opioid analgesics. Although these guidelines are not expressly stated to be the standard of care, they have incredibly detailed guidelines for patient evaluation and risk stratification, development of treatment plan and goals, informed consent, initiating an opioid trial, ongoing monitoring and adapting the treatment plan, periodic and unannounced drug testing, consultation and referral, discontinuing opioid therapy and creation of medical records. These guidelines are specific, thorough and if a medical practice is not complying with these recommendations they can expect to see them used by Plaintiff's attorneys in litigation to their advantage.

Currently much of the local and state specific litigation is aimed at deep pocketed pharmaceutical companies and chain pharmacy/distributors. There are active cases filed by the Attorney General of Alabama, the Attorney General of Delaware, the Attorney General of South Carolina, the City of Baltimore, the City of New York, the City of Philadelphia, as well as individual counties in Colorado and Indiana, among others. These lawsuits seek to recover additional public spending traceable to the opioid epidemic. The governmental entities claim they have been injured because the defendants typically, opioid manufacturers, distributors, and pharmacies placed opioids into the hands of citizens and thus increased spending for governmental services. These cases can easily be viewed through the prism of New England Compounding Center meningitis cases. Once the money from the pharmaceutical companies runs out, a surge of cases against the individual physicians and other medical providers is certain to follow with increased regularity.

The Attorney General of the United States is also joining these efforts. More than 400 health care providers were recently charged with taking part in a health care fraud and opioid scam totaling more than 1.3 billion dollars. Many of these providers were charged for conspiring to generate a bill for fraudulent and high-reimbursement prescriptions benefiting the pharmaceutical companies, sales representatives, as well as the physicians writing the prescriptions. The prosecution made it clear that medical facilities must implement protocols and procedures to prevent over-prescribing these medications even in the face of patient and outside corporate pressure.

The leading Federal Organization involved in crafting guidelines in treating pain is the Center for Disease Control. In 2016, the CDC released twelve guidelines for prescribing opioids for chronic pain. Although these “guidelines” are not “mandates”, medical practices can expect Plaintiff’s to use them to establish the standard of care in negligence cases. These guidelines are roughly as follows:

1) Opioids should not be used as the first option or routine for chronic pain
2) Before prescribing opioids, goals for pain and function should be established

3) Before prescribing opioids, risks and benefits should be discussed with the patient
4) Immediate release, instead of extended release, medications should be used when starting opioid treatment
5) The lowest effective dosage should be used and increases should be used as slowly as possible
6) Only the lowest amount of opioids necessary should be prescribed for acute pain
7) Long acting and extended release opioids should not be used for acute pain
8) Frequent follow ups to reassess risk, lower dosages, and discontinue usage are necessary
9) Prescribers should constantly evaluate risk factors for opioid related harms like addiction
10) State prescription drug monitoring programs should be frequently checked for prescriptions from multiple providers
11) Providers should drug test
12) Secure treatment for addiction when needed

These CDC regulations are frequently cited in litigation by both expert witnesses and Plaintiff's counsel as the minimum standards for practitioners. There are also AMA medical ethics rules, Medicaid provider rules, and DEA prescription requirements that can be used by Plaintiff's to establish the "standard of care" for prescribing medications.

III. The Standards You Are Held To

The standard by which physicians are judged in opioid litigation is the same as any other malpractice suit: what a reasonably prudent would do in the same or similar circumstances. However, this standard of care is complicated by a number of non-binding guidelines from federal and state agencies such as the DEA, CDC, AMA and over a dozen other organizations. The expansive number of organizations offering guidelines can make it difficult to keep track of the requirements for prescribing these powerful medications. However, there are some central themes to most of these suggested practices.

Physicians should conduct an initial patient evaluation as well as consult their states prescription database to determine if the patient is already receiving opioid medications from another provider. A physician should also consider an initial drug screen, a pregnancy test, and medical records from all past providers. Finally, a physician should take special care to carefully document the condition that the prescription is designed to treat and how non-opioid medications have failed to treat the condition. The physician should calculate and document the patient's morphine milligram equivalent (MME) so that the dosage can be monitored and tapered when desired. The physician should then consult the patient on treatment plans and goals, including the end of opioid therapy. This treatment plan should last no longer than 90 days, and then reevaluated at that time. The patient should provide his or her informed consent for the treatment including the known risk of addiction. Finally, the physician should not provide refills with less than 72 hour notice, should not allow their patient to seek opioids from another provider, and not allow the patient to share the medication with others. Finally the physician should schedule frequent follow up visits to examine pain levels, activity levels, mental health, level of dependency and possibility of addiction. Although it is recommended that practitioners review all of the available and applicable guidelines for their state and specialty, these are the main tenants that they will be expected to follow moving forward.

A final word of caution to medical providers is to be cognizant of financial incentives that could encourage the prescribing of opioid medications either directly or indirectly. For instance, in the last five years five of the largest opioid manufactures in the United States donated nearly $9 million over five years to patient advocacy groups like U.S. Pain Foundation, American Academy of Pain Medicine, American Pain Society and The National Pain foundation. Some of these donations were as insignificant as conference sponsorships but if medical providers are active in these organizations, or accept donations directly from these pharmaceutical makers, you can expect these relationships to be exposed during discovery and be a potential basis for a large punitive damages award.

A similar, yet not as obvious, issue can occur with patient satisfaction reporting and financial rewards for high scores. Many physicians report that they are lax about opioid pain medication prescriptions because their patients desire them and they want to retain "happy patients." When those high patient satisfaction results are directly tied into physician compensation, it is easy to make the argument that a physician has put their financial interests ahead of doing what they know is right for the patient, even if it makes them unhappy. This could be another potential source for a punitive damages award.

Many compare opioid litigation to the tobacco cases brought in the late 1990s. In both situations, plaintiffs allege manufacturers have made billions selling a product while concealing and downplaying its risk. In addition, both public health issues have gained intense media scrutiny. However, some experts believe opioid litigants will face larger hurdles than tobacco plaintiffs. Plaintiffs may have an uphill battle convincing a jury that opioids (an FDA approved product) are defective. Further, in many states, if the drug's packaging warns prescribers about a risk, manufacturers have no legal duty to also warn patients. Finally, some experts feel it will be hard for plaintiffs to prevail on claims that a product manufacturer should be accountable for harms that arise from misuse of a product. In tobacco cases, injured smokers were using the product as intended however in opioid cases excessive doses may have been prescribed by a physician, the plaintiff may have taken more than was prescribed, or obtained the opioids illegally. While manufacturers could be liable for misuse (if it was reasonably foreseeable) causation might be difficult to prove.

Should opioid litigation be patterned after tobacco litigation? While the tobacco litigation resulted in a settlement of over $200 billion many states diverted settlement monies intended to reduce tobacco use and offset smoking related public health costs. Only 5-8% of the settlement was actually used for anti-tobacco programs. Thus, many experts caution against repeating that mistake with a similar opioid settlement.

In December 2017, Judge Dan A. Polster of Cleveland, Ohio was assigned to oversee discovery of the federal opioid cases consolidated for pretrial purposes in the multi-district litigation. Judge Polster has aggressively organized the litigation and is working to determine what manufacturers, distributors, retailers and the DEA knew and when they knew it. He has indicated he wants these cases resolved sensibly and expeditiously. Judge Polster acknowledges that any settlement should do more than just provide for settlement monies, rather he is attempting to reduce the number of opioids and ensure they are being used properly. He has appointed three special masters to assist him with this litigation given its complex nature.

As we sift through the rules, regulations and new standards of care that have been established in response to the opioid epidemic medical practices, physicians and hospitals must take steps to determine the necessary requirements for their practice and location, and implement them as soon as possible. To not change will expose them to increasing liability for the downstream effects of their patient's use or abuse of opioid drugs, and make them prime targets for Plaintiff's attorneys and even state and federal regulators.