REMEDIAL MEASURES TO CURB OPIOID ABUSE

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Opioids are usually not dangerous when used over a short period and in the manner prescribed by a physician.[1] The problem is that they can cause euphoria so that they are misused or taken in larger amounts than prescribed.[2] Even when used properly, people may develop a dependency and seek higher dosages or turn to unauthorized sources to obtain the opioids.[3] These outlets include visiting a pill mill where a doctor prescribes narcotics inappropriately, physician shopping whereby the patient sees multiple doctors at the same time, and pharmacy diversion which occurs when an employee of a pharmacy or physician forges a prescription.[4]

GOVERNMENT ACTION

Opioid abuse has caught the attention of the government in recent times. This lead Congress to enact the Comprehensive Addiction and Recovery Act ("CARA"), which covers a spectrum of preventative measures to protect against abuse and to promote increased access to opioid reversal medication.[5] The law also provides funding to detect and treat those in prison with addiction problems and encourages drug monitoring programs to help states supervise prescription drug diversion.[6]

In 2016, the FDA changed the labeling requirements for opioids to include information notifying healthcare providers and consumers of the significant dangers related to the use of particular opioid drugs.[7] It also initiated an Opioid Action Plan to decrease prescription misuse while permitting those with chronic pain to obtain effective pain-management choices.[8] It even approved a new composition for OxyContin to limit the misuse of the drug.[9]

The Drug Enforcement Administration tackled the abuse problem by reducing the quantity of most Schedule II opiates and opioid related medicines that may be made in the United States by 25 percent.[10] Some narcotics, such hydrocodone, have even more severe restrictions. For instance, the manufacturers of this drug may only make 66 percent of the quantity made in 2015.[11] These amounts were established after the government determined the appropriate medical needs for the medication; estimated retail use based upon prescriptions issued and information from the agency's own records for controlled substance sales.[12]

Former Attorney General Jeff Sessions, took an aggressive stance on drug abuse, which position led the Drug Enforcement Administration to express a desire to hire its own staff of prosecutors to pursue cases pertaining to drug trafficking, money laundering and asset forfeiture.[13] This move would be the first time that the DEA will have its own attorneys to prosecute drug-related offenses.[14]

The CDC in 2016 issued the "Guideline for Prescribing Opioids for Chronic Pain." This guideline addresses patient management for those with chronic, non-cancer pain.[15] The 12 points of the guidelines follow three specific principles.[16] First, for those patients with chronic pain, non-addicting, non-opioid therapy is preferred to opioids. In cases of nerve related (neuropathic) pain, such as peripheral neuropathy, for example, anticonvulsant and antidepressant therapy are effective means of pain control. Non-medication approaches, such as exercise therapy, psychological intervention, sleep modification, and pain management programs that emphasize psychological support such as cognitive-behavioral therapy are helpful.[17] Second, if opioids are used, physicians should begin with the lowest effective dose, and gradually increase it as needed—"start low and go slow."[18] Third, patients taking opioids must be closely monitored. Sedating medications including benzodiazepines and alcohol must be avoided. Not only are these substances habit forming, but they can also increase the possibility of opioid-induced respiratory depression and death.[19] To ascertain that the patent is in fact taking the opioids, not diverting it

elsewhere and not concurrently consuming drugs and alcohol, urine drug screens should be done at the start and periodically throughout treatment.[20]

In 2017, the Food and Drug Administration announced that it is committed to looking at all aspects of narcotics abuse and the agency has formed a steering committee to look at additional regulatory schemes to combat this problem.[21]

The initiatives would suggest that the full weight of the federal government is devoted to stemming the improper distribution of pain medication. An investigation by 60 Minutes and the Washington Post suggests that this assumption may be incorrect. These news services reported that in April of 2016, certain members of Congress, with ties to drug companies, convinced the DEA and Department of Justice to allow the passage of the Ensuring Patient Access and Effective Drug Enforcement Act. While this law sailed through Congress, it turns out that the legislation provides a much friendlier posture towards the drug industry by weakening attempts to stop the flow of opioids.[22] The statute makes it more difficult for the DEA to stop large shipments of opioids from drug manufacturers that may be fueling the drug epidemic.[23] A major change in the law raised the burden of proof for identifying dangers to local communities, from "imminent" threats to "a substantial likelihood of immediate" threats. This alternation hinders the DEA's ability to pursue drug companies that fail to report questionable or suspicious orders of opioids.[24]

State Law

The practice of medicine and the regulation of pharmacies are the provinces of the states, which play a crucial role in drug abuse and diversion issues.[25] One of their major initiatives is the Prescription Drug Monitoring Program ("PDMP"). These statewide databases involve the "prescribing and dispensing of controlled substance, including patients who might be seeking prescriptions from multiple doctors."[26] These programs check for possible abuse or rerouting of opioids and assist physicians' identity those patients who may be at risk for medication abuse and those who could be helped by early intervention.[27] PDMPs target "physician shopping" by sending reports to healthcare providers of abnormal prescribing behavior to locate irresponsible opioids dispensing. These databases obtain information from pharmacies who directly report to the state when a prescription is filled.[28]

California was the first state in 1939 to establish a drug-monitoring program and every state except Missouri has or will be implementing a PDMP.[29] These measures have a variety of purposes but usually consist of three things: the collection of prescription information from doctors and pharmacists, the storing of all prescribing data and the creation of rules governing those who can access the databases.[30] Additional justifications include improving patient care, looking into opioid diversion and arranging for early recognition of drug abuse patterns.[31]

Pain Management Contracts

Physicians should ascertain whether a patient can adhere to a drug treatment plan if opioids are prescribed, and if there are signs for developing an addiction.[32] A resultant offshoot is that some states require physicians to have the patient execute a pain management or opioid contract. For instance, such agreements are mandated in Florida,[33] New Hampshire and Massachusetts.[34] Physicians in other states may require pain contracts as part of their practices.

Court Action

Lawsuits involving opioid addiction and drug overdoses have arisen in a variety of contexts from civil lawsuits against drug manufacturers, physicians, clinics and pharmacies to criminal prosecutions and suspensions of the licenses of physicians. Theories of wrongdoing include negligence, breach of warranty, products liability, medical malpractice, violations of state consumer laws, and fraudulent misrepresentations.[35]

Suits against drug manufacturers tend to not be successful with a number of defense verdicts or summary judgments being granted. Claims against physicians, however, have achieved mixed results. This section will provide examples of these cases.

The Wrongful Conduct Rule

There are a number of cases in which people who have abused or misused opioids have sued various entities involved in the dispensing of medication. A primary defense is that the plaintiffs should be barred from recovery because of their own misconduct. Several states have even adopted this idea into what is known as the wrongful conduct rule. For example, in Price v.

Purdue Pharma Company, the plaintiff sued multiple defendants for injuries that he suffered from ingesting OxyContin.[36] This is a Schedule II narcotic that includes oxycodone.[37] The facts show that the plaintiff engaged in doctor shopping by simultaneously seeing different physicians who gave him opioids and by going to several pharmacies to obtain OxyContin.[38] The court granted the defendants' motion for summary judgment on the basis of "ex dolo malo non oritur actio," which means "no Court will lend its aid to a man who founds his cause of action upon an immoral or an illegal act."[39] In the instant case, the plaintiff's lawsuit was based upon his own misconduct by improperly obtaining opioids at the time his alleged injuries occurred. Therefore, he was barred from recovery.[40]

A case that has received some fanfare is Tug Valley Pharmacy, LLC v. All Plaintiffs Below in Mingo County. This West Virginia matter involved 29 former patients of the Mountain Medical Center who claimed that the defendants negligently prescribed and dispensed controlled substances, causing their addiction.[41] The facts demonstrate that the plaintiffs were treated at the Center for injuries resulting from auto accidents or workplace injuries. The defendants then prescribed controlled substances which were filled at their pharmacies, resulting in claimants' criminal activities associated with the drugs.[42] The Center was eventually raided by the FBI which revealed multiple violations of federal and state laws pertaining to the improperly dispensing of opioids. The plaintiffs argued that the defendants worked in concert with the druggists who knew that the defendants were pill mills and the pharmacies refilled the opioid prescriptions too soon or excessively.[43] The defendants moved for summary judgment based upon the wrongful conduct rule.[44] The court noted that it has adhered to the notion that if a party substantially contributes to his own damages, he should be barred from recovery.[45] However, any attempt to make the rule into a "per se" bar would be inappropriate. It is up to the jury to weigh the actions of the parties and to determine the extent to which the actions of each one contributed to the injuries.[46]

Liability of Healthcare Providers

The case law is conflicting on the liability of a physician premised upon the overprescribing of medication or the patient's developing an addiction. Some cases have found liability when the doctor provides too much medication without proper cause or fails to conduct a proper investigation.[47] These cases frequently show that the number of pills issued greatly exceeded the recommend dosage or that the prescriptions continued to be refilled without a physical examination.[48] Other courts have found no liability, especially when the patient has a previous history of substances abuse.[49]

For example, Koon v. Walden involves a worker who visited the defendant for pain relief and became addicted to opioids.[50] Koon was prescribed narcotics, and after one week, the physician continually increased the amounts and dosages of the drugs. This plaintiff became addicted, which severely affected his family relationships. Eventually, he was hospitalized in a drug rehabilitation center and went through withdraw and emotional distress.[51] Koon claimed that the physician negligently failed to weigh the risks of opioid use versus the benefits of the medication, failed to monitor his intake of pills and overprescribed the amount of opioids.[52] The defense countered that the plaintiff did not provide proper information to the defendant, nor did he follow the doctor's instructions for taking and weaning himself off of the drugs. The jury returned with a verdict of $17,600,000 but found the physician 67 percent at fault and the plaintiff 37 percent responsible.[53] The verdict was adjusted accordingly.

Malpractice suits against physicians are an obvious response to opioid complications but the surprising development is the aggressive prosecution of healthcare providers who play a role in opioid abuse. This prosecution started as a consequence of the DEA's enactment of the OxyContin Action Plan in 2001, which pursues criminal charges against doctors for violating the Controlled Substances Act. This action has resulted in the increasing prosecutions or license suspensions of those who became "drug pushers" as the result of their liberal dispensing of narcotics.[54] This aggressiveness is demonstrated by the attention grabbing headlines in March 2017 which blared "Opioid Rx Abuse Probe Sees a Record 31 Doctors Hit with Sanctions in New Jersey."[55]

Fathalla Mashali, M.D. provides an example of a doctor who was prosecuted for prescribing high doses of opioids to people with addictions. Prescriptions were frequently dispensed without a physical examination and it was common for Dr. Mashali to see more than 100 patients in a single day. The doctor pleaded guilty

to 44 counts of healthcare fraud, conspiracy to commit mail fraud and money laundering.[56]

Liability of Pharmacists

While the physician issues the prescription and determines how the medication is to be taken, the apothecary has the matching obligation to guarantee that the prescription is legal, filled properly and not destined for abuse.[57]

Abrams v. Bute provides a summary of the rules concerning the liability of a pharmacy.[58] The decedent underwent surgery at a hospital where he was given narcotics for pain. The patient was discharged a few hours later and told to take hydromorphine every three to four hours. The prescription was filed at CVS and taken upon his arrival home. About one hour later, the patient started gasping for air.[59] Unfortunately, he expired and an autopsy demonstrated that he died from a narcotic overdose. CVS was sued on the theory that the prescribed dosage was so high, and that it had a duty to confirm that the amount was proper.[60] The pharmacy countered that they had no duty to warn the decedent about using the prescribed dose or to take steps to guarantee that the amount ordered was proper. CVS filled the medicine exactly as ordered by the doctor and the responsibility for informing the user about the drug's danger is on the manufacturer.[61] The court noted that the pharmacist's role is to accurately fill the medicine in accordance with the instructions provided by the doctor. Thus, it is reluctant to impose a new duty that would go beyond the need to accurately fill the medicine.[62] The only time a pharmacist owes a duty beyond accurately filling the prescription is when additional factors would alert a reasonably prudent druggist to a possible problem. The motion for summary judgment filed by CVS was granted.[63]

Compare this result with Powers v. Thobhani, which allowed a suit against a pharmacy to proceed.[64] The plaintiff was being treated for neck and back pain and her doctor prescribed six different narcotics over a six month period. At times, the doctor would order additional medication before the pills from the earlier prescriptions ran out.[65] Despite this questionable medication history, the defendant filled every prescription without question, and at times, filled the pill orders early. The plaintiff died and a post-mortem examination determined that she expired from a "combined drug overdose."[66] Suit was filed against the pharmacy on the basis that it owed the decedent a duty to provide for her health and safety, and that the pharmacist breached the prevailing standard of care.[67] The court ruled that liability can only be imposed upon a drug store when it fails to exercise due care in filling prescriptions.

Liability of Pharmaceutical Companies

OxyContin, a Scheduled II narcotic, was introduced with a great deal of fanfare and promise. The drug, manufactured by Purdue Pharma, LP, contained oxycodone but was made in a time-released format that provided 12 hours of sustained pain relief.[68] Purdue Pharma embarked upon an aggressive campaign to sell OxyContin because of its time-released format specifically for pain unrelated to cancer.[69] The manufacturer claimed that the narcotic offered less of a potential for abuse and addiction than faster-acting drugs such as Percocet or Vicodin. This hype became the cornerstone of its marketing efforts that enabled the business to sell over $1 billion of OxyContin annually.[70]

As people started to die from OxyContin, lawsuits were filed against Purdue Pharma in an ever increasing pace. Complaints contained counts for such things as negligence, breach of warranty, products liability, violation of consumer protection laws, inadequate warnings and negligent marketing.[71] The pharmaceutical giant took the aggressive step to fully litigate these many claims and won most of the lawsuits. For instance, in Bodie v. Purdue Pharma, the plaintiff argued that OxyContin was sold without proper warnings about the dangers of the drug and that Purdue made misrepresentations about the pills' characteristics.[72] The court granted the defendant's motion for summary judgment and noted that the failure to have proper warnings was not the proximate cause of the plaintiff's addiction. After all, the prescribing doctor was well aware of the drug's dangers but still provided the medication for the plaintiff's pain.[73] The assertion that the defendant breached the implied warranty of merchantability also failed, because OxyContin is fit for its intended purpose as a medication for pain.[74]

Purdue Pharma's early litigation success did not continue because of the government's intervention. In 2007, Purdue Pharma agreed to a $600 million fine to settle criminal charges that it engaged in misleading advertising by telling doctors and consumers that OxyContin was less likely to be misused as other pain medications.[75] The firm also consented to a $130

million payout to help resolve personal injury claims from those who maintained that they had become addicted to the medication.[76]

Since this settlement, a number of actions have been filed against opioid manufacturers by different governmental entities, who claim that the drug companies are partially responsible for the drug epidemic.[77] Cities have taken an aggressive role in filing lawsuits. For instance, in City of Chicago v. Perdue Pharma L.P., Chicago sued a number of pharmaceutical companies for consumer fraud, misrepresentation, making false statements, insurance fraud and unjust enrichment.[78] The defendants moved to dismiss the claims but the court held that the complaint was sufficiently specific in the allegations that the defendants violated the laws on consumer fraud and deceptive practices. The Court dismissed the counts alleging that the marketing efforts constituted an unfair practice and violated the municipal false claims ordinance.[79] As of January 2017, the defendants were still attempting to have the remaining claims dismissed, to which the City replied: "Contra to the court's directions, defendants have mounted a blunderbuss attack on the third amended complaint that relitigates previously argued and necessarily decided issues."[80]

CONCLUSION

Everyone is playing catch-up to solve the opioid crisis. Congress and various governmental agencies have implemented a number of laws, regulations and guidelines to control the issuance of opioids and physicians have been told to follow the adage "start slow and go slow.

It is not surprising that opioid use has spilled over into the legal arena. More than half of those arrested for a crime test positive for illicit drugs and opioid use has been linked to driving under the influence, domestic violence, prescription fraud, faking symptoms to obtain medication and doctor shopping.

Prescription drug monitoring programs have been implemented along with patient management contracts to avoid abuse issues. Equally as important, there has been a growth of lawsuits to hold doctors, pharmacies and drug manufacturers responsible for the complications from this type of medication. The government has also moved to revoke the licenses of offending physicians and to hold them criminal liable. Whether these efforts will be successful remains to be seen but it beats the alternative of doing nothing to curb the opioid crisis.

Notes

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