

EDUCATIONAL OBJECTIVES

After participating in this activity pharmacists and pharmacy technicians will be able to:

- Discuss the kinds of behaviors by health care practitioners that can lead to criminal charges
- Describe the potential legal and regulatory outcomes of reckless prescribing
- Identify the "red flags" that should cause a pharmacist or pharmacy technician to question a prescription's legitimacy
- Discuss the positive and negative consequences of increased scrutiny of aberrant prescribing habits



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LAW: Prescription for Murder

ABSTRACT: When health care practitioners demonstrate substandard behavior, they can be penalized by license suspension, loss of a license or certification, or paying damages in a law suit. However, their behavior can also lead to criminal charges and more severe penalties including incarceration. This continuing education activity provides examples of indifferent behavior by pharmacists that has resulted in legal jeopardy. It also describes the increasing scrutiny and occurrence of criminal charges, including murder, being brought against health care practitioners for excessive or reckless prescribing and dispensing of controlled substances. It reminds pharmacy staff members of their obligations to prevent abuse and overdose.

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INTRODUCTION

Pharmacists and technicians are well aware that misconduct and mistakes in the pharmacy can bring about serious consequences and potential penalties. The most familiar repercussions from misdeeds by pharmacists result in cases of civil liability (e.g., a malpractice suit). If found liable, pharmacists will have to pay monetary damages to the injured party, and/or face imposition of sanctions by a regulatory board which could lead to suspension or forfeiture of their license or a fine. However, health care professionals are increasingly facing the threat of criminal charges for various transgressions. Tougher penalties may include incarceration. This continuing education activity examines some recent instances of health care professionals who have been accused, and in some cases, convicted of criminal behavior for their actions.

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PHARMACISTS AS BAD ACTORS

Some disturbing examples of poor behavior by pharmacists with fatal outcomes have given rise to severe punishment. In one well known case in 2012,¹ New England Compounding Center (NECC) in Framingham, MA was found to have produced and distributed vials of injectable compounded drugs contaminated with fungi. Administration of the contents resulted in meningitis, killing 64 people (later updated to 76) in 20 states and sickening more than 700 others. The compounding pharmacy allegedly shipped tainted batches of drugs produced with expired ingredients and made under non-sterile conditions.¹ Patients developed fungal meningitis and other infections after receiving spinal injections of the contaminated products. Investigations revealed that NSCC's staff failed to follow normal sterilization procedures and record keeping procedures. Some vials were shipped containing a greenish liquid. The events were so egregious that authorities arrested at least 14 of the pharmacy's employees and charged them with offenses including racketeering, mail fraud, conspiracy, and contempt. The pharmacy's co-owner and its supervising pharmacist were charged with at least 25 acts of second-degree murder.¹

At trial, the jury acquitted the pharmacists of the murder charges, but convicted them of more than 50 counts of racketeering, conspiracy, mail fraud, and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead. The owner received a sentence of nine years and the supervising pharmacist was sentenced to eight years in prison.² Another pharmacist was later sentenced to two years in prison and another received a sentence of two-years probation, home confinement, and 100 hours of community service. In all, 13 individuals including pharmacists and technicians were convicted of 178 criminal charges arising from the outbreak.²

In another notorious example, an infusion pharmacist in Kansas was charged with compounding and providing diluted, sub-potent injectable preparations to his pharmacy's patients. Most of the suspect products were cancer chemotherapy products, along with antibiotics, HIV medications, and fertility drugs.³ At least 72 different drugs were diluted to strengths that were lower than the label reflected. When tested by the FDA, most of the samples contained from 17% to 39% of the required dose with some containing no active ingredient at all. The full scope is unknown, but as many as 98,000 prescriptions dispensed to more than 4,000 patients were potentially at risk.⁴ The pharmacist pled guilty to 20 counts of tampering and adulterating prescription drugs and was sentenced to 30 years in federal prison.⁴ This deplorable event also received national media exposure, altering the public's perception of pharmacists, and was featured in an episode of CNBC's program, *American Greed*.⁵

The examples cited above likely invoke little, if any, sympathy from pharmacists and technicians for the wrongdoers who



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deliberately and callously put patients at lethal risk. However, criminal penalties have also resulted from unintentional mistakes with disastrous consequences. One particularly tragic case⁶ garnered national attention and led to establishing standards for pharmacy technicians in many states. In it, a hospital pharmacist received a prescription for Eposin (the chemotherapeutic etoposide phosphate) which was to be mixed in an intravenous bag with normal saline for chemotherapy. The patient, Emily Jerry, was a two-year old infant suffering from a yolk-sac tumor near her spinal cord. After chemotherapy and surgery, the tumor had shrunk dramatically but her physicians prescribed one final dose of drug. A technician who was distracted while talking on the phone mistakenly diluted the drug with 23.4% sodium chloride instead of normal saline. The girl went into a coma and died a few days later from cerebral edema.⁶

The pharmacist was charged with negligent homicide and pleaded no contest to involuntary manslaughter. He was sentenced to six months in prison, six months of home confinement with electronic monitoring, 400 hours of community service, a \$5,000 fine, and payment of court costs. The pharmacist claimed that he felt rushed due to workplace issues that day,⁶ something that many pharmacists and technicians can relate to, but this did not mitigate his legal responsibility. The technician was not charged with any criminal misconduct and, being an uncertified tech, did not receive any regulatory sanctions either.⁶ The pharmacist was liable for the technician's actions as her supervisor.⁶ (After this case, Emily's parents created the Emily Jerry Foundation. The Foundation partners with the American Society of Health System Pharmacists (ASHP) to advocate for state oversight and competency requirements for pharmacy technicians who have compounding responsibilities. This is one positive outcome and explains why standards for techs are becoming more strenuous. See: [https://emilyjerryfoundation.org/.](https://emilyjerryfoundation.org/))

CONTROLLED SUBSTANCE DISTRIBUTION

Other recent examples of egregious conduct by health care professionals include complicity in the diversion of controlled substances.

CRIME SCENE

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Widespread, Multidisciplinary Bust

A notable event occurred in April 2019, when the Drug Enforcement Agency (DEA) arrested 60 individuals and charged them with illegal participation in the prescribing and distribution of opioids and other controlled substances and with health fraud schemes. This has been described as the largest prescription opioid law enforcement operation ever.⁷ The arrests occurred in a region including Kentucky, West Virginia, Ohio, Tennessee, and Alabama, an area particularly hard hit by the opioid crisis. The 60 individuals included 31 physicians, eight nurse practitioners, and seven pharmacists. The cases involved the prescribing and dispensing of 350,000 opioid prescriptions and more than 32 million dose units in a two-year period, equivalent to one dose for every man, woman, and child in the affected area.⁸ In one instance, a physician alleged to have been at one time the highest prescriber of controlled substances in Ohio, was charged along with several pharmacists with operating a “pill mill” (a term used primarily by local and state investigators to describe a doctor, clinic or pharmacy that is prescribing or dispensing powerful narcotics inappropriately or for non-medical reasons) in Dayton, Ohio. According to the indictment, that pill mill dispensed more than 1.75 million doses of controlled substances between October 2015 and October 2017⁸

Among those arrested was an Alabama doctor who allegedly recruited prostitutes and other young women with whom he had sexual relationships to become patients at his clinic, while simultaneously allowing them to take illicit drugs at his house.⁷ Another physician in Alabama was charged for allegedly prescribing opioids despite knowing that patients failed drug screens and were addicts, in exchange for cash payments and a “concierge fee.”⁷ In another occurrence, a dentist allegedly unnecessarily removed teeth from patients to justify prescribing opioid analgesics.⁷

Other Recent Cases

In 2016, a jury convicted a Florida pharmacist of dispensing and distributing oxycodone outside the usual course of professional

practice and without a legitimate medical purpose.⁹ The pharmacist is alleged to have knowingly filled fake prescriptions for addicts and drug dealers, totaling more than 500,000 doses of oxycodone over a three-year period. The buyers paid cash—up to \$1000 per prescription—and the recipients resold many of the pills on the street. The pharmacist also provided pills in exchange for sex. He was sentenced to more than 24 years in prison.⁹

Both a pharmacist and technician were recently implicated in Arizona.¹⁰ The pharmacist-owner and the technician were charged with processing fraudulent prescriptions for 200,000 dose units of oxycodone and hydrocodone along with alprazolam and promethazine with codeine liquid. Some of the drugs were given to intermediaries who passed them on to street-level drug dealers. The pharmacist was sentenced to 10 years in prison while the technician received a four-year sentence.¹⁰

REGULATORY DISCRETION

Pharmacists and technicians are likely supportive of the actions taken above, which have focused on large-scale improper prescribing and dispensing of drugs that have directly fueled the opiate crisis. However, recent efforts by regulatory and law enforcement agencies have upped the ante.

Although not an example of criminal prosecution, a California initiative referred to as the “Death Certificate Project”¹¹ has changed the way that regulatory bodies charged with oversight of health care professionals have scrutinized practitioners’ performance and their actions’ outcomes. Prosecutors have replicated this oversight, as will be discussed in the next section.

The Medical Board of California, under this project, has launched investigations into physicians who prescribed opioids to patients who experienced fatal drug overdoses, in some cases months or even years after the prescriptions were written.¹¹ The goal of the program, launched in 2015, is not necessarily to link a specific prescription to a specific death. Rather, it examines physicians’

prescribing *patterns* and uncovers those whose patterns the board considers are so dangerous that they put patients at risk of developing dependence that can lead to fatal overdose.¹¹ Ordinarily, investigations arise from complaints filed with a Board, but here the Board acts on its own initiative. The investigation begins with the Board's review of death certificates that list prescription drug overdose as a cause. The agency then cross-checks the state prescription drug database to identify physicians who prescribed controlled substances to these deceased patients going back up to three years before their deaths.¹²

As of January 2019, the medical board had investigated approximately 450 physicians and formally accused at least 64 physicians of negligent prescribing; five have lost their licenses, and six have been put on probation.¹² In addition to the physicians, the medical board referred the names of 72 nurse practitioners, physician assistants, and osteopathic physicians to their respective licensing boards for potential action. Four nurse practitioners are facing investigations.¹² In some cases, the medical board investigated a physician even though the cause of death included multiple drugs prescribed by many physicians. In other cases, the medical board investigated prescribers when patients used prescription painkillers to commit suicide.¹²

One physician was disciplined after two of his patients died of overdoses. He was accused of failing to screen one of his patients for aberrant drug behavior, not checking the prescription database, and not coordinating his care with other prescribers.¹² Other accusations against physicians included failure to order drug tests to ensure a patient was not abusing substances, prescribing fentanyl patches to a patient receiving benzodiazepines, failure to appropriately sever the doctor-patient relationship, and writing illegible notes.¹²

Sanctions can include revocation of the physician's license to practice medicine, public reprimand, or other penalties.¹³ One physician's license was suspended for 30 days and the medical board permanently barred him from prescribing any controlled substance. He was also required to perform 100 hours per year of non-medical community service and take courses on proper prescribing procedures.¹³

A San Francisco addiction medicine specialist received a letter from the Board in 2018 regarding a patient who fatally overdosed in 2012. The letter stated that the patient had died of acute intoxication from a combination of methadone and diphenhydramine. The letter asked him to respond to the allegations or, if he delayed, face a citation or fine of \$1,000 per day. The physician had refilled the patient's prescription for methadone the day before the overdose but claimed that a 10-milligram dose (what the physician prescribed) was not toxic. He also said he never prescribed diphenhydramine and claimed that the patient could only have died if he was not taking the



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drug as directed or mixing it with another drug. A year after responding to the medical board, he was still waiting for a resolution. Five others have also been waiting more than a year and nearly half have waited more than seven months. Only two have been exonerated to date.¹¹

In some cases, investigations prompted by a death certificate have identified other living patients for whom that provider had prescribed controlled substances.¹² In these cases, the medical board sends a letter to the patient saying that the board "is reviewing the quality of care provided to you by Dr. -- ." It asks the patient to promptly authorize the doctor to turn over his or her medical records to the board. It also threatens to subpoena the records if the patient refuses. The board's executive director defended the project saying that the effort has uncovered patterns of excessive prescribing that demonstrate gross negligence and incompetence.¹⁴

Some medical groups have criticized the project as a "witch hunt" and an "inquisition."^{11,14} One criticism is that the physician being investigated did not necessarily write the prescription that led to the patient's death. Patients may also have

overdosed on mixtures of prescription, illegal drugs or alcohol. Another criticism is that the matters may involve prescriptions they wrote as long as nine years earlier when different pain management standards were in effect. Over several years, two factors encouraged the use of strong analgesics¹¹:

- Public policy urged physicians to treat pain more aggressively to provide comfort for patients
- Payers measured quality of care on the basis of whether patients said their pain was well-controlled.

It was noted that in 2001, the California legislature mandated 12 hours of continuing education for all physicians on appropriate pain prescribing in the belief that pain was being undertreated.¹³ The potential for disciplinary review is causing many physicians to refuse legitimate requests for painkillers from patients.¹³

MORE SERIOUS CHARGES

Recently there has been a trend to seek more severe penalties for alleged excessive prescribing than a fine or suspension of licensure—holding practitioners criminally liable for reckless or negligent prescribing. Let’s examine some cases brought against health-care practitioners over the past few years.

Charge: Murder, Weapon: Opioid

In what is perhaps the first case where a health care practitioner was criminally convicted of a patient’s overdose death, a Florida physician running a pill-mill was found guilty in 2002 of manslaughter in the death of four patients who died of oxycontin overdoses.¹⁵ At the time, the physician was the #1 prescriber of the drug in Florida. He had gained a reputation among patients and pharmacists for indiscriminate prescribing of opioids (notably oxycodone and hydrocodone) for anyone willing to pay for an office visit. The physician claimed in his defense that he was bound to take patients at their word when they complained of pain and suffering. He faced a sentence of more than 30 years in prison for his conviction which included other charges (racketeering and unlawful delivery of controlled substances).¹⁵

In 2016 a California jury found a physician guilty of second-degree murder of three patients who died of drug overdoses. This is believed to be the first time a physician was found guilty of murder for reckless opioid prescribing.¹⁶ In an earlier (2015) case, another physician running a pill-mill in Florida was charged with first-degree murder for overprescribing opioids leading to the death of a patient.¹⁷ The Florida case arose from a crackdown on Florida’s pill-mills which are blamed for promoting opioid abuse, with 33 individuals facing federal indictment on drug related charges, including two pharmacies and a pharmacist-owned wholesale distributor.¹⁷ In this particular case, the jury found the physician not guilty because they believed that the patient was responsible for his own actions that contributed to his death; the physician was instead convicted on a minor drug charge.^{16,17} Had the physician been convicted of the murder charge, he could have faced life imprisonment.¹⁶

SIDEBAR: The Legal Lingo^{16,19}

A brief description of terms may be helpful in understanding the charges that have been brought against a health care provider.

- **Homicide** is the killing of another person. Murder and manslaughter are forms of homicide that are unjustifiable.
- **Murder** generally refers to an intentional killing which is premeditated, or where there is intentional harm that causes a person’s death, or where a person behaves in a way that shows extreme disregard for life, resulting in the victim's death.
- **Manslaughter** (sometime called criminal negligence) may be the charge where there is no intent to kill nor extreme, reckless conduct, but the death results from criminal or reckless negligence or disregard for life where the killer should have known that his or her actions were inherently dangerous.

The distinctions are not precise. Most cases described below rely on the concept of “reckless prescribing” where the health care provider should have realized that his or her actions posed an undue risk to patients, as in the California case described above.

Returning to the California case, the physician was convicted of murder. She wrote more than 27,000 opioid prescriptions over a 3-year period (an average of 25/day) and prescribed drugs to at least a dozen patients who died from overdoses.¹⁶ She allegedly wrote prescriptions after conducting a 3-minute patient assessments with no physical examination although the patients had obvious signs of dependence. She had received several previous notifications from coroners and law enforcement that some of her patients had fatally overdosed, but continued to prescribe large amounts of opioids that allegedly led to patient overdose deaths. She was sentenced to 30-years-to-life in prison.¹⁶

The physician appealed her conviction arguing, in part, that other physicians who saw her patients and pharmacies which filled her prescriptions were also culpable. The Appellate Court denied her appeal noting that “she knew that the drugs she prescribed were dangerous and that the combination of the prescribed drugs, often with increasing doses, posed a significant risk of death.”¹⁸

PAUSE AND PONDER: A 40 year old women walks up to the pharmacy counter with an unsteady gait and, slurring her words, presents two apparently valid prescriptions: one for an opiate analgesic and one for a benzodiazepine. What should the pharmacist do?

In Iowa, a physician pain-specialist was charged with seven counts of involuntary manslaughter for the overdose deaths of patients.¹⁶ The physician was accused of recklessly writing prescriptions for high-dose opioids to patients showing clear signs of abuse. The jury acquitted the physician, indicating they could not find that the patients died from the drugs that he prescribed (i.e., they may have died from drugs bought on the street) or that they may have died from unrelated medical causes.¹⁶ This case demonstrates the difficulty prosecutors sometimes face when seeking a murder/manslaughter conviction or showing that the prescription provided by a particular physician is the cause of death.

In contrast, a 76-year old Massachusetts physician was charged with involuntary manslaughter (among other charges, including illegal prescribing of controlled substances and Medicare fraud) in December 2018 for the overdose death of a patient.²¹ The deceased woman was determined to have died from the combined effects of fentanyl, morphine, codeine, and butalbital, all prescribed by the physician. First responders reported they found her with two fentanyl patches on her abdomen. They also found prescription bottles containing morphine, oxycodone and Fioricet (acetaminophen, butalbital, and caffeine) with codeine in the home, all prescribed by the charged physician,²¹ providing a more plausible connection between the physician's actions and the overdose death.

A Pennsylvania physician was found guilty of unlawfully prescribing opioids to 23 former patients, including a woman who died after ingesting the medication.²² The physician allegedly wrote more than 27,000 opioid prescriptions over a four-year period and was convicted of money laundering and tax evasion in addition to his role in the death. He was sentenced to more than 27 years in prison.²² Former patients testified that that they regularly received prescriptions from the physician for high doses of oxycodone and other opioids over the course of several years. The physician did not perform medical examinations or verify their prior medical treatment. Evidence was also presented that the physician repeatedly falsified patient medical records and omitted some information in order to legitimize the prescriptions. Some pharmacists stopped filling his prescriptions because they were suspicious of the volume of opioids he prescribed. Former patients also testified that they became dependent and addicted to opioids as a result of the drugs prescribed by the physician. Evidence showed that the physician even prescribed high dose opioids to patients who he knew had recently completed drug rehabilitation and detoxification programs, resulting in those patients becoming re-addicted.²² The physician unsuccessfully challenged his conviction. He maintained he should not be held responsible for the woman's death because the evidence showed that she had a history of psychiatric issues, and committed suicide by intentionally ingesting 40 pills.²³ The judge denied the defense pointing out that the woman died of respiratory arrest from the drugs that the defendant had prescribed.²³



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PAUSE AND PONDER: What criteria should law enforcement use to distinguish between aggressive pain management and “drug dealers in white coats”?

In these kinds of cases, prosecutors are applying a charge normally used to convict street drug dealers, “drug delivery resulting in death,” to target physicians whose prescribing leads to patient overdose.²² After the Pennsylvania trial, the prosecutor proclaimed that the conviction set a precedent for taking action against physicians whose prescription opioids can be tied to the death of a patient. He added that more convictions should be expected as prosecutors become more adept at differentiating between active pain management and violations of proper prescribing standards.²²

A New York doctor was indicted on 231 counts, including second-degree manslaughter stemming from the deaths of two patients.²⁴ He reportedly prescribed 680 doses of oxycodone per month for one patient. He also faces charges of reckless endangerment related to prescribing drugs to eight surviving patients. The physician is said to have routinely prescribed a common combination dubbed the “Holy Trinity” of an opioid (usually oxycodone), a benzodiazepine (usually alprazolam), and a muscle relaxant to his patients.²⁴ As pharmacists know, all three drugs can depress the respiratory system and are extremely dangerous in combination. He is also said to have ignored observations of his patients' mental and physical deterioration and reports of involvement in multiple vehicle accidents.²⁴

A California physician gained the nickname “Candy Man” for his willingness to prescribe large quantities of opioids.²⁵ He was convicted in 2015 of 79 counts of writing medically unnecessary prescriptions for narcotics and benzodiazepines including one for a patient who died of an overdose. (In all, at least 20 of his patients died of overdoses but only one was included in the charges.) He was sentenced to 27 years in prison.²⁵ The physician claimed that he had spent decades running a family medicine practice focused on low-income, elderly, largely Spanish-speaking patients. He alleges he began to treat larger



numbers of pain management patients after deciding there weren't enough physicians in the area providing such a service. He also expressed that pain is subjective and requires listening to and observing patients rather than relying on tests.²⁵ In testimony, the physician acknowledged that he showed poor judgment, but maintained that he was "tricked" by patients who lied to obtain the opioids. The prosecutors successfully argued that it was his responsibility to avoid feeding the patients' addictions.²⁵ Many patients drove long distances to meet with the physician, who prescribed what authorities believed to be unusually large amounts of drugs. His practices caught the attention of others in the medical community, including some pharmacies that refused to fill his prescriptions.²⁵

PAUSE AND PONDER: Should a pharmacist be expected to spot these red flags and be considered complicit in any resulting harm if he or she ignores them?

In March 2019, a Kansas physician was sentenced to life imprisonment after being found guilty of writing prescriptions for a man who died of an overdose when prescribed alprazolam and methadone.²⁶ The physician allegedly would write prescriptions for paying patients if they merely responded "yes" when asked if they were in pain. The physician defendant allegedly kept no medical records, performed no physical examinations or physical tests, gave massive amounts of opioids to patients with little demonstrated medical need, and knew that patients were traveling extremely long distances in search of opioids. The judge presiding over the trial noted that there was ample evidence that the physician was prescribing opioid medications in amounts likely to lead to addiction, and had an established record of unscrupulous prescribing practices.²⁶

In August 2019, the California State Attorney General's Office brought a murder charge against a physician for the overdose opioid deaths of four patients.²⁷ Conviction could bring a life sentence. The physician allegedly wrote prescriptions for 180-300 doses of drugs such as hydrocodone and oxycodone, despite warnings from pharmacies and insurance companies.²⁷

Pain Prescriptions, Prosecution, and Push-Back

A particularly interesting case involves another New York physician. It has generated a great deal of attention. The physician was accused of causing the deaths of six patients and contributing to the deaths of others.²⁸ His Buffalo area clinic allegedly wrote more opioid pain prescriptions than any hospital in the state. The head of the DEA's New York division compared the clinic to a "modern-day version of 19th Century opium dens."²⁸ Prosecutors alleged the physician signed blank prescriptions that others filled out while he was out of town; patients could call in for refills which were processed by staff who weren't properly trained or certified. Nurse practitioners and physicians assistants allegedly issued hundreds of prescriptions/day for substances such as oxycodone, fentanyl, and tapentadol for patients they barely knew, sometimes without even consulting their charts. Prosecutors also claimed that the clinic prescribed opiate treatments that caused some patients to become so addicted that they sought heroin and other street drugs. In some cases, the clinic staff allegedly gave out opioid prescriptions to patients who had previously overdosed.²⁸ He could face 20 years to life in prison if convicted.²⁸

On the surface, the allegations against the physician appear to be consistent with other examples of reckless prescribing and their contribution to the opioid epidemic. However, his arrest sparked a response from leaders of local, state, and regional medical societies. They stated that threatening well-meaning physicians will only worsen the difficulty that many patients encounter in finding a physician willing to help them when suffering from chronic pain.²⁹

One doctor stated that "if law enforcement officials become the judges of what constitutes appropriate medical care, the chilling effect on doctors and harmful impact on patients could be immense."²⁹ Advocates said that if more physicians fear they may be prosecuted for prescribing opioid medications, more doctors will refuse to see or keep patients who suffer from complicated pain. They also claimed that temporary closure of the physician's clinic during prosecution created a major local public health crisis, with many patients having nowhere else to go. They cited a patient with four failed back surgeries, others with multiple complications, and some who were bedridden and wheelchair-bound without their narcotic pain medication.²⁹

Physicians filling in for the accused also were quoted as being impressed with the quality of the practice and the safeguards that were in place.³⁰ The defendant's lawyer also argued that the percentage of overdose deaths associated with his practice was well below the national average.³⁰ Patients denied pain medications while the clinic was closed became concerned about undergoing withdrawal and may have turned to street drugs as a substitute.³⁰ One commentator noted that individuals "who are committed to obtaining opioids for getting high, or to selling drugs on the street for profit, are often very accomplished at deceiving compassionate physicians."³⁰ The prosecutor in this case, however, strongly rejected the notion of patient responsibility and likened it to blaming the victim.³⁰

SUMMARY AND CONCLUDING REMARKS

Pharmacists and technicians are, of course, aware that their actions have consequences. This continuing education activity is a reminder that penalties can go beyond the awarding of damages in a civil lawsuit or loss of license in a regulatory board action. They may include criminal prosecution and even incarceration. Examples where pharmacists have been sentenced to prison include deliberate adulteration of drugs and widespread violations of the Controlled Substances Act regarding opioid distribution.

One area where criminal penalties are becoming more common is in the well-meaning effort to combat the drug overdose crisis. Drug overdoses claimed more than 70,000 lives in 2017³¹ and law enforcement and regulatory officials are becoming increasingly aggressive in cracking down on opioid prescribing. Health care practitioners, including pharmacists, have been punished for indiscriminate prescribing and dispensing of very large quantities of opioids and other controlled substances without a legitimate medical need. However, physicians are also facing less familiar charges of manslaughter or murder when patients have died as a result of a drug overdose. Can pharmacists also be found responsible?

Traditionally, in cases of civil liability (e.g., malpractice suits), pharmacists have been shielded by the doctrine of "learned intermediary."³² Courts consistently ruled that the pharmacist does not have a general duty to warn patients about the drugs they dispense. Instead the burden was placed on the manufacturer to provide general warnings to physicians who would then have a duty to provide adequate warning to patients about the drugs they prescribe.³³ The rationale was that physicians were better positioned to provide warnings since they decided which medications to prescribe; they also had access to the patient's complete medical history. However, as pharmacists have taken on more responsibility for patient wellbeing (e.g., counseling and prescribing), they are less able to hide behind the traditional defense that the pharmacist's duty to the patient is merely to accurately and passively fill the prescriber's order. With increased recognition of the pharmacist's duty to

PAUSE AND PONDER: In all of the examples noted above where a prescriber was charged with manslaughter or murder, a pharmacist must have been involved in the dispensing of the fatal dose. In how many of these instances could/should a pharmacist have intervened (and possibly have saved a life)?

warn patients of the risks of drugs in cases of civil liability, the learned intermediary concept has begun to erode, although not yet completely, and courts are holding pharmacists more accountable.^{32,33}

It should be noted that these approaches have to date involved regulatory agency decisions and civil liability, and not criminal accusations. Criminal accusation entails different standards. However, it is not unthinkable that a prosecutor could bring criminal charges against both a physician and a pharmacist in the case of an overdose death, relying on the same principles of accountability and recklessness currently being applied to physicians.³⁴ This is especially likely if the pharmacist ignores important signals.

Pharmacists and technicians have a responsibility to monitor the prescribing of controlled substances and a legal duty to prevent drug diversion. The DEA is very clear that pharmacists share responsibility with the prescriber for preventing prescription drug abuse and diversion. The DEA Pharmacist's Manual states that the "CSA holds the pharmacist responsible for knowingly dispensing a prescription that was not issued in the usual course of professional treatment" and that "(p)harmacists have a personal responsibility to protect their practice from becoming an easy target for drug diversion."³⁵

The DEA publishes a list of "guidelines" that pharmacists are expected to consider before dispensing controlled substances.³⁵ (See **Table 1** next page.) These parameters are not codified in any statute, but the DEA relies on them when deciding to bring actions against pharmacists. The pharmacist who ignores these red flags is taking a great risk. As described earlier, regulators are examining health care professionals' prescribing history when a patient dies from a lethal overdose of a prescription drug. There has been a corresponding increase in both regulatory and criminal sanctions. The usual prescription monitoring plan at the state level also contains data on the dispensing of controlled substances to the deceased individual. It is not a large leap to see the pharmacist who ignores accepted practice and willingly fills questionable prescriptions to an overdose victim could be subject to the same scrutiny—and potential criminal liability—as the prescriber.³⁴

As one commentator³⁰ has pointed out "(t)he top opioid prescriber in your state will inevitably be subjected to increased scrutiny and risk of prosecution alleging inappropriate prescribing or over-

Table 1. Fraudulent Prescription Red Flags (DEA)³⁵

The following criteria may indicate that a prescription was not issued for a legitimate medical purpose:

- The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in the area.
- The patient appears to be returning too frequently. A prescription that should last for a month in legitimate use is being refilled on a biweekly, weekly or even a daily basis.
- The prescriber writes prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. Drug abusers often request prescriptions for "uppers and downers" at the same time.
- The patient presents prescriptions written for other people.
- A number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician.
- People who are not regular patrons or community residents show up with prescriptions from the same physician.

The following criteria may indicate a forged prescription:

- Prescription looks "too good." The prescriber's handwriting is too legible.
- Quantities, directions, or dosages differ from usual medical usage.
- Prescription does not comply with the acceptable standard abbreviations or appears to be textbook presentations.
- Prescription appears to be photocopied.
- Directions are written in full with no abbreviations.
- Prescription is written in different color inks or written in different handwriting.

prescribing. Unfortunately, following strict, well-established monitoring and prescribing protocols may not prevent entanglement in the legal system." Pharmacists also should not expect to avoid legal entanglements merely by following standard protocols.

The "Candy Man" case discussed above shows both the positive and negative pharmacist response to aberrant prescribing. As noted earlier, many pharmacists refused to fill prescriptions from the physician charged in the case and reported their concerns to authorities.²⁵ On the other hand, four Santa Barbara pharmacists were accused by the California Board of Pharmacy of ignoring the "red flags." They were forced to surrender their licenses and pay \$15,000 fines. Some of the "red flags" documented by the Board were³⁶:

- prescription monitoring database which showed evidence of doctor and pharmacy shopping and duplicate treatments
- potent drug combinations being prescribed
- patients driving long distances and paying in cash
- patients returning early, sometimes by weeks, for refills
- the pharmacies not aware of a diagnosis, and
- evidence that other nearby pharmacies were refusing prescriptions.

In 2018, the DEA reaffirmed the importance of being aware of these guidelines. In ordering the revocation of a pharmacy's license, the DEA noted the pharmacy's disregard of the "presence of red flags of diversion."³⁷ The show cause order (a court order, made upon the motion of an applicant, that requires a party to appear and provide reasons why the court should not perform or not allow a particular action) specifically relied on certain conduct that the pharmacy failed to consider including the following³⁷:

- multiple customers filling prescriptions on the same day for the same drugs in the same quantities
- patients traveling long distances to have their prescriptions filled
- cash payments
- early refills
- filling two prescriptions on the same day for two patients with the same last name and street address, and
- filling two prescriptions on the same day for the same customer for the same immediate release controlled substance with different doses.

The DEA may find a violation of the shared responsibility if they prove that the pharmacist acted with actual knowledge that the prescription lacked a legitimate medical purpose or if they showed "willful blindness" of the red flags. ("Agency precedent has made clear that, when presented with a prescription clearly

not issued for a legitimate medical purpose, a pharmacist may not intentionally close her eyes and thereby avoid positive knowledge of the real purpose of the prescription.”³⁷) It is reasonable to expect that in a criminal prosecution, prosecutors will rely on ignoring red flags to evaluate a pharmacist’s behavior and culpability.

Greater prescription scrutiny is another likely event. West Virginia recently passed an amendment to its Controlled Substances Monitoring Program Database requiring that instances of drug overdose or suspected overdose be reported. It also mandates that pharmacists report additional information including who picked up the prescription and whether it was paid for in cash.³⁸

Effect on Pain Patients

The intensified attention on the prescribing and dispensing of opioids has resulted in another phenomenon: greater difficulty for pain patients to access opioid analgesics.³⁹⁻⁴¹ It is estimated that 10% to 20% of U.S. adults (about 50 million people) suffer with chronic pain, with 8% having high impact pain defined as pain lasting at least three months associated with one major activity restriction (e.g., being unable to work, attend school, or do household chores).⁴⁰ The economic cost of chronic pain due to medical expenses, lost productivity, and disability programs is estimated to be \$560

billion/year.⁴⁰ Pain also has a major impact on mortality, health, and the quality of psychological and social life, including an increased risk of depression and suicide.³⁹

As scrutiny increased, primary care physicians began referring patients to pain specialists who are becoming overwhelmed with the demand.¹³ Restrictions on prescribing have also contributed. One author³⁰ who has disparaged regulators as “meddling legislators, who believe they have the knowledge to micromanage medicine,” has criticized laws restricting opioid prescriptions to a seven-day supply for acute pain. He notes, “a patient who still has pain on the eighth day may be expected to suffer” and that a patient who receives a prescription for a 10-day supply of pain medication may not be able to get the prescription filled at all. Patients report increasing numbers of practitioners refusing to write prescriptions for opioids, and pharmacies refusing to fill prescriptions while facing hostile reactions and stigma from pharmacists.^{38,40}

Pharmacists have a difficult balancing act when presented with an opioid prescription. They need to be mindful of the patient’s overall situation and environment when they dispense or counsel on a prescription for controlled substances. Blindly ignoring the surrounding circumstances could result in a pharmacist trading a white coat for an orange jump suit.

Figure 1. Avoiding Criminal Charges in Pharmacy Practice

Best

- 1 **Be COMMUNITY CHAMPIONS.** Know your state and local Board of Pharmacy representatives.
- 2 **Attend State meetings that address prescribing and dispensing laws.** Voice your opinion and discuss the pros and cons of tightening regulations.
- 3 **Advocate for patients who experience barriers to obtaining adequate pain relief.** Make sure your local and state regulatory representatives are aware of problems.

Better

- 1 **Monitor patients’ medication adherence closely,** and intervene early if problems may be developing.
- 2 **Educate patients about the risks of opioids and benzodiazepines,** and advise them to talk to their prescribers about them.
- 3 **Watch for aberrant prescribing habits** in your community, and engage appropriate help when needed.

Good

- 1 **Know your state and local law** with respect to all aspects of practice.
- 2 **Conduct yourself in a professional manner** at all times.
- 3 **Review the DEA’s Fraudulent Prescription Red Flags** periodically



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