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"Pharmacy Law Update"

November/December 2017



**ALWAYS CHECK YOUR CPE MONITOR ACCOUNT.
TYPICALLY, CREDITS APPEAR IN THAT ACCOUNT WITHIN 7
DAYS AFTER WE RECEIVE QUIZ ANSWERS.**

CREDITS FOR 2017.
WE MUST RECEIVE QUIZ ANSWERS BY MIDNIGHT DEC 31, 2017.
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TO ceinfo@wfprofessional.com

This is the annual double lesson for November & December. Additionally, it provides 3.0 (0.3 CEUs) contact hours of credit, and fulfills the pharmacy law CE requirement in most states. (Check your Board of Pharmacy requirements for specifics). We focus on and summarize 14 recent legal cases in which aspects of pharmacy practice have been addressed by a court of law. Each case scenario presents a factual situation and a legal analysis by the court of that situation. Significant practice-based conclusions can be drawn from the result of each case. The goal is to provide understanding of judicial expectations of pharmacists and technicians.

This lesson is intended for pharmacists & technicians in all practice settings. **The program ID # for this lesson is 707-000-17-011-H03-P for pharmacists, and 707-000-17-011-H03-T for technicians.**

Participants completing this lesson by October 31, 2020 may receive full credit. Release date for this lesson is November 1, 2017.

To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

If you have any comments, suggestions or questions, contact us at the above address, or call 1-847-945-8050. **Please write your name, NABP eProfile (CPE Monitor®) ID Number & birthdate (MM/DD) in the indicated space on the quiz page.**

The objectives of this lesson are such that upon completion participants will be able to:

For Pharmacists:

1. List the responsibilities of pharmacists in the dispensing of controlled substance medications.
2. Describe the legal requirements for medication error prevention.
3. Discuss the legal implications of expanded pharmacy practice responsibilities products.

For Technicians:

1. List the responsibilities (if any) of technicians in the dispensing of controlled substance medications.
2. Describe technicians' legal requirements for medication error prevention.

All opinions expressed by the author/author(s) are strictly their own and are not necessarily approved or endorsed by W-F Professional Associates, Inc. Consult full prescribing information on any drugs or devices discussed.

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INTRODUCTION

This lesson summarizes 14 recent legal cases in which aspects of pharmacy practice have been addressed by a court of law. Each case scenario presents a factual situation and a legal analysis by the court of that situation. Significant practice-based conclusions can be drawn from the result of each case. Language in quotations is taken directly from the court's legal opinion. These opinions are more than personal points of view. They often represent binding law of the jurisdiction in which they were issued, and the court's reasoning may be persuasive, although not binding, in other jurisdictions. Regardless of the legal significance of each case, the lessons learned are significant for pharmacy practitioners. The pharmacy-based learning opportunities that these case scenarios present serve as useful guidance for pharmacists and technicians.

CASE NUMBER ONE: NEW MEXICO, 2017

Issue: Alleged "Too Early" Dispensing of Excessive Opioids.

Facts Presented by the Court: This case is an appeal from dismissal of a lawsuit brought by the personal representative of the estate of a patient who died at the age of nineteen from an overdose of physician-prescribed opioids. On December 1, 2009, the patient died from multiple drug toxicity. The autopsy report identified the drugs in her system as oxycodone, oxymorphone, and alprazolam.

The pharmacy did not dispute the plaintiff's interpretation of the record showing that the pharmacy filled OxyContin prescriptions for the patient between two and twenty-three days "too early" on at least seven occasions between May 28, 2009 and September 21, 2009. At least some of these prescriptions contained the words "OK to fill early" or a similar indication that the prescription could be filled "early." On a few occasions, the patient paid a substantial amount of cash to purchase OxyContin from the pharmacy, and at least once paid \$1,107 for 90 OxyContin 80mg tablets in September 2009. An October 2009 "addendum" note by an on-call physician indicated receipt of a call from an unidentified pharmacist reporting that the patient had "presented to the pharmacy for early refill" and had offered to pay over \$1,000 cash, despite the fact that she would have received the medication at no charge through Medicaid three days later.

Judicial Observations: The pharmacy claimed, in its defense, that "a pharmacist who accurately fills a prescription medication as prescribed by the doctor has no liability exposure to one who is injured by the drugs on claims the amounts were excessive, unless the pharmacist has some reason to know the specific customer will be harmed." The court somewhat sarcastically referred to this defense argument as a "clerical accuracy standard." The court was not impressed with the pharmacy's claim that it had no responsibility other than technical accuracy in order processing.

Reacting to the pharmacy's "clerical accuracy" argument, the court responded that "the circumstances presented here involve repeated "early" fills of opioid medications prescribed in combination with benzodiazepines, and at least one instance in which the patient paid a substantial amount of cash to purchase OxyContin from the pharmacy, although her prescription was paid with insurance on other occasions." In addition, an expert testified that "early" prescription requests "are evidence of excessive use of the controlled substance, in excess of the prescribed dose, and that excess use places the patient at risk of death or serious injury, increases abuse, dependence and addiction, and may be evidence of diversion." The court

reversed dismissal of the lawsuit against the pharmacist, remanding the case to the trial court for further proceedings against the pharmacy. The court indicated that pharmacists have more responsibilities than "clerical accuracy."

Lessons of the Case: How early is too early? Answering this question is a constant challenge for pharmacists who are required by law to monitor controlled substance prescriptions. Drug seeking by diverters and abusers can be hard to distinguish from relief seeking by legitimate chronic pain patients. They both want the medication as quickly as it can be provided to them. Just as people fill up the gas tank before they run out of gas, and they replenish the pantry before the food supply is exhausted, pain patients need to keep a steady supply of medication on hand.

Somewhat early requests for opioids are fine. Too early requests for opioids are not fine. How can pharmacists tell the difference? The key in this case was the added fact of the patient offering, and paying, a huge amount of cash money for an early supply of opioids. Patients on Medicaid or other insurance shouldn't be doing this. Too early by itself may not be a major concern. But too early combined with another factor, such as the patient living a long distance away from the pharmacy, or the patient living at the same address as several other people who are also using high-dose opioids, should cause a pharmacist to question the legitimacy of a prescription. The defendant pharmacy in this case may eventually win. But the court decided not to dismiss the case without learning more about the facts and what was known by pharmacy personnel when the medications were dispensed early.

CASE NUMBER TWO: FLORIDA, 2017

Issue: Pharmacist Cooperation with Law Enforcement by Honoring a Fraudulent Prescription.

Facts Presented by the Court: A pharmacist was fired because she cooperated with a law enforcement "sting operation," by dispensing alprazolam to a person, when she knew the telephoned prescription was fraudulent. She sued her former employer, contending that she had been fired in retaliation for complying with legal requirements applicable to a pharmacist.

The pharmacist was employed in various capacities by the pharmacy from 1988 until the pharmacy terminated her employment in 2014. On November 20, 2014, she became suspicious of the alprazolam prescription, prompting her to call the prescribing physician to verify the prescription's legitimacy. The physician's office manager informed the pharmacist that the prescription was fraudulent, and the office manager immediately notified the police. A law enforcement officer told the office manager that nothing could be done unless the pharmacist actually filled the prescription. The office manager relayed this information to the pharmacist and then gave the physician's "authorization" to honor the fraudulent prescription. The pharmacist honored the prescription, and the perpetrator was arrested by police who were in the pharmacy.

During the following days, management investigated the incident and concluded that the pharmacist should be discharged from employment for violating company policy. The policy specifically said that pharmacists are prohibited from "complying with law enforcement requests to dispense medicine pursuant to fraudulent prescriptions during a sting operation."

Judicial Observations: The pharmacist's lawsuit alleged that the pharmacy's policy prohibiting cooperation with law enforcement was unlawful. The court noted that Florida state law provides, "an employer may not take any retaliatory personnel action against an employee because the employee has objected to, or refused to participate, in any activity, policy, or practice of the

employer which is in violation of a law, rule, or regulation.

The court disagreed with the pharmacist's argument that the company policy was in violation of the law. In fact, the court noted that the policy "simply echoes state and federal laws that prohibit pharmacists from knowingly dispensing medications pursuant to fraudulent prescriptions." While recognizing that the pharmacist's argument was sympathetic, the court nevertheless dismissed her case against the pharmacy.

Lessons of the Case: Law enforcement personnel want to make "big arrests" for crimes that will result in significant prison terms. This is probably the reason why the police wanted the pharmacist to actually dispense the medication to the perpetrator. An arrest for phoning in a fraudulent prescription is not as big a deal as an arrest for possession of controlled substances, and it is harder to prove. The possession arrest is a better arrest because it leads to a longer sentence and it is easier to prove. But pharmacists aren't responsible for making law enforcement's job easier. And law enforcement shouldn't make a pharmacist's job more difficult.

The pharmacy's policy makes sense. Pharmacists should not commit a crime to help police catch someone else who is committing a crime. And physicians can't "authorize" pharmacists to commit a crime by honoring a fraudulent prescription. Nobody can do that. If the police think that phoning in a fraudulent prescription is too unimportant a crime to pursue, then pharmacists should simply refuse to dispense the medication. Violating a company policy and breaking the law are not a wise choice for a pharmacist, regardless of the reason.

CASE NUMBER THREE: INDIANA, 2017

Issue: Pharmacist Defamation of Physician When Refusing Opioid Prescriptions.

Facts Presented by the Court: Several patients of a pain management physician presented opioid prescriptions to pharmacies owned by the defendant pharmacy company. The pharmacies refused to honor the prescriptions. Pharmacy personnel allegedly made comments that were critical of the physician and of his practice.

The physician contended that all of the statements made by pharmacy personnel were untrue. The physician filed a lawsuit against the pharmacy company, alleging defamation and other legal violations related to the derogatory statements made about him by pharmacy personnel. Both the physician and the pharmacy company filed motions requesting that the court rule in their favor.

Judicial Observations: The key element of the court's ruling on the motions was whether the statements made by pharmacy personnel were defamatory *per se*. If a statement made about a person is defamatory *per se*, that means the statement in and of itself is defamatory regardless of the circumstances, and it entitles the defamed person to damages. The court held that, when viewed in context, and given their plain and natural meaning, the statements made by pharmacy personnel that the physician's "license has been suspended or revoked," that the physician "has been arrested, and if he hasn't been, he should be, therefore find a new doctor," that the physician "has been to jail and is a bad doctor," and that the physician "is under DEA investigation" conveyed the message that the physician was involved in criminal conduct as well as misconduct in his profession. The court determined that the statements were defamatory *per se*.

Lessons of the Case: Pharmacists have a legal responsibility to decline purported prescriptions that have not been issued for a legitimate medical purpose or in the usual course of professional practice. As this case suggests, the refusal of a prescription should not be accompanied by insulting statements about the prescriber—particularly if those statements are not true. The law requires that pharmacists decline prescriptions that violate legal requirements. This is not a blanket rejection of a drug or of a prescriber or of a patient. A different prescription for the same drug, issued by the same prescriber, for the same patient, might be perfectly acceptable. Negative editorial comments about the drug or the prescriber or the patient can come back to haunt the pharmacist who makes them. It is the prescription that cannot be honored.

Pharmacists have a responsibility to educate patients about their medications. Given this responsibility, pharmacists may occasionally use language that patients interpret as pejorative (Disapproving) (i.e. "this dose is quite high," "we usually don't see this drug used four times daily," "these drugs taken together can be problematic"). It is impossible to completely avoid using language like this since patient welfare is a primary concern for pharmacists. Statements like this can be made without insulting the prescriber or the drug or the patient. But the urge to use stronger language that impugns (disputes the truth) the drug or the prescriber or the patient must be resisted.

CASE NUMBER FOUR: NEW MEXICO, 2017

Issue: Wrongful Conduct by a Drug Diverter Who Sued a Pharmacist.

Facts Presented by the Court: A nurse practitioner knew that a patient "was recovering from prescription pill use and approached him because of his known vulnerability." The nurse practitioner "proposed to write prescriptions for powerful narcotic pain pills" for the patient, then the patient would have the prescriptions filled, and the patient would share half of the medication with the nurse practitioner. The patient agreed to participate in the scam and he took these fraudulent prescriptions to the defendant pharmacy where they were honored.

As a result of obtaining and using these opioids, the patient and his wife "became addicted to the drugs, lost custody of their child, and lost employment." The patient was arrested for driving while intoxicated, and his wife suffered an overdose. They then sued the pharmacist for "negligent provision of pharmacy services" and for acting "in wanton disregard of the rights of the plaintiffs." The pharmacy urged the court to dismiss the case based on the "wrongful conduct rule."

Judicial Observations: "It is a well-settled rule of law that a person cannot maintain an action if, in order to establish his cause of action, he must rely, in whole or in part, on an illegal or immoral act or transaction to which he is a party, or where he must base his cause of action, in whole or in part, on a violation by himself of the criminal or penal laws." Based on this definition of the "wrongful conduct rule," the court concluded that the "plaintiffs instigated and actively participated in a scheme to acquire opioids through fraudulent prescriptions, and they shared the fruits of their acquisition with" the nurse practitioner. "If this court allowed plaintiffs to recover for their injuries, plaintiffs would in essence be rewarded for their illegal behavior." Applying the "wrongful conduct rule," the court dismissed the case against the pharmacist.

Lessons of the Case: Pharmacists have huge challenges in identifying fraud and deceit in the acquisition of pain medications when a prescriber and a patient have entered into a conspiracy to victimize the pharmacist based on the pharmacist's compassion and good will toward pain patients. Not every jurisdiction recognizes the importance of the "wrongful conduct

rule." Fortunately, this case is well-reasoned and persuasive. It can serve as the basis for legal protection of pharmacists from ridiculous lawsuits filed by drug diverters who want to profit from their own criminal activities.

CASE NUMBER FIVE: OHIO, 2016

Issue: Patient Confidentiality and Conversations Between Two Pharmacists.

Facts Presented by the Court: A patient brought to the defendant pharmacy an Adderall prescription from her obstetrician/gynecologist. The pharmacist contacted the prescriber and questioned why a prescription for Adderall would be issued to a pregnant patient. The prescriber explained that it was a valid prescription for a legitimate medical purpose. The pharmacy declined the prescription and returned it to the patient. The patient took the prescription to a second pharmacy where the pharmacist initially declined to honor the prescription, because the pharmacist at the first pharmacy had called to tell the second pharmacist "that it's wrong to give a pregnant woman Adderall." Eventually the second pharmacist did honor the prescription. The patient sued the first pharmacy, claiming that there was a breach of privacy and that her HIPAA rights had been violated by the call made from the first pharmacist to the second pharmacist.

Judicial Observations: The court noted an expert report in which a pharmacist hired by the plaintiff stated that the first pharmacist had "engaged in conduct that exhibited a lack of professionalism as well as violating patient confidentiality." The court then turned to the specific language of the HIPAA legislation, which says "a covered entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is related to items such as patient safety activities." Applying this language to the facts of the case, the court concluded that the first pharmacist had "acted in accordance with the standard for use of private medical information under HIPAA." Because the first pharmacist's conduct was based on concerns that a pregnant woman may be at risk when prescribed certain medications, "contacting another pharmacy which would be providing medication to her would address these concerns relating to patient safety." The patient's case against the first pharmacy was dismissed.

Lessons of the Case: Patient-related information shared between two health professionals for the purpose of promoting a patient's best interests is allowed under traditional pharmacy confidentiality standards and the HIPAA law. If the rule were otherwise, then patient safety would be adversely affected, because a health professional who had identified a concern about a patient's welfare could not share that concern with other health professionals caring for the same patient. The incidence of adverse outcomes for patients would increase. Regardless of this standard, professional concerns about a patient's welfare should be conveyed to another health professional in a factual manner that includes the basis of any concerns expressed. The second health professional is then in a position to interpret the information and either act on it or reject it. Simply conveying concerns to another health professional does not violate patient confidentiality.

CASE NUMBER SIX: CONNECTICUT, 2017

Issue: Whether a Pharmacy Misfill Case is Medical Malpractice or Ordinary Negligence.

Facts Presented by the Court: A patient allegedly was dispensed hydralazine rather than the hydroxyzine that had been prescribed for her. Her lawsuit against the dispensing pharmacy was not accompanied by a certificate of good faith and an expert opinion letter, as is required in Connecticut medical malpractice cases. The defendant pharmacy moved the court to dismiss the case since the formal requisites of a medical malpractice case had not been met. The plaintiff claimed, however, that the lawsuit was based on ordinary negligence, and not medical malpractice, therefore, there was no requirement for a certificate of good faith or an expert opinion letter.

Judicial Observations: The court noted that a lawsuit is based on medical malpractice, and is not based on ordinary negligence, when three conditions are met: (1) the defendant is sued in the capacity of a medical professional, (2) the alleged negligence is of a specialized medical nature that arises out of a medical professional-patient relationship, and (3) the alleged negligence is substantially related to medical diagnosis or treatment and involves the exercise of medical judgment. Applying this legal standard, the court said, "a lay person cannot read a prescription and know how to fill it, only a trained and licensed pharmacist can engage in that activity and it requires that they utilize their specialized knowledge and exercise the degree of skill commonly applied by pharmacists in filling prescriptions." The case was dismissed, because the requirements applicable to a medical malpractice lawsuit had not been met.

Lessons of the Case: As a health care profession, pharmacy incorporates specialized expertise, and courts are cautious not to judge pharmacists without the benefit of expert evaluation of pharmacist conduct. This is the purpose of legislation in many states that requires any medical malpractice lawsuit to be supported by expert opinion. In the absence of that expert opinion, the lawsuit will automatically fail. In this case, the patient argued that confusing one drug for a very different drug with a look-alike and sound-alike name is ordinary negligence because it does not require professional expertise. The patient is effectively saying that any lay person can see that there was negligence in the processing of the prescription, and that an expert's opinion is unnecessary. The court disagreed with the patient, based on its understanding that what may seem simple isn't necessarily simple. Pharmacy establishes its own standards of practice, and those standards must be respected in a lawsuit based on pharmacy error. Without expert witness evaluation, a case against a pharmacist based on a misfilled prescription will fail.

CASE NUMBER SEVEN: NEW HAMPSHIRE, 2016

Issue: Pharmacy Error and Continuous Quality Improvement.

Facts Presented by the Court: A pharmacy received a patient's prescription for a Combipatch 0.05mg/0.14mg transdermal system. A pharmacy technician erroneously processed the order with Combipatch 0.05mg/0.25mg transdermal system. The pharmacist failed to detect the error during final check. Fifteen days later, the pharmacy received a prescription for Losartan 50mg tablets. A pharmacy technician processed the order with Lovastatin 20mg tablets. Again, the pharmacist failed to detect the error during final check. The pharmacist was disciplined by the board of pharmacy based on these two errors.

Judicial Observations: The court noted that the board of pharmacy had disciplined the pharmacist for failing to comply with a specific state law requiring the pharmacist to "ensure that the medications dispensed to Patient A and B conformed with the prescriptions issued

to them." However, the law cited by the board of pharmacy actually didn't say that. The law stated that the pharmacist-in-charge (the disciplined pharmacist was the pharmacist-in-charge) must "establish quality assurance guidelines to ensure the medication dispensed is in conformance with the prescription received." The court said that the board of pharmacy had erred in construing the cited law to require the pharmacist "to ensure that there would be no dispensing errors, rather than to require him to establish quality assurance guidelines designed to achieve that result." The court vacated the board of pharmacy's discipline of the pharmacist because there was no evidence that quality assurance guidelines had not been established.

Lessons of the Case: Error is inevitable. From a regulatory perspective, there is a difference between errors by pharmacists who have tried to prevent their errors, and errors by pharmacists who have made no effort to prevent their errors. The former pharmacists can be forgiven as fallible humans, because at least they tried, even though they failed. The latter are more difficult to forgive because they didn't even try. The law on which the board based its disciplinary action in this case required the development and implementation of a quality improvement program. It did not require perfection in the practice of pharmacy. Simply because two errors occurred in a pharmacy does not mean there was no quality improvement program in place. Even when an excellent quality improvement is fully functioning, there may still be errors. Licensing agencies that discipline licensees must base the discipline on proof that a specific law has been violated. Assuming that the specific law might have been violated is not enough. In the absence of evidence that the pharmacist-in-charge failed to establish a quality improvement program, the discipline in this case fails. The alleged violation was not proven, regardless of the fact that errors were committed.

CASE NUMBER EIGHT: MISSOURI, 2016

Issue: Discipline of Pharmacist for Unsupervised Pharmacy Technician.

Facts Presented by the Court: A pharmacist and pharmacy owner from Missouri traveled to Chicago for a continuing education seminar. The pharmacist had arranged for another pharmacist to work at his pharmacy during the trip. However, the other pharmacist did not report to work due to his wife's illness. When a pharmacy technician reported to the owner that the relief pharmacist has not reported to work, the owner instructed the technician to close the pharmacy but to leave the doors open so that staff could explain to patients that they could not pick up their medications because no pharmacist was on duty.

The technician also notified the pharmacist-owner that a physician had telephoned in an order for chemotherapy medication to be compounded for a patient that day. The owner initially instructed the technician not to prepare the medication, but later changed his mind and instructed the technician to compound the chemotherapy and deliver it to the physician's office. The technician did as she was told. Fortunately, there was no evidence that the patient suffered any adverse effect of the chemotherapy.

The board of pharmacy was informed that someone was practicing pharmacy without a license at the pharmacy. After an inspection by an investigator from the board of pharmacy, the pharmacist-owner's license was placed on probation for one year. The pharmacist appealed from this discipline.

Judicial Observations: The court observed that the pharmacist stated at his hearing that "he thought he did the right thing in directing his staff to compound and dispense the chemotherapy drugs, and he would do the same thing again for the benefit of the patient." The pharmacist

admitted that he knew it was a violation of the law for an unlicensed person to practice pharmacy, but "if he were presented with the same situation, he would break the law again." The pharmacist claimed that he "used his professional judgment to violate the law when he felt that it was in the patient's best interest."

The court responded to the pharmacist's statements: "Simply put, the regulations in question are not suggestions for use, they are mandatory rules established and designed to protect the public." The court found that there was no excuse for the pharmacist's "flagrant disregard of the regulations." The court concluded that the pharmacist's "decision to pick and choose which mandatory regulations he believes himself to be bound by in his expertise is nothing short of the sort of arrogance that the regulations are designed to guard the public against." The disciplinary action that placed the pharmacist-owner on probation was upheld by the court.

Lessons of the Case: The court's strong reaction to the pharmacist's arguments is hardly a surprise. There is probably no pharmacist anywhere who fails to understand that compounding of chemotherapy by a pharmacy technician who is not under a pharmacist's supervision is unlawful and may subject a pharmacist to discipline for authorizing such activity. There may be times when a pharmacist feels compelled to violate legal requirements based on the principle that a patient's best interests are being served. Nevertheless, if such a violation is discovered by the board of pharmacy, it is virtually certain that discipline will result. Sometimes there is a price to be paid for principled actions. When that happens, the best approach is always to apologize and promise never again to commit a violation. Confronting a regulatory agency and promising to continue violating applicable laws in the future is an unwise approach. Humility and apology are far better responses than arrogance and defiance.

CASE NUMBER NINE: NEW YORK, 2017

Issue: Pharmacist Discharged for Fear of Needles.

Facts Presented by the Court: A pharmacist suffered from trypanophobia—fear of needles. The pharmacy where he was employed discharged him "because he could not comply with a company policy that required pharmacists to administer immunization injections to patients." In 2011, the pharmacist's employer, and other large pharmacy chains, "started requiring pharmacists to perform immunizations in order to fill an unmet need for vaccinations in the healthcare market." Pharmacist job descriptions were revised to require pharmacists to hold a valid immunization certificate, and included a reference to immunizations in the list of "essential duties and responsibilities" for pharmacists.

The pharmacist obtained a note from his treating physician, stating that the pharmacist was "needle phobic and cannot administer immunization by injection." The pharmacist wrote a letter to his supervisor explaining that his trypanophobia caused him to experience "lightheadedness, paleness, and a feeling that I may faint" and that, as a result he "would never even consider trying to become an immunizing pharmacist." The pharmacist said that he believed his condition was covered by the Americans with Disabilities Act (ADA), and requested that the pharmacy provide him with a reasonable accommodation. The pharmacy told the pharmacist that the ADA does not apply to trypanophobia, and that the pharmacist would lose his job if he did not perform immunizations.

The pharmacist's employment was terminated and he sued the pharmacy for violation of the ADA.

Judicial Observations: The court stated that the ADA prohibits discrimination in employment against a "qualified individual on the basis of disability." A "qualified individual" is defined as one who, "with or without reasonable accommodation, can perform the essential functions of the employment position that such individual holds or desires." Employers may not discriminate against people with disabilities that do not prevent job performance, but when a disability renders a person unable to perform the essential functions of the job, that disability renders him or her unqualified.

Applying this law to the facts of the case, the court concluded that immunizations are an essential function of a pharmacist, and that a reasonable accommodation must enable a pharmacist to perform that essential function, regardless of whether the pharmacist can perform other functions of the pharmacy profession. The court then concluded that there was no possibility for a reasonable accommodation of the pharmacist. The pharmacist's suggestion that the pharmacy hire a nurse or other pharmacist to perform immunizations during his shifts was rejected by the court. It is not a reasonable accommodation to hire someone else to perform a pharmacist's essential functions.

The pharmacist failure-to-accommodate claim was dismissed.

Lessons of the Case: Pharmacy is a profession in transition. The expanding role of pharmacists may require that they come in contact with patients' body fluids, that they perform medical procedures for the benefit of patients, or that they involve themselves in critical life-or-death activities such as resuscitation. Some pharmacists, who were trained in the traditional practice of pharmacy, may react by saying "hey, I didn't bargain for this." Other pharmacists may be unable to perform expanded pharmacy roles due to a disability or other factor. As this case suggests, employers of pharmacists need not accommodate persons with disabilities when it is impossible for the person to perform the essential functions of a pharmacist. Fortunately, there are still sufficient pharmacy job opportunities that do not require functioning in an expanded role. Pharmacists who suffer from a disability that cannot be accommodated will need to find one of those opportunities.

CASE NUMBER TEN: MICHIGAN, 2017

Issue: Error in a Pharmacist-Managed Anticoagulation Service.

Facts Presented by the Court: In 2008, a patient underwent surgery to replace his aortic valve. Following that surgery, the patient was prescribed warfarin, and was monitored by the pharmacist-managed anticoagulation clinic at the patient's hospital. Three pharmacists staffed that clinic. In January, 2014, "based on actions and recommendations from the pharmacists at the anticoagulation clinic, the patient discontinued use of warfarin." "The pharmacists incorrectly believed that the patient had a bioprosthetic valve when in fact the patient actually had a mechanical valve." The patient suffered a stroke.

The patient sued the hospital for medical malpractice, based on the alleged negligence of the three pharmacists who staffed the anticoagulation clinic.

Judicial Observations: The court considered the hospital's contention that the patient's lawsuit was not accompanied by a sufficient affidavit of merit, as is required in a Michigan medical malpractice case. In particular the hospital pointed to a requirement that when the alleged malpractice is in a specialty area, the affidavit be submitted by a professional person in that same specialty area. The hospital claimed that the pharmacist who submitted the patient's affidavit of merit did not hold the PharmD degree as did all three pharmacists who staffed the

anticoagulation clinic, and that the pharmacist who submitted the affidavit had no experience in anticoagulation care. The patient's lawyers responded that for pharmacists, as opposed to physicians, the specialist requirement did not apply.

Without directly considering the specialist issue (because it didn't have to), the court ruled that the affidavit was insufficient. "Although it states the standard of care, it fails to specify how each of the pharmacists breached that standard of care or what actions they should have taken to comply with the standard of care. The affidavit simply lists a number of actions taken by the pharmacists as a group, and concludes that such actions violated the standard of care. It fails, however, to specify which actions were taken by which individual, or what actions each individual should have taken to comply with the standard of care." The court ruled that the affidavit was insufficient.

Lessons of the Case: Specialty pharmacy is now a huge focus within the profession. Pharmacists no longer all do essentially the same thing. They probably never did, but specialization in the profession has become particularly important within the last decade or so. Just as has been the case in physician malpractice litigation, courts will need to sort out whose expertise is valid in helping a jury understand the standard of practice for specialty pharmacy, and whether a defendant pharmacist breached that standard. A pharmacist who is not an expert in the field of a pharmacy defendant's specialty practice will confuse, rather than clarify, the issues. Courts prefer clarification over confusion. It is inevitable that rules will evolve to require specialty pharmacy expert witness testimony in a case alleging malpractice in that pharmacy specialty.

CASE NUMBER ELEVEN: MISSISSIPPI, 2016

Issue: The Challenge of "As Directed" Directions.

Facts Presented by the Court: A child was taken to the emergency department of a hospital, where the child was diagnosed with Molluscum contagiosum, a viral infection of the skin. The ED physician prescribed a product called Verr-Canth, and wrote a sig on the prescription to "apply as directed by the pharmacy." The patient's mother presented the prescription to a pharmacy that did not stock Verr-Canth, but was willing to compound a similar medication with cantharidin, subject to the ED physician's approval. The pharmacist contacted the physician who instructed the pharmacist to compound a lotion or solution with 0.7% cantharidin. The physician gave no further instructions at that time. The pharmacist compounded the medication and dispensed it to the mother, labeled with the directions "apply as directed" and to repeat in three weeks. The mother applied the medication to the child's skin "generously" and "over large parts of his body." The child suffered second degree burns and eventually recovered.

The mother filed a lawsuit on behalf of the child against the physician, the hospital, and the pharmacy. A jury returned a verdict totaling \$3 million. The jury apportioned 75% negligence to the physician and 25% negligence to the pharmacy, meaning that each party was responsible for paying the assigned portion of the total verdict. The physician appealed the verdict, arguing that the judge had improperly denied him a "superseding cause" jury instruction, which might have resulted in no liability for the physician and full liability for the pharmacy.

Judicial Observations: The legal principle of "superseding cause" is stated this (somewhat complicated) way: "Although one may be negligent, if another, acting independently and voluntarily, puts in motion another and intervening cause which efficiently thence leads to unbroken sequence to injury, the latter is the proximate cause and the original negligence is relegated to the position of a remote and, therefore, a non-actionable cause." In effect, this complex language means that the last person to commit an act of negligence is responsible

for the consequences of the negligence, even if other negligence has preceded the last negligence. For example, if a pharmacist negligently dispenses the wrong strength of a drug, and a nurse negligently administers the drug to the wrong patient, it is the nurse who will be held liable and not the pharmacist, if there is harm to the wrong patient. In this scenario, the nurse's negligence is a superseding cause of harm to the wrong patient. The pharmacist has no liability, even though the pharmacist was negligent, because the pharmacist's wrong strength error had nothing to do with the nurse's wrong patient error.

The physician in this case argued on appeal that he had issued the prescription in a way that directed the pharmacist to include specific instructions for use by the patient. The physician argued that the pharmacist had changed the prescription, without authority, by omitting the words "by the pharmacist" from the "apply as directed" language. Therefore, the physician argued that the jury should have been instructed to consider the pharmacist as a superseding cause of the patient's injuries.

The court noted expert witness testimony of a pharmacist who had testified at trial:

"Q: And did the failure of the pharmacy to comply with the pharmacy regulations; taking action as a pharmacy as a whole, that they failed to comply with the pharmacy regulations?"

A: Yes.

Q: And did the pharmacy's failures in those respects in this case solely cause the adverse event?"

A: Yes. A pharmacist was the last person to touch this prescription. They should have been the one to make sure that it was going to be dispensed correctly or else this wouldn't have happened."

Based on this testimony, and on its analysis of the facts and the applicable legal principles, the court reversed the verdict and ordered a retrial to include a superseding cause instruction to the jury.

Lessons of the Case: Prescriptions with an "as directed" sig are perhaps the greatest liability risk in pharmacy. Prescribers often don't give patients directions with such prescriptions, or patients forget the directions they have been given, and inevitably patients end up using the medication incorrectly even when the pharmacist has processed the prescription exactly as it was issued. Everybody, including the physician, the pharmacist, and the pharmacy, are potential defendants if a lawsuit ensues. It isn't fair, but it's a fact.

In this case, the challenge to the pharmacist was exacerbated, because the physician requested that the pharmacist provide directions to the patient. At least arguably, the pharmacist did change the directions by excluding the "by the pharmacist" language from the medication label. Had that language been included in the label, the mother might have asked the pharmacist for additional directions on the use of cantharidin, which is particularly nasty stuff.

Under circumstances like this, when a seldom prescribed medication is ordered, and when the possibility of misuse by the patient is high, pharmacists would be well advised to avoid placing "as directed" on a prescription label. A sensible policy at a pharmacy would be to decline a prescription when the prescriber fails to include directions on that prescription, if the prescribed medication is at high risk for adverse events and the patient has not previously used the medication. These are usually not emergency situations. The patient can return to the prescriber and request that specific directions be added to the prescription. Or the patient can wait until the pharmacist has been able to clarify the directions with the prescriber.

CASE NUMBER TWELVE: MASSACHUSETTS, 2016

Issue: Pharmacist Responsibility to Resolve Third Party Coverage Problems.

Facts Presented by the Court: After suffering a seizure a patient was prescribed Topamax by her physician. Her pharmacy informed her that after the first dispensing the third-party payer would not cover the medication without prior authorization by the physician. The pharmacist instructed the patient to contact the physician to obtain the documentation required by the prior authorization rule. Three months later, the patient had a second seizure. The pharmacist then informed the patient's stepfather that the third-party payer had denied coverage for lack of prior authorization. The pharmacist stated that he could not honor the prescription unless the patient paid for it. The patient and her family attempted to obtain the prior authorization by telephoning the physician several times during the next two months.

The pharmacy's computer system permitted the pharmacist to send a courtesy fax to the prescribing physician whenever a claim was denied for lack of prior authorization, although this was not required. The pharmacy did not maintain records of these faxes, so it was unknown whether a fax was sent to the physician by the pharmacist.

The patient died after suffering a third seizure. Her estate sued the pharmacy, claiming that the pharmacy had promised to send the physician a fax and call his office to obtain prior authorization, but had not done so. The pharmacy moved to dismiss the case, contending that it had not assumed a duty to obtain prior authorization from the physician on behalf of the patient.

Judicial Observations: The court ruled that merely telling the patient and her family that it would contact the physician did not create a legal duty because the pharmacists had expressly instructed her and her family to contact the physician themselves, which they did, apparently to no avail. The court referred to "existing social values, customs, and considerations of policy" in concluding that recognizing such a legal duty for pharmacists "would place an onerous burden on pharmacies," obligating them "to monitor or supervise the prescribing physicians, and, in essence to share the responsibility" to provide third-party plans with the necessary prior authorization. The case against the pharmacy was dismissed.

Lessons of the Case: One of the most frustrating aspects of contemporary pharmacy practice is meeting the requirements of third-party plans. On the one hand, patients need medications to treat their medical conditions. On the other hand, plan sponsors want the least expensive plan that does not pay for unnecessary medications. Rules like prior authorization are designed to assure that patients get medications they need, but do not get medications they do not need. Unfortunately, patients have not been taught that they have responsibilities to negotiate the third-party pay system, in partnership with physicians and pharmacists. When the plan they have chosen (or that their employer has chosen) imposes a rule as a condition of receiving medication, patients can't escape responsibility by saying to the pharmacist, "that's your problem." The court in this case understood that. Patients who choose to be covered by a pharmaceutical benefit plan must participate in meeting the requirements of that plan. Alternatively, they may pay for their medications themselves.

CASE NUMBER THIRTEEN: MASSACHUSETTS, 2016

Issue: Alleged False Claims for Payment by a Pharmacy.

Facts Presented by the Court: A pharmacist alleged that three pharmacies he knew of, and where he had worked, had violated the federal False Claims Act (FCA) by dispensing drugs labeled with incorrect expiration dates and then billing the federal government for expired drugs. When filing such a lawsuit, a person can become a "relator" who is asserting the interests of the United States of America, and the relator may be entitled to a portion of a financial recovery awarded to the United States based on the claim. The pharmacies asked the court to dismiss the FCA claim.

Judicial Observations: The FCA imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." A "claim includes direct requests to the government for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits programs." To succeed with an FCA case, the relator "must provide details that identify particular false claims for payment that were submitted to the government." This specificity requirement prevents relators from filing allegations of fraud merely in the hopes of conducting embarrassing discovery and forcing settlements.

The relator alleged that the pharmacies were required to submit prescription expiration dates to Medicaid and Medicare, and that they had submitted false expiration dates. The pharmacies asserted that pharmacies do not submit expiration dates to Medicaid and Medicare. The relator then "backtracked and alleged that pharmacies are required to submit data regarding the number of days supply they have provided to the patient, "and that "a drug dispensed with a false expiration date causes a false certification of "days supply" because the drug will not be safe and effective for the full number of days it is dispensed."

The court explained that "the relator does not identify a single false claim submitted by any of the three defendants. While the relator does allege that the prescription vials were mislabeled or misbranded because they contained a false expiration date, he does not plead one claim submitted to the government which billed for expired drugs or contained a false date in the claim itself."

The FCA claim based on outdated medications was dismissed.

Lessons of the Case: Because the government can't be in all places at all times, it relies on insider whistleblowers to provide information to authorities about illegal activities at worksites where the FCA may have been violated. The procedure is for the relator to file a lawsuit against the alleged violator, and the government may or may not join in the lawsuit. In exchange for the inside information about fraud in federal programs, the government extends financial incentives to the whistleblower for providing information that otherwise would likely go undiscovered.

Some pharmacists have taken advantage of the financial incentives that these so-called *qui tam* cases provide. They have collected huge sums of money. However, far more pharmacists have initiated unsuccessful *qui tam* cases, resulting in wasted time and money. An unsuccessful pharmacist relator may find it difficult to overcome a tarnished reputation that results from making unsupported allegations against a former employer. The law has established a high bar for FCA cases, and pharmacists should think twice before initiating such a legal action. The law frowns on fraud, but it also frowns on those who groundlessly allege fraud merely in the hopes of causing embarrassment and forcing a settlement.

CASE NUMBER FOURTEEN: ILLINOIS, 2016

Issue: Allegedly Illegal Generic Substitution.

Facts Presented by the Court: A child was prescribed Concerta to treat ADHD. The child's father brought the prescription to the defendant pharmacy, where the pharmacist allegedly substituted a generic product that was not equivalent to Concerta. The father filed a lawsuit against the pharmacy on behalf of the child, but the lawsuit did not allege that the child "received any less therapeutic effect with the generic," he asserted only that "defendants did not abide by the guidelines for pharmacists when filling prescriptions." The pharmacy requested that the case be dismissed, because the lawsuit did not allege any damages.

Judicial Observations: The court noted that the lawsuit "has not alleged or suggested that the generic failed to act in the same manner as Concerta or failed to provide the patient with safe and effective treatment for his ADHD. So, in the end, even with the substitution, the patient got what his physician and father desired, namely effective treatment for ADHD." The father relied on statements made by the FDA about Concerta and generics, but the court observed that the FDA statements "merely indicated there had been only an isolated number of cases where the generic failed to have the same therapeutic effect as Concerta." The lawsuit did not allege any facts suggesting that the patient fell within that limited number of cases.

The court concluded that the lawsuit had not alleged any "facts that show any concrete physical or financial harm" as the result of the generic substitution. Therefore, the pharmacy's motion to dismiss the lawsuit was granted.

Lessons of the Case: It is the state board of pharmacy's responsibility to assure that pharmacists follow the laws applicable to pharmacy practice. If harm occurs to a patient as the result of legal violations, then patients, or their representatives, may also take legal action against the offending pharmacy. In the absence of harm to the patient, the only recourse is disciplinary action by the board of pharmacy. A private citizen can't sue a pharmacy based solely on a violation of the law, in the absence of harm caused by the violation.

In this case, the alleged generic substitution may or may not have been legal. In the absence of alleged harm to a patient, a court isn't even going to consider the legality issue. There is no point. There must be harm to a patient for a lawsuit by a patient against a pharmacy to succeed.

This case illustrates why there have been so few lawsuits against pharmacies based on generic substitution, despite the fact that there have been millions, perhaps hundreds of millions, of generic substitutions by pharmacists. A plaintiff filing such a lawsuit must prove not only that an illegal substitution occurred, but that there was harm to the patient that would not have occurred had the originally prescribed drug been dispensed rather than a generic. This is an almost impossible burden of proof. Generic substitution is a pharmacy activity that poses a low risk of legal liability.

CONCLUSION

Pharmacy law case scenarios facilitate an understanding of judicial expectations of pharmacists and technicians, which reflect public expectations. The likelihood that any practicing pharmacist or technician will encounter exactly the same challenge as was represented in any of the scenarios presented here is small but real. The likelihood that the general principles of these cases will confront any practicing pharmacist or technician is quite high. Some of the case scenarios review mistakes that have made. Other case scenarios review alleged mistakes that were determined by the court not to have been real mistakes. Whether the mistake was real or not, all scenarios provide guidance on how to improve a pharmacy practice by meeting professional responsibilities.

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LESSON EVALUATION

Please fill out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does the program meet the learning objectives?

List responsibilities for dispensing controlled drugs YES NO

Describe legal requirements for medication error prevention YES NO

Discuss legal implications of expanded pharmacy responsibilities YES NO

2. Was the program independent & non-commercial? YES NO

3. Relevance of topic Low Relevance Very Relevant

1 2 3 4 5 6 7

4. What did you like most about this lesson? _____

5. What did you like least about this lesson? _____

6. How would you improve this lesson? _____

Please Mark the Correct Answer(s)

"PHARMACY LAW UPDATE" NOV/DEC 2017

1. In the 2017 New Mexico case where the pharmacist was alleged to have dispensed opioids too early, approximately how much case money did the patient offer to pay for her medication, rather than waiting for Medicaid coverage?

- a. \$10.
- b. \$100.
- c. \$500.
- d. \$1,000.

2. Why would legitimate pain patients want to acquire an additional supply of opioids somewhat early?

- a. To keep a steady supply of medication on hand.
- b. To sell for money to buy luxury items.
- c. To play a trick on their pharmacist.
- d. As a dare to law enforcement.

3. A specialty pharmacy dispenses oral chemotherapy agents that appear in the 2016 NIOSH list. The pharmacy policy is 3. Who may authorize a pharmacist to honor an illegal prescription that has been confirmed as fraudulent?

- a. The prescriber.
- b. An agent of the prescriber.
- c. The local police.
- d. Nobody.

"PHARMACY LAW UPDATE" NOV/DEC 2017

- 4. If local police to whom a fraudulent prescription has been reported think that a fraudulent prescription is too unimportant a crime to pursue, what should a pharmacist do?**
 - a. Conduct an intervention for the patient.
 - b. Simply refuse to dispense the medication.
 - c. Contact the FBI.
 - d. Convene a meeting of members of the patient's family.
- 5. Which of the following statements would be advisable for a pharmacist to make when declining to honor a controlled substance prescription?**
 - a. Your doctor is trying to kill you.
 - b. Your doctor should be arrested.
 - c. Your doctor is under DEA investigation.
 - d. None of the above.
- 6. When a pharmacist considers whether to honor a controlled substance prescription based on concerns that the prescription may not be legitimate, what should be the primary focus of those considerations?**
 - a. The reputation of the prescriber.
 - b. The behavior of the patient.
 - c. The legality of the prescription itself.
 - d. The manufacturer of the drug.
- 7. Under the law, there is a policy of now allowing people who have engaged in illegal activity to sue somebody else to recover damages caused by the plaintiff's own illegal activity. What is that policy called?**
 - a. Informed Consent.
 - b. Risky Business.
 - c. Wrongful Conduct Rule.
 - d. False Claims Act.
- 8. Under traditional pharmacy confidentiality standards and the HIPAA law, is it permissible for one health care provider to contact another health care provider and share information that relates to patient safety activities? Assume that both health professionals have or had a professional relationship with the patient in question.**
 - a. Yes.
 - b. No.
- 9. In the case related to the pharmacist's erroneous dispensing of hydralazine when hydroxyzine was prescribed, did the court rule that this is a case of medical malpractice?**
 - a. Yes, because pharmacy standards must be respected in a lawsuit.
 - b. No, because it is ordinary negligence.
- 10. In the case that addresses the out-of-town pharmacist who authorized his technician to mix chemotherapy without pharmacist supervision, was the explanation that this was done "for the benefit of the patient" accepted as a reason to absolve the pharmacist of any legal violation?**
 - a. Yes, the discipline of the pharmacist was overturned by the court.
 - b. No, the discipline of the pharmacist was upheld by the court.
- 11. When a pharmacist has made a mistake, such as allowing an unsupervised technician to compound chemotherapy, and the board of pharmacy holds a hearing to consider disciplinary action against the pharmacist, what is the best approach for the pharmacist to take?**
 - a. Antagonism and defiance.
 - b. Confrontation.
 - c. A promise to violate the law again in the future.
 - d. Humility and an apology.
- 12. What is trypanophobia?**
 - a. Fear of needles.
 - b. Fear of the dark.
 - c. Fear of error.
 - d. Fear of risk.
- 13. Against what type of discrimination in the workplace does the ADA protect workers?**
 - a. Age.
 - b. Nationality.
 - c. Disability.
 - d. Religion.
- 14. In the Michigan case from 2017, where the anticoagulation clinic recommended that the patient with a mechanical heart valve discontinue warfarin, from what department of the hospital was the anticoagulation clinic staffed?**
 - a. Medicine.
 - b. Surgery.
 - c. Pharmacy.
 - d. Nursing.

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- 15. In the Mississippi case from 2016, in which the pharmacist compounded cantharidin lotion, under what legal principle did the physician contend that the pharmacist could be held fully liable for the harm that was caused to the patient?**
- Alternate liability.
 - Alternative fact.
 - Extended warranty.
 - Superseding cause.
- 16. In a lawsuit based on harm to a patient following the use of "as directed" in a prescription and on a prescription label, who are the potential defendants?**
- The physician.
 - The pharmacist.
 - The pharmacy.
 - All of the above.
- 17. In the case where the patient's third-party payer imposed a condition that needed to be met before the patients Topamax prescription would be covered, what was that condition?**
- Generic substitution.
 - Prior authorization.
 - Waived copay.
 - None of the above.
- 18. If a pharmacist files a claim against a pharmacy based on the pharmacist's belief that a False Claims Act violation has occurred, what is that pharmacist called?**
- Relator.
 - Manager.
 - Barrister.
 - Negotiator.
- 19. In the Illinois case from 2016, alleging liability for an illegal generic substitution of Concerta, what damages did the plaintiff claim had been caused by the substitution?**
- Death.
 - Hearing loss.
 - Vision loss.
 - None.
- 20. Who has the responsibility to assure that pharmacists follow the laws applicable to pharmacy practice?**
- State boards of pharmacy.
 - Schools of pharmacy.
 - Continuing Pharmacy Education providers.
 - Patient advocacy groups.