Overview of Recent Pharmacy Law Cases

ACTIVITY DESCRIPTION
This class reviews six legal cases in which allegations were made that pharmacy personnel had failed to meet their legal responsibilities. The facts and conclusions of the cases are discussed. Recommendations to promote regulatory compliance are provided.

TARGET AUDIENCE
The target audience for this activity is pharmacists, pharmacy technicians, and nurses in hospital, community, and retail pharmacy settings.

LEARNING OBJECTIVES
After completing this activity, the pharmacist will be able to:

- List the ways in which a pharmacy technician can identify the correct patient when medication is delivered.
- Discuss the limits of a pharmacy technician’s objections to a pharmacy policy.
- Describe the responsibility of a pharmacy technician upon being informed by a patient of unexpected symptoms following drug use.

After completing this activity, the pharmacy technicians will be able to:

- List the ways in which a pharmacy technician can identify the correct patient when medication is delivered.
- Discuss the limits of a pharmacy technician’s objections to a pharmacy policy.
- Describe the responsibility of a pharmacy technician upon being informed by a patient of unexpected symptoms following drug use.
- Describe ways that pharmacists can improve the safety tone of a pharmacy work environment by utilizing simple management skills.

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Learning Objectives

- Discuss the circumstances under which a pharmacist's license may be revoked by the state board of pharmacy.
- Describe the responsibility of pharmacists to refrain from making disparaging remarks about prescribers.
- Describe the manner in which a pharmacist can utilize information provided by a technician.
- List the factors that distinguish between a pharmacy technician and a pharmacy intern.
Review of Six Cases

- Kolozsvari v Doe, Indiana, 2011.
- Thomas v Costco, California, 2014.
- Franklin v K-mart, Virginia, 2014.

Analysis of Cases

- Parties
- Issue
- Facts
- Allegations
- Rationale
- Result

Many of these cases are on appeal from a motion for summary judgment.

Some names of individuals are redacted.

Kolozsvari v. Doe, Indiana Ct of App, 2011

- Parties: Patient & Husband sue Physician, Pharmacist, and Pharmacy.
- Issue: Whether the lower court erred in granting summary judgment for the defendants because pharmacists never have any duty to warn patients about prescribed medications.

Kolozsvari (Facts)

- Physician ordered OsmoPrep prior to colonoscopy. Patient took Rx to pharmacy. Computer alerted re potential interaction with Lisinopril based on boxed warning; pharmacist overrode.
- Next day, patient experiences tingling in fingers & forearms, physician’s office reschedules colonoscopy & reorders OsmoPrep with new Rx.
- At pharmacy, patient reports tingling to tech who tells pharmacist & pharmacist says it is not the drug.
- Patient alleges adverse effect resulting in need for renal dialysis.
- Summary judgment for pharmacy—no duty.
Kolozsvari (Rationale)

- “The practice of medicine has become more specialized, and consumers have come to rely more and more upon pharmacists and pharmacies—which often have national resources to support their operations—for help in understanding the effects and interactions of various prescription and over-the-counter medications.”
- “We hold that [the pharmacy] and [the pharmacist] had a duty of care to Christine either to warn Christine of the side effects of Osmoprep or to withhold the medication.”
- Summary judgment for defendants reversed.

Lessons From The Kolozsvari Case

- Pharmacists can learn of potential risks for patients based on information provided to the pharmacists from:
  - Computer alerts.
  - Package inserts (boxed warnings).
  - Patient reports after using medications.
- Judicial views of the pharmacist’s professional role are evolving.
  - Consumer expectations.
  - Pharmacy resources.
  - Physician specialization.

Blais v. Rhode Island Dept of Health Superior Ct of RI, 2014

- Parties: Pharmacist sues the Director of the RI Department of Health.
- Issue: Whether the Director of the Dept. of Health has the authority to revoke the license of a pharmacist based on a dispensing error, contrary to the recommendation of a hearing officer who had determined that a temporary suspension was appropriate.

Blais (Facts)

- A compounded prescription for omeprazole contained morphine. This caused lethargy in infant, but no permanent damage. Mother filed complaint with Board of Pharmacy.
- Pharmacy inspection determined that “there was really no organized pattern for where the drugs were located,” and that everything was “very cluttered and disorganized.”
- Director issued a summary suspension.
- Hearing officer recommended suspension, probation, continuing education.
- Director revoked the pharmacist’s license.
Blais (Rationale)

- “Where a hearing officer is able to examine evidence and live testimony first-hand, the law accords more weight to his or her findings than to a reviewing administrative official who does not hear such testimonial evidence.”
- “Pharmacists cannot be held to a standard of perfection.”
- “Dispensing errors do occur and are expected to be a part of the learning process for a pharmacist.”
- Director exceeded authority; pharmacist’s license reinstated, with probation and CE requirements.

Lessons From The Blais Case

- Errors in pharmacy are to be expected, and they must be used for improvement.
  - Record the errors.
  - Consider improvements that can be made.
  - Implement strategies to prevent future errors.
  - There may be a minor punishment.
- Government executives cannot ignore findings and conclusions of hearing officers.
  - Testimony offered in hearings.
  - Facts and evidence reviewed.
  - Larger picture of intended & unintended consequences.

Thomas v. Costco
US Dist. Ct, California, 2014

- Parties: Former pharmacy technician sues former employer.
- Issue: Whether former pharmacy technician was unlawfully terminated from employment after protesting the pharmacy’s filling of “too many prescriptions for narcotics.”

Thomas (Facts)

- Technician disagreed with pharmacy policies on opioids, and he was given a transfer.
- Former tech continued to criticize pharmacy policy; new supervisor asked him “who made you the police officer of the pharmacy?”
- Wore a shirt with picture of crying doctor in jail and the words JUSTICE and PILLS KILL. Warned not to wear shirt, but wore again.
- On disciplinary paperwork, said “when [the employer] chooses to publicly address curbing the nationwide epidemic of prescription drug abuse, I will stop wearing my shirts.”
- Employment terminated for insubordination.
Thomas (Rationale)

- Jury found in favor of pharmacy.
- Former tech claimed to have been engaging in protected activity (whistle blowing).
- “An employee’s discipline is deserved if the employee’s activity unreasonably interferes with the employer’s interest in maintaining a harmonious and efficient workplace.”
- “The jury, after a fair trial, concluded that the weight of the evidence showed that [the former technician] was fired because he refused to abide by [the employer’s] dress code.”
- Jury verdict affirmed.

Lessons From The Thomas Case

- Pharmacists value observations and perspectives of technicians.
  - Patient behaviors.
  - Patient comments.
  - Concerns about process.
- The pharmacy workplace is not the right venue for political activity.
  - Withdraw to a non-pharmacy assignment.
  - Speak up, and then move on.
  - Employers have a right to maintain a harmonious workplace.

Emara v. Multicare

- Parties: Former pharmacy technician/intern sues former employing pharmacy.
- Issue: Whether the pharmacy technician/intern was terminated from employment based on his race, national origin, and sex, or was instead terminated because he was working outside the scope of his job assignment.

Emara (Facts)

- Plaintiff was admitted to pharmacy school, after which he obtained licenses as both a pharmacy technician and a pharmacy intern.
- “Technicians are not permitted to perform intern functions under any circumstances, nor any other function that requires discretion.”
- Plaintiff was hired as a pharmacy technician.
- “It is undisputed that Plaintiff counseled patients regarding their medications without the supervision of a mentor.”
Emara (Rationale)

• “If Plaintiff—a technician not having attended a day of pharmacy school and without a mentor—had mistakenly counseled a patient, then [the pharmacy] would be looking at a multi-million dollar tort lawsuit instead of this one.”
• “Plaintiff appears to be an over-eager student whose enthusiasm trumped his better judgment.”
• “No reasonable jury could conclude that the Plaintiff was terminated for discriminatory reasons.”
• Summary judgment for Defendant pharmacy.

Lessons From The Emara Case

• Pharmacy technician and pharmacy intern responsibilities are a matter of role and not of status.
  - Technicians may not perform activities that require the judgment of a pharmacist.
  - Interns may perform judgmental activities with a preceptor’s supervision.
• Roles must be clarified at the start of employment and, if necessary, during a shift.
  - Questions about role should be welcome at any time.
  - Supervising pharmacists must assure a complete understanding of supportive personnel roles.

Let’s Take A Short Break

Franklin v. K-mart
U.S. Dist. Ct., Virginia, 2014

• Parties: Patient’s estate sues pharmacy for giving patient medication intended for a person with a similar name.
• Issue: Whether it is the standard of care in pharmacy to confirm the identity of the patient when medication is dispensed.
Franklin (Facts)

- “Plaintiff alleges that on March 11, 2011, Mr. Walker Franklin attempted to pick up a prescription for prednisone at the pharmacy. Instead of prednisone, Defendant sold him a prescription for ramipril that was intended for William Franklin.”
- Technician testified “she knew Walker Franklin by sight and would recognize him.” She “would not even need to ask him his name.” She “did not realize she sold him the wrong medication, but knows that now.”
- Patient died.

Franklin (Rationale)

- Expert witness pharmacist testified that it is the standard of care to verify that the correct medication is given to a patient.
- “A pharmacy must somehow verify it delivers the right medication to the right patient, and can use unique identifying information to do so.”
- “In its simplest form, a pharmacy, through its employees, is required by the standard of care to verify that the correct medication is given to a patient.”
- On standard of care, summary judgment for Plaintiff.

Lessons From The Franklin Case

- Patient identification is a standard of care.
  - In institutional setting, this is done by checking the wrist band.
  - In community setting, this is done by verifying unique patient information.
- Friendly customer service requires remembering the name of patients.
  - Be particularly aware of “will-call” meds for patients with similar names.
  - Refer to policy as reason for asking repeated information.
  - Standards must be met at all times; no exceptions.

LeFrock v. Walgreens

- Parties: Physician sues pharmacy for slander.
- Issue: Whether evaluative statements made by a pharmacist to a patient, regarding the prescriber, can serve as the basis of a slander claim if the prescriber perceives the statements to be false and harmful to the prescriber’s reputation.
LeFrock (Facts)

• “LeFrock filed this complaint for claims that various [pharmacy] employees defamed him by making false statements pertaining to his medical reputation and ethics.”
• “Here, the statements at issue were made by a pharmacist to pharmacy customers at the time the customers attempted to fill prescriptions, and the apparent purpose of the statements was to inform the customers about the physician who wrote the prescriptions.”
• The pharmacy filed a motion for summary judgment.

LeFrock (Rationale)

• “False statements which suggest that someone has committed a dishonest or illegal act are defamatory per se and are, therefore clothed in a presumption of malice.”
• “The presumption ceases to exist when the Defendant has a qualified privilege to make the statements.”
• “The pharmacists acted in good faith and were upholding a legitimate interest.”
• “Since the pharmacist has a duty beyond merely following the doctor’s instructions robotically, the pharmacists exercised their due diligence by informing the customers, as necessary, of any relevant information regarding the prescribing physician.”

Lessons From The LeFrock Case

• Pharmacists have a responsibility to explain to patients potential problems with drug therapy.
  • This responsibility may include some information that seems critical of the prescriber.
  • Any such information should be provided in good faith for the benefit of the patient.
• Declining a prescription is always a tricky situation.
  • Patients deserve an explanation.
  • Any explanation provided should be free from bias and ill will toward the prescriber.

Summing Up

• Pharmacist legal responsibilities are expanding, and are related to available knowledge.
• Pharmacy technicians play an important, yet limited, role in supporting pharmacists.
• Order processing accuracy continues to be a key legal responsibility for pharmacists.
• Patients have a right to know about the risks of prescribed medications, and communication with patients must be done for their benefit.
Question & Answer Time
EXAM QUESTIONS

1. Many pharmacy law legal cases are on appeal from a motion that would dismiss the case if the motion were granted. What is this procedural motion called?
   b. Constitutionality.
   c. Liability.
   d. Deposition.

2. According to the Kolosvari case (Indiana, 2011), the pharmacist who learned of an interaction between OsmoPrep and lisinopril had a duty to perform what action for the benefit of the patient?
   a. The case mentioned a duty to either warn the patient or withhold the medication.
   b. The case did not mention either warning the patient or withholding the medication.
   c. Warning the patient; but the case did not mention withholding the medication.
   d. Withholding the medication; but the case did not mention warning the patient.

3. In the Kolosvari case (Indiana, 2011), from what source did the court say a pharmacist can learn of potential risks for patients?
   b. Package inserts.
   c. Patient reports after using a medication.
   d. All of the above.
4. In the Kolosvari case (Indiana, 2011), what rationale was offered by the court to justify its view of the pharmacist’s evolving professional role?
   a. Consumer expectations.
   b. Pharmacy resources.
   c. Physician specialization.
   d. All of the above.

5. Which of the following statements was made by the court in the Blais case (Rhode Island, 2014), in which the pharmacist’s license was revoked after a compounding error?
   a. “Pharmacists are unskilled and inept.”
   b. “Mistakes are welcome events in pharmacy practice.”
   c. “Pharmacists cannot be held to a standard of perfection.”
   d. All of the above.

6. According to the Blais case (Rhode Island, 2014), whose findings are afforded more weight than those of a reviewing administrative officer who does not hear testimonial evidence?
   a. A board of pharmacy inspector.
   b. A hearing officer who examines evidence and live testimony first-hand.
   c. The FDA.
   d. A prescribing practitioner.

7. The pharmacy technician who sued his former employer in the Thomas case (California, 2014) voiced his objections to what types of medications?
   a. Antibiotics.
   b. Oral contraceptives.
   c. Opioids.
   d. Antihypertensives.
8. In the Thomas case (California, 2014), the court held that the former employee had interfered with what interest of the former employer’s?
   a. Freedom of speech.
   b. Freedom of religion.
   c. Maintaining a harmonious and efficient workplace.
   d. Clear decision making.

9. The Emara case (Washington, 2013) is about a student who was recently admitted to pharmacy school and who obtained what type of license?
   a. Both pharmacy technician and pharmacist intern licenses.
   b. Neither pharmacy technician nor pharmacist intern licenses.
   c. A pharmacist intern license, but not a pharmacy technician license.
   d. A pharmacy technician license, but not a pharmacist intern license.

10. In the Emara case (Washington, 2013), how did the court describe the plaintiff?
    a. “A dishonest fellow.”
    b. “An over-eager student.”
    c. “An evil-doer.”
    d. “A mistake waiting to happen.”

11. What type of error was the subject of the Franklin case (Virginia, 2014), in which the patient died after receiving ramipril?
    a. Wrong dose.
    b. Wrong dosage form.
    c. Wrong patient.
    d. Drug-drug interaction.
12. According to the court in the Franklin case (Virginia 2014), what is a standard of care in pharmacy?
   a. Medication therapy management.
   b. Patient identification.
   c. Immunizations.
   d. Prescribing privileges.

13. In the LeFrock case (Florida, 2015), a physician was not pleased with comments made about him by a pharmacist, and the physician filed a lawsuit based on what legal claim?
   a. Slander.
   b. Malpractice.
   c. Misadventure.
   d. Wrongdoing.

14. Which of the following statements was made by the court in the LeFrock case (Florida, 2015)?
   a. “Pharmacists should keep their mouths shut.”
   b. “The pharmacist has a duty beyond merely following the doctor’s instructions robotically.”
   c. “A pharmacist is a mere technician.”
   d. “Honesty is the best policy.”

15. A lesson taught by the LeFrock case (Florida, 2015) is that information provided by a pharmacist to a patient should be provided in what manner?
   a. As briefly as is humanly possible.
   b. In a way that will intimidate the patient into following the prescriber’s therapeutic plan, regardless of adverse drug effects.
   c. Using gestures and mannerisms that will entertain and be memorable.
   d. In good faith and for the benefit of the patient.