OVERVIEW OF RECENT PHARMACY LAW CASES

DAVID BRUSHWOOD, JD, RPH
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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 and pharmacy technicians in hospital, community, and retail pharmacy settings.

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

- Discuss the circumstances under which a pharmacist 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 pharmacy technician.
- List the factors that distinguish between a pharmacy technician and a pharmacist intern.

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.

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ABOUT THE AUTHOR
David Brushwood is professor of Pharmaceutical Outcomes and Policy at the University of Florida College of Pharmacy. A graduate of the schools of pharmacy and law at the University of Kansas, professor Brushwood practiced both professions prior to entering academia. Professor Brushwood has developed error prevention programs for several pharmacy chains. His research interests are in the areas of regulating for outcomes, medication error prevention, and pain management policy. He has received grant funding from numerous agencies including the Robert Wood Johnson Foundation, the National Institutes of Health, and the National Community Pharmacy Foundation. Professor Brushwood received the 2012 Pellegrino Medal. The award honors nationally-recognized leaders “for contributions to healthcare ethics in the selfless spirit of Edmund D. Pellegrino.” He also has twice been selected as a Mayday Scholar in Pain Policy by the American Society of Law, Medicine & Ethics. Professor Brushwood is a frequent contributor to pharmacy journals and to law journals. He developed, and serves as an advisor for the UF online Master of Science in Pharmacy, a graduate program offering seven areas of specialization in regulatory pharmaceutical fields.

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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 an 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.

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 to 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