2015 Pharmacy Case Law Update

Roger Morris, R.Ph., J.D.
Quarles & Brady, LLP
William J. Stilling, B.S. Pharm., M.S., J.D.
Parsons Behle & Latimer

Supporter

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Disclosures

• Roger Morris and William Stilling declare no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Learning Objectives

• Target Audience: Pharmacists and Pharmacy Technicians
• ACPE#: 0202-9999-16-016-L03-P
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• Activity Type: Knowledge-based

• At the completion of this knowledge-based activity, participants will be able to:
  – Describe the facts, reasoning, and holdings of federal and state court cases over the last year that are relevant to the attendee’s practice of pharmacy.
  – List the three most important cases for attendee’s practice.
  – Explain whether recent rulings will affect the attendee’s behavior in providing pharmacy services and, if so, what those changes will be.
  – Describe how these cases may impact the future practice of pharmacy.
Self-Assessment Questions

1) Which of the following best describes a holding in a recent case?

a) A state board of pharmacy cannot sanction a pharmacist-in-charge (“PIC”) for acts the PIC was unaware of.
b) A state board of pharmacy can hold a PIC liable for a single dispensing error made by another pharmacist on duty at the same time.
c) A state board of pharmacy can hold a PIC liable for violations of record-keeping and security requirements even if the PIC is unaware controlled substances theft occurred.
d) A state board of pharmacy can hold a PIC criminally liable for thefts that another person committed in the pharmacy.

2) Which of the following best describes the learned intermediary doctrine (“LID”)?

a) Traditionally, the LID protects drug manufacturers and pharmacists from suits that claim failure to warn a patient.
b) The LID deems pharmacists to be learned professionals who have a duty to warn about drugs side effects and interactions.
c) The LID protects physicians from liability if they prescribe according to the indications in the package insert.
d) The LID protects pharmacists from liability in failure to warn cases, but cannot be applied in federal court because it is a state law doctrine.

3) According to recent administrative decisions by the DEA, pharmacists have a duty to check that the prescriber has a current DEA number.

a) True.
b) False.

4) Which of the following is not accurate about liability based on respondeat superior (“RS”)?

a) RS is not based on the actual liability of an employer, but is based on the fact that an employee commits a tort.
b) RS applies to make an employer liable only if the employee is acting within the scope and course of employment.
c) RS is a strict liability doctrine and an employer is liable for all acts of an employee while the employee is at work.
d) RS can apply to make an employer liable for a tort even if the employee was violating the employer’s policies.

5) Which three cases are most relevant to your practice. Identify appropriate solutions that can be implemented to avoid similar issues?
6) Identify an emerging trend in pharmacy enforcement and litigation relevant to your practice. What steps can you take to stay on top of or adapt to the trend?

Overview of Cases

• Administrative law
  – Pharmacist-in-Charge Liability
    • Stemberg v. California State Board of Pharmacy, 239 (Cal. App. 4th 1159)
  – Due Process–Pharmacist Licensure

Overview of Cases

• Antitrust
  – Exclusion of Pharmacies
  – State Regulatory Boards Immunity

Overview of Cases

• Civil Procedure
  – Spoliation of Evidence—Pharmacy’s Duty to Retain Misfills
  – Conscientious Objection
    – First Amendment (Emergency Contraception)
      • Stormans, Inc. v. Wiesman, 794 F.3d 1064 (9th Cir. 2015)

Overview of Cases

• Constitutional Law
  – First Amendment—Off-Label Use
  – Controlled–Substances
    – Constitutionality
      • McFadden v. United States, 135 S. Ct. 2298 (June 18, 2015)
    – Duty to Verify DEA Registration
      • Farmacia, Yani, 80 Fed. Reg. 29,053 (May 20, 2015)
      • JM Pharmacy Group Inc. d/b/a/ Farmacia Nueva and Best Pharma Corp., 80 Fed. Reg. 28,667 (May 19, 2015)

Overview of Cases

• Criminal
  – Criminal (charging non-pharmacist with pharmacy law violations)
    – PMP Records
Overview of Cases

• Defamation
  – Physician against Pharmacist
  – Duty to Fill

Overview of Cases

• Fraud and Abuse
  – False Claims
    • United States v. Express Scripts, Inc., 602 F. App’x 880
  – False Claims – Generic Substitutions
  – False Claims & Anti-Kickback Statute
  – Consumer Fraud

Overview of Cases

• Employment
  – ADA
  – Overtime Class Action
  – Medical Marijuana

Overview of Cases

• Medicaid
  – Reimbursement Challenges (cuts to reimbursement)
  – DEA Authority to Enforce Controlled Substances Act

Overview of Cases

• Negligence
  – Duty Not to Dispense
    • Oleckna v. Daytona Disc. Pharmacy, 162 So. 3d 178 (Fla. Dist. Ct. App. 2015)
  – Expert Testimony (qualification–pharmacist for standard of care)
    • Reilly v. Cohen, 121 A.D.3d 961 (2014)
  – Privacy
    • Patient Privacy – Vicarious Liability

• Product Liability
  – Learned Intermediary Doctrine
  – Product Liability (applicability to pharmacists)
    • Randol Mill Pharmacy v. Miller, 465 S.W.3d 612 (Tex. 2015), reh’g denied (Sept. 11, 2015)
Overview of Cases

- **Product Liability**
  - Expert Opinion (qualifications)
  - Expert Opinion (qualifications–pharmacovigilance)
    - Decker v. GE Healthcare Inc., 770 F.3d 378 (6th Cir. 2014)

Administrative Law—Pharmacist-in-Charge Liability

- **Sternberg v. California State Board of Pharmacy, 239 (Cal. App. 4th 2015)**
  - RELIEF SOUGHT: Pharmacist sought a writ of administrative mandate (i.e., appealed) to challenge the California State Board of Pharmacy’s decision to discipline his license for theft of controlled substances in a pharmacy where he was a pharmacist-in-charge (PIC) when he had no knowledge of the thefts.

Administrative Law—Pharmacist-in-Charge Liability

- **Sternberg v. California State Board of Pharmacy, 239 (Cal. App. 4th 2015)**
  - ISSUE: Can the California Board of Pharmacy sanction a pharmacist for a technician’s theft of controlled substances and record keeping and inventory violations based solely on his position as a PIC?
  - HOLDING: The court affirmed the Board of Pharmacy’s decision that the PIC was responsible for the technician’s theft of controlled substances and for violations of laws that govern record keeping and security in the pharmacy even though he had no knowledge of the theft.

Administrative Law—Due Process—Pharmacist Licensure

  - RELIEF SOUGHT: Plaintiffs, “tax delinquents,” filed motion for summary judgment after suing the California Tax Board, DMV, and Board of Pharmacy, alleging violation of their due process rights under the Fourteenth Amendment.
  - ISSUE: Did state agencies deprive plaintiffs of due process under the Fourteenth Amendment by not providing a hearing before depriving them of drivers’ licenses and pharmacy licenses?
  - HOLDING: Court granted the pharmacist’s motion for summary judgment, holding that the state had deprived her of due process by not affording her a meaningful opportunity to be heard.

Antitrust—Exclusion of Pharmacies

  - RELIEF SOUGHT: Pharmacy owner sued prescription drug program third party administrator of violating the Sherman Antitrust Act.
  - ISSUE: Does excluded pharmacy have a valid monopolization claim against third party administrator (or PBM)?
### Antitrust—Exclusion of Pharmacies

**Star Discount Pharmacy, Inc., et al v. MedImpact Healthcare Sys.**

- **HOLDING:** The circuit court affirmed the district court and held that plaintiffs (pharmacies) provided no evidence of harm to competition among pharmacies due to lower reimbursement rates, as required under the Sherman Act.

### New Antitrust Lawsuit against PBM for Exclusion of Pharmacies:

- On January 15, 2016 six compounding pharmacies sued Express Scripts, Inc. (“ESI”) in the Eastern District of the U.S. District Court of Missouri alleging ESI and other PBMs are jointly boycotting compounding pharmacies and shifted patients to pharmacies in which ESI has an economic interest.

### Antitrust—State Regulatory Boards Immunity


- **RELIEF SOUGHT:** FTC sought injunctive relief against the North Carolina Board of Dental Examiners to stop Board from: (i) prohibiting non-dentists from providing teeth whitening services or products, (ii) discouraging the provision of such goods or services, and (iii) communicating to third parties that such provision violated state law.

### ISSUES:

1. Were Board’s actions anti-competitive?
2. Were Board’s actions protected by state-action immunity?

### Antitrust—State Regulatory Boards Immunity

- **HOLDINGS:** Supreme Court affirmed Fourth Circuit’s decision, finding:
  1. Board’s actions were anti-competitive.
  2. Board’s actions were not protected by state-action immunity.

### Civil Procedure

**Spoliation of Evidence & Pharmacy’s Duty to Retain Misfills**

  - **RELIEF SOUGHT:** Patient sought sanctions against pharmacy for willful spoliation of evidence after Walgreens destroyed bottle and pills returned after a misfill.
  - **ISSUES:**
    1. Did Walgreens have a duty to preserve evidence (bottle/pills)?
    2. Was Walgreens on notice of potential litigation due to misfill?
Civil Procedure
Spoliation of Evidence & Pharmacy’s Duty to Retain Misfills
• Burton v. Walgreen Co.
  – HOLDINGS: Court denied plaintiff’s motion because Walgreens admitted error and there was no prejudice from destruction of prescription.
    1. Walgreen had a duty to preserve evidence. However, the evidence was destroyed in accordance with its internal policies and was not destroyed purposely or willfully because.
    2. Walgreens was on notice of potential litigation.

Conscientious Objection
First Amendment (Emergency Contraception)
• Stormans, Inc. v. Wiesman, 794 F.3d 1064 (9th Cir. 2015)
  – RELIEF SOUGHT: Pharmacy and pharmacists with religious objections to dispensing emergency contraceptives, brought action against Washington Pharmacy Quality Assurance Commission challenging the rules requiring a pharmacy to deliver or dispense drugs.
  – ISSUE: Are Washington’s pharmacy regulations, requiring pharmacies and pharmacists to deliver and dispense drugs, unconstitutional?

Conscientious Objection
First Amendment (Emergency Contraception)
• Stormans, Inc. v. Wiesman
  – HOLDING: The delivery rules are constitutional. They are "rationally related to Washington’s legitimate interest in ensuring that its citizens have safe and timely access to their lawful and lawfully prescribed medications."
  – SUBSEQUENT ACTIVITY: A petition for a writ of certiorari is pending before the U.S. Supreme Court. A response to the petition is due on March 7, 2016.

Constitutional Law
First Amendment—Off-Label Use
  – RELIEF SOUGHT: Pharmaceutical manufacturer sought an injunction against the FDA to prohibit FDA from deeming Vascepa as misbranded, arguing the First Amendment protected its promotion of the drug for "off-label" use.
  – ISSUE: Does the First Amendment protect a drug manufacturer that promotes a drug for "off-label" use when such promotion is truthful and non-misleading?

Constitutional Law
First Amendment—Off-Label Use
• Amarin Pharma, Inc. v. FDA
  – HOLDING: The court granted Amarin’s request for a preliminary injunction, holding that Amarin had standing to bring First Amendment claim and that truthful and non-misleading speech cannot form the basis for the prosecution of a misbranding claim.

Controlled Substances
Constitutionality
• McFadden v. United States, 135 S. Ct. 2298 (June 18, 2015)
  – RELIEF SOUGHT: Defendant appealed jury’s conviction for distribution of controlled substance analogues because the jury instructions failed to include the applicable mental state required for the crime.
  – ISSUE: Did the district court’s jury instructions fail to convey the correct mental state as required by the Analogue Act?
Controlled Substances
Constitutionality
• McFadden v. United States
  – HOLDING: The court vacated the judgment because jury instructions failed to convey the correct mental state as required by the Analogue Act and remanded the case to the Fourth Circuit.

Controlled Substances
Duty to Verify DEA Registration
• Farmacia, Yani, 80 Fed. Reg. 29,053 (May 20, 2015)
  – RELIEF SOUGHT: In two separate DEA actions against pharmacies, each pharmacy appealed the decision of an administrative law judge (“ALJ”) to deny applications for DEA registration.
  – ISSUE: Does a pharmacy have a duty to verify the DEA registration of prescribers under the DEA corresponding liability regulation?
  – HOLDING: • In the Farmacia Yani case, the Administrator afforded minimal weight to the failure to verify DEA registrations and held the DEA application in abeyance for six months until the pharmacy personnel completed a course on controlled substances dispensing and corresponding liability.
  • In JM Pharmacy Group, the Administrator likewise gave nominal weight to the pharmacists not ensuring the DEA numbers were current, but denied the registration because the pharmacy falsified its renewal application.

Criminal
Charging Non-pharmacist with Pharmacy Law Violations
  – RELIEF SOUGHT: Defendant sought reversal of judgment and sentence after he was found guilty for violation of the Florida Controlled Substance Act and Pharmacy Act.
  – ISSUE: Can Florida criminally charge a non-pharmacist for violation of its pharmacy practice act (Fla. Stat. Ann. § 465.015) for dispensing a prescription drug without a prescription?
  – HOLDING: The state may not prosecute a non-pharmacist for dispensing a prescription drug without being furnished a prescription under § 465.015(2)(c). The court reversed the guilty verdict for Count II and affirmed the guilty verdict for Count.

Criminal—PMP Records
  – RELIEF SOUGHT: Criminal defendant appealed court’s decision to grant Indiana Board of Pharmacy’s refusal to provide her prescription records pursuant to INSPECT—Indiana’s electronic prescription monitoring program.
  – ISSUE: Did the court err by ruling Lundy’s INSPECT records were not discoverable because Lundy knew where she could possibly obtain records of her prescription?
Criminal—PMP Records

• Lundy v. State
  – HOLDING: The court reversed and remanded. Lundy was entitled to her INSPECT report from the Board.

Defamation
Physician against Pharmacist

  – RELIEF SOUGHT: Physician sued Walgreens for alleged defamatory statements made by Walgreens pharmacists.
  – ISSUES:
    1. Did pharmacists commit slander against physician during consultation with patient?
    2. Were comments made during the consultation privileged?

Defamation—Physician against Pharmacist

• Lefrock v. Walgreen Co.
  – HOLDINGS:
    1. Pharmacists did not commit slander against physician during consultation with patient.
    2. Comments made during the consultation were privileged.

Defamation—Duty to Fill

  – RELIEF SOUGHT: Physician and eight patients sued mail-order pharmacies for breach of duty to honor prescriptions and to fill as written. Physician sued for defamation.

Defamation—Duty to Fill

• Kadambi v. Express Scripts
  – ISSUES:
    1. Does Indiana pharmacy law, purportedly requiring pharmacists to honor all prescriptions from a physician, create a private cause of action?
    2. Does Indiana anti-SLAP (strategic lawsuit against public participation) statute bar plaintiff’s defamation claim?
    3. Are pharmacist statements to patients regarding reason for refusal to dispense protected by qualified privilege?

Defamation—Duty to Fill

• Kadambi v. Express Scripts
  – HOLDINGS:
    1. As to claim under Indiana pharmacy law, court granted pharmacies’ motion to dismiss on the pleadings.
    2. Court denied motion to dismiss under anti-SLAP law because the law did not afford protection to pharmacies.
    3. Court denied defendant’s motion for summary judgment on qualified privilege because fact question existed about whether statements to patients were made in good faith.
Employment--ADA
  – RELIEF SOUGHT: Pharmacist sued former employer for violation of the Americans with Disabilities Act (ADA) and the New York State Human Rights Law (NYSHRL).

Employment--ADA
• Stevens v. Rite Aid Corp.
  – ISSUES:
    1. Did employer violate the ADA and the NYSHRL after terminating a pharmacist who refused to provide vaccinations because of trypanophobia (needle phobia)?
    2. Is trypanophobia a recognized disability?
    3. Did Rite Aid fail to provide reasonable accommodations to the employee?
    4. Were the awarded damages excessive?

Employment--ADA
• Differences in Damages by Jury and Court on Rehearing
  - Type of Damages | Jury       | Court’s Decision
                   |           |           
                   | Back Pay  | $485,633  | Same       
                   | Overtime  | $1,227,188| Same       
                   | Total     | $2,612,821| $1,637,821 (or new trial)

Employment--ADA
• Stevens v. Rite Aid Corp.
  – HOLDINGS:
    1. The court held there was sufficient evidence to support each of the jury’s findings except for the finding that Rite Aid failed to provide reasonable accommodation by not allowing time off for “desensitization.”
    2. The jury’s damages award was proper except for the non-pecuniary award for $900,000, which the court reduced to $125,000. In the alternative, plaintiff could try the case again.

Employment Overtime Class Action
  – RELIEF SOUGHT: CVS sought summary judgment against pharmacist who filed putative class action complaint alleging CVS denied overtime to floater pharmacists in violation of Fair Labor Standards Act (FLSA) and Pennsylvania Wage Payment and Collection Law (“WPCL”).
  – ISSUE: Was Baugh entitled to the longer three-year statute of limitation (“SOL”) rather than the standard two-year SOL under FLSA?

Employment Overtime Class Action
• Baugh v. CVS Health, et al.
  – HOLDING: Court dismissed Baugh’s complaint because he filed too late (past the two-years SOL) for claimed wages under FLSA. However, his claims under WPCL survived and Baugh will have to pursue them in state court.
Employment
Medical Marijuana

  – RELIEF SOUGHT: Terminated employee appealed dismissal of his suit against employer alleging that his termination was based on his “lawful” state-licensed use of medical marijuana.
  – ISSUE: Was plaintiff’s use of medical marijuana under Colorado’s Medical Marijuana Amendment lawful under Colorado’s law that prohibits employment discrimination for “lawful” activities (Colo. Rev. Stat. § 24-34-402.5)?

Employment
Medical Marijuana

• Coats v. Dish Network
  – HOLDING: The Colorado Supreme Court affirmed because the employer did not terminate plaintiff for a “lawful activity” (see § 24-34-402.5). The court reasoned that marijuana use is illegal under federal law and nothing in § 24-34-402.5 limited the term “lawful” to state law. The term was used in its general unrestricted sense, indicating that a “lawful” activity is one that complies with all state and federal laws.

Fraud and Abuse
False Claims

  – RELIEF SOUGHT: Qui tam relator appealed district court’s dismissal of his False Claims Act (“FCA”) claims.
  – ISSUE: Were the relator’s FCA claims precluded by the public disclosure rule?

Fraud and Abuse
False Claims

• United States v. Express Scripts, Inc.
  – HOLDING: Third Circuit affirmed district court decision because relator was not the original source of information that served as the basis for the FCA claims.

Fraud and Abuse—False Claims
Generic Substitutions

  – RELIEF SOUGHT: Relator brought qui tam claims under the federal FCA and the Indiana false claims act alleging defendant misrepresented drug prices.
  – ISSUE: Did relator sufficiently allege a FCA claim by alleging pharmacy’s reward program allowed patients to purchase prescriptions at a lower price than the pharmacy used for usual and customary price calculations?

Fraud and Abuse—False Claims
Generic Substitutions

• Doe v. Houchens Indus., Inc.
  – HOLDING: Court denied motion to dismiss because relator stated plausible claims under the FCA.
Fraud and Abuse
False Claims & Anti-Kickback Statute
  - RELIEF SOUGHT: Relator brought qui tam action against pharmacy defendants alleging violation of the False Claims Act (FCA) and the Anti-Kickback Statute (AKS).
  - ISSUE: Should the State of Washington’s motion for leave to file an amended complaint-in-intervention be granted?

Fraud and Abuse
False Claims & Anti-Kickback Statute
  - HOLDING: Washington’s motion was denied because it delayed moving for leave to amend and granting the motion would be prejudicial to Accredo.
  - SUBSEQUENT HISTORY–SETTLEMENT: In May 2015, Accredo Health Group agreed to pay $45 million to federal authorities to settle claims that it had participated in patient referral kickback schemes. In November 2015, Novartis agreed to pay $390 million to the U.S., New York, and other states.

Fraud and Abuse
Consumer Fraud
  - RELIEF SOUGHT: Defendants moved to dismiss City’s complaint alleging multiple violations of Chicago Municipal Code and state law in connection with pharmaceutical manufacturers’ marketing of certain drugs.
  - ISSUE: Were City’s allegations sufficient to state a claim that pharmaceutical manufacturers’ marketing practices violated Chicago Municipal Code?

Fraud and Abuse
Consumer Fraud
- City of Chicago v. Purdue Pharma L.P.
  - HOLDING: Court dismissed claims as a matter of law against all defendants except Purdue because City failed to allege facts sufficient to meet all the elements of the applicable code section. Court dismissed claims against Purdue except for two claims that survived because Purdue made statements about opioids on its website that could have been seen by area physicians and patients.

Medicaid
Reimbursement Challenges
  - RELIEF SOUGHT: Medicaid providers sued Idaho’s Department of Health and Welfare (“IDHW”) for failing to amend Medicaid reimbursement rates.
  - ISSUE: Can Medicaid providers sue a state in federal court to obtain injunctive relief for inadequate reimbursement under the Medicaid Act?

Medicaid
Reimbursement Challenges
- Armstrong v. Exceptional Child Ctr., Inc.
  - HOLDING: The U.S. Supreme Court reversed the Ninth Circuit. Medicaid providers do not have a private right of action to challenge inadequate reimbursements under the Medicaid Act.
Medical Marijuana
DEA Authority to Enforce Controlled Substances Act

  - RELIEF SOUGHT: Medical marijuana dispensary asked the court to dissolve a permanent injunction that prohibited it from dispensing medical marijuana under California’s Compassionate Use Act because Congress prohibited the Department of Justice ("DOJ") from using any resources to interfere with a state’s ability to implement its own medical marijuana laws.

Negligence
Duty Not to Dispense

  - RELIEF SOUGHT: Patient’s widow appealed dismissal of her claims against pharmacy and pharmacist for filling controlled substances too often, which she claimed resulted in husband’s death.
  - ISSUE: Did the pharmacy and its pharmacists have duty to inquire into or refuse to fill prescriptions being prescribed too often?

Negligence
Duty Not to Dispense

  - RELIEF SOUGHT: Patient’s estate appealed dismissal of complaint in which estate alleged pharmacies negligently failed to monitor and act on excessive methadone prescriptions.
  - ISSUE: Does a pharmacy have a duty to monitor a patient’s prescription history for excessive and abnormal prescriptions, or to communicate a corresponding warning to the patient or prescribing physician?

Negligence
Duty Not to Dispense

- Hernandez v. Walgreen Co.
  - HOLDING: The court affirmed the trial court and dismissed the complaint against the pharmacies because Illinois law does not require a pharmacy to monitor a patient’s prescription history for excessive and abnormal prescriptions, or to communicate a corresponding warning to the patient or prescribing physician.
Negligence
Expert Testimony
• Reilly v. Cohen, 121 A.D.3d 961 (2014)
  – RELIEF SOUGHT: Patient sued physician for medical
    malpractice.
  – ISSUE: Can a pharmacist help establish the standard of care
    in a medical malpractice action against a physician?

HOLDING: The court reversed the trial court’s denial of
physician’s motion for summary judgment in part because a
pharmacist can help establish the standard of care in a
medical malpractice action against a physician.

Privacy
Patient Privacy – Vicarious Liability
  Jan. 15, 2015)
  – RELIEF SOUGHT: Patient sued pharmacy and its employees
    for negligence, professional malpractice, and invasion of privacy.
  – ISSUES:
    1. Is pharmacy employer liable under theory of respondeat
       superior for pharmacist employee’s access and divulging of
       patient information?
    2. Did Hinchy’s original complaint allege a viable claim of
       negligence/professional malpractice against Walgreen?

HOLDING:
1. Walgreen was liable under theory of respondeat
   superior for pharmacist employee’s accessing and
   divulging patient information.
2. The court determined that while Hinchy did not explicitly
   raise a precise negligence/professional malpractice claim,
   Hinchy stated a viable claim with supporting argument and
   evidence.

Product liability
Learned Intermediary Doctrine (“LID”)
• Watts v. Medicis Pharm. Corp., No. CV-15-0065-PR,
  – RELIEF SOUGHT: Plaintiff who suffered from drug-induced
    lupus sued pharmaceutical company for product liability and
    consumer fraud action. Plaintiff appealed the trial court’s
    dismissal of her complaint. Court of Appeals vacated and
    remanded, Arizona Supreme Court granted review.
  – ISSUES:
    1. Is the LID inconsistent with Arizona’s comparative fault tort
       system?
    2. Does the Arizona Consumer Fraud Act apply to consumer
       advertising by a drug manufacturer or seller?
**Product Liability**

**Learned Intermediary Doctrine**

- Watts v. Medicis Pharm. Corp.
  
  **HOLDING:** Arizona Supreme Court:
  
  1. Reversed Court of Appeals, ruling the LID generally applies to prescription drug manufacturers and is not incompatible with the Uniform Contribution Among Tortfeasors Act.
  2. Affirmed Court of Appeals, ruling Prescription drugs are "merchandise" for purposes of Arizona Consumer Fraud Act applies to consumer advertising by a drug manufacturer or seller.

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**Product Liability**

**Applicability to Pharmacists**

- Randol Mill Pharmacy v. Miller
  
  **ISSUES:**
  
  1. Were pharmacy and its employees engaged in "the dispensing of prescription medicines" under the Texas Medical Liability Act (TMLA) when they compounded an injectable lipoic acid?
  2. Are plaintiff's claims "health care liability claims" subject to the requirements of the TMLA?

  **HOLDING:** Texas Supreme Court reversed and remanded because:
  
  1. Pharmacists were engaged in "the dispensing of prescription medicines" under the TMLA when they compounded an injectable lipoic acid.
  2. Plaintiff's claims were subject to the requirements of the TMLA. Plaintiff's failure to file expert report required dismissal with prejudice.

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**Product Liability**

**Expert Opinion (pharmacologist qualifications)**

  
  **RELIEF SOUGHT:** Seven year-old child (Samantha) and her parents sued manufacturer and its parent company J&J after she ingested several doses of OTC ibuprofen and developed a life threatening skin disorder.

  **ISSUES:**
  
  1. Did the FDCA preempt plaintiffs' claim?
  2. Did the trial court err by allowing a pharmacologist to testify as an expert about causation?
  3. Was the jury award of damages excessive?

  **HOLDING:** The court affirmed the trial court's and jury's decisions.
  
  1. Preemption: The FDCA did not preempt the claim that defendants failed to warn that dermatological symptoms could lead to a life threatening condition.
  2. Expert testimony of pharmacologist: Plaintiffs' expert witness, though not a doctor, was able to testify on causation because of his experience and education.
  3. Damages: The court affirmed the jury's $63 million award.
### Product Liability
**Expert Opinion (qualifications–pharmacovigilance)**

- **Decker v. GE Healthcare Inc.**, 770 F.3d 378 (6th Cir. 2014)
  - Relief Sought: Patient sued manufacturer after being injected with gadolinium based contrast agent and developed nephrogenic systemic fibrosis (“NSF”).
  - Issues:
    1. Did the district court judge abuse its discretion by allowing a pharmacovigilance expert testify about adverse event reports (“AER”)?
    2. Did the court err when it excluded the testimony of a physician, who had no expertise in pharmacovigilance, about the significance of AERs?

### Holdings
The Sixth Circuit affirmed the district court and held that the district court did not err by making erroneous evidentiary rulings, denying motion for a new trial, or failing to issue jury instructions.

1) Which of the following best describes a holding in a recent case?
   a) A state board of pharmacy cannot sanction a pharmacist-in-charge (“PIC”) for acts the PIC was unaware of.
   b) A state board of pharmacy can hold a PIC liable for a single dispensing error made by another pharmacist on duty at the same time.
   c) A state board of pharmacy can hold a PIC liable for violations of record-keeping and security requirements even if the PIC is unaware controlled substances theft occurred.
   d) A state board of pharmacy can hold a PIC criminally liable for thefts that another person committed in the pharmacy.

2) Which of the following best describes the learned intermediary doctrine (“LID”)?
   a) Traditionally, the LID protects drug manufacturers and pharmacists from suits that claim failure to warn a patient.
   b) The LID deems pharmacists to be learned professionals who have a duty to warn about drugs side effects and interactions.
   c) The LID protects physicians from liability if they prescribe according to the indications in the package insert.
   d) The LID protects pharmacists from liability in failure to warn cases, but cannot be applied in federal court because it is a state law doctrine.

3) According to recent administrative decisions by the DEA, pharmacists have a duty to check that the prescriber has a current DEA number.
   a) True.
   b) False.

4) Which of the following is not accurate about liability based on respondeat superior (“RS”)?
   a) RS is not based on the actual liability of an employer, but is based on the fact that an employee commits a tort.
   b) RS applies to make an employer liable only if the employee is acting within the scope and course of employment.
   c) RS is a strict liability doctrine and an employer is liable for all acts of an employee while the employee is at work.
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5) Which three cases are most relevant to your practice. Identify appropriate solutions that can be implemented to avoid similar issues?

6) Identify an emerging trend in pharmacy enforcement and litigation relevant to your practice. What steps can you take to stay on top of or adapt to the trend?

Questions?

Contact Information

Roger Morris
Quarles & Brady, LLP
(602) 229-5269
rmorris@quarles.com

Bill Stilling
Parsons Behle & Latimer
(801) 536-6765
bstilling@parsonsbehle.com