Pharmacy Case Law Update 2016:
“Worse Than an Unruly Horse, It is an Imaginary One…”

Col(r) David W. Bobb, BSPh, MA, JD
Office of the National Coordinator
U.S. Dept. of Health and Human Services

CPE Information and Disclosures

David W. Bobb declares 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.

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CPE Information

- Target Audience: Pharmacists & Technicians
- ACPE#: 0202-0000-16-174-L03-P/T
- Activity Type: Knowledge-based

Learning Objectives

1. Describe the "corresponding responsibility" standard under DEA Regulation 21 USC 829, § 309 and define "legitimate medical purpose" the Controlled Substance Act.
2. Explain the Wrongful Conduct Rule versus the comparative negligence theory and the rationale behind the court’s reasoning.
3. List actions by a pharmacist that could be construed as “outrageous conduct” when filling a prescription.

Self-Assessment Questions

1. In respect to controlled substance prescribing and dispensing, the concept of "legitimate medical purpose":
   A. Is not defined in the Controlled Substance Act
   B. Has been left to the federal courts and the DEA to construe
   C. Has been interpreted as "in accordance with a standard of medical practice recognized and accepted in the United States"
   D. All of the above

Self-Assessment Questions

2. Commonly cited reasons for barring claims under the "wrongful conduct rule" include:
   A. To avoid condoning or encouraging illegal conduct
   B. To prevent wrongdoers from profiting from their illegal acts
   C. To avoid damage to the public’s perception of the legal system
   D. To prevent wrongdoers from shifting responsibility to other parties
   E. All of the above
**Self-Assessment Questions**

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**Self-Assessment Questions**

3. In Holley vs. CVS, The U.S. District Court defined outrageous conduct to include:

A. Insults, indignities, threats, annoyances, petty oppressions, and occasional acts that are definitely inconsiderate and unkind
B. Conduct so extreme in degree as to go beyond all possible bounds of decency
C. Conduct so atrocious as to be utterly intolerable in a civilized society
D. B and C only
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**Disclaimer**

This program is not intended to be, and should not be viewed as, legal advice as it contains only general principles of law and my interpretations of court decisions. For specific circumstances, you are strongly urged to contact an attorney familiar with the laws of your state or jurisdiction. Likewise, it does not represent the official position of any Department or Agency of the United States Government. In short, it’s simply my best professional opinion designed to help you…

**Controlled Substance Dispensing**

14-1223
United States Court of Appeals, DC Circuit
District of Columbia (Texas)
2015

What actions must a pharmacist take when filling a controlled substance prescription to ensure DEA standards are met?

**Controlled Substance Dispensing**

- **The Parties**
  - Plaintiff, The Medicine Shoppe, San Antonio, TX
  - Drug Enforcement Administration
  - Defendant, Loretta Lynch, US Attorney General
- **Questions**
  - Does the manner in which the DEA imposes a “corresponding responsibility” standard on pharmacists exceed it’s authority?
  - Does the DEA require pharmacists to act beyond the scope of their state licenses?
  - Is the “legitimate medical purpose” standard inconsistently defined and applied by the DEA?
- **“Corresponding Responsibility”**
  - DEA Regulation 21 CFR § 1306.04 requires that pharmacists have a responsibility along with the prescriber to assure that a prescription for a controlled substance is issued for a “legitimate medical purpose” and in the practitioner’s usual course of professional practice.
- **“Legitimate Medical Purpose”**
  - Is not defined in the Controlled Substance Act
  - Has been construed by federal courts and the DEA as “in accordance with a standard of medical practice recognized and accepted in the United States”
  - Much confusion between federal and state governments
**Controlled Substance Dispensing**

- Held
  - The United States Court of Appeals for the District of Columbia Circuit denied the Medicine Shoppe’s petition for review without comment
  - The DEA Order to revoke the Medicine Shoppe’s controlled substance Certificate of Registration stands

- Damages
  - N/A
  - But what if you own, or work at The Medicine Shoppe???

**Wrongful Conduct Rule**

**Tug Valley Pharmacy, LLC v. All Plaintiff's Below in Mingo County**

*Supreme Court of Appeals of West Virginia*  
West Virginia  
2015

Is illegal activity on the part of a defendant a bar to any recovery in a negligence case?  
What is the Wrongful Conduct Rule?

**Wrongful Conduct Rule**

- The Parties
  - Plaintiffs, 29 individuals in Mingo County, WV  
  - Defendant, Tug Valley Pharmacy (and 2 others)  
  - Defendant, Mountain Medical Center (and 4 physicians)

- Questions
  - Can a person who engaged in criminal conduct to acquire and abuse controlled substances maintain an action against a pharmacy for causing or contributing to that person’s addiction?  
  - Does the Wrongful Conduct Rule apply?

- Damages
  - None yet…the case continues…

**Pharmacist Standard of Care**

*CIV 13-1055 JB/KBM, CIV 15-0184 JB/KBM*  
*United States District Court, D. New Mexico*  
New Mexico  
2016

What is the nature of a pharmacist’s duty when accompanying a physician on rounds?

**Pharmacist Standard of Care**

- The Parties
  - Plaintiff, Mrs. Gallegos (representing decedent)  
  - Defendant, Raymond G. Murphy VA Medical Center  
  - Defendant, Dr. Wood, Physician  
  - Defendant, “Unnamed Pharmacist”

- Question
  - When accompanying a physician on rounds, does a pharmacist have a duty to challenge inappropriate prescribing when the pharmacist has access to information such that he/she knew, or should have known, the prescriber was ordering inappropriate therapy?
Pharmacist Standard of Care

- Held
  - “The Court cannot soundly conclude, as a matter of law, that the unnamed pharmacist or representative of the pharmacy owed no duty to the decedent.”
  - “…the pharmacist’s proximity to the patient and the prescribing physician, set it apart from cases in which a pharmacist mechanically fills a prescription.”
  - “Expert testimony and discovery will help the Court to make this determination at a later stage in the case.”

- Ruling
  - The case continues…

Intentional Infliction of Emotional Distress

- The Parties
  - Plaintiff, Sadie Mae Holley
  - Plaintiff, Sara B. Holley, Sadie Mae’s Mother
  - Defendant, CVS Caremark Corporation

- Questions
  - When mis-filling a prescription, was CVS’ conduct intentional or reckless, outrageous and intolerable?
  - Was Sara Holley’s distress severe?
  - Are the alleged wrongful conduct and emotional distress causally connected?

- Held
  - “The test [for outrageousness] is not whether CVS’ actions meet an objective definition of the term, but whether considering the totality of CVS’ behavior, it would lead a reasonable person to exclaim, ‘Outrageous!’”
  - Mrs. Holley’s alleged symptoms are sufficiently specific and severe to state a plausible intentional infliction of emotional distress claim.

- Ruling
  - The court denies CVS’ 12(b)(6) motion to dismiss…the case continues…

Pharmacist Standard of Care

Jeanne M. Sorenson as executor of the estate of Darryl Ray Sorenson
v.
Professional Compounding Pharmacists of Western Pennsylvania, Inc., Charlotte Pain Management Center, Anzaohealth Corporation, et. al.
Case No. 2D15-441
District Court of Appeal of Florida, Second Dist.
Florida
2016

What standard of care must an out of state pharmacy use when compounding a pain pump prescription?

- The Parties
  - Plaintiff, Jeanne M. Sorenson, on behalf of Decedent, Darryl Ray Sorenson
  - Defendant, Compounding Pharmacists of Western PA
  - Defendant, Charlotte Pain Management Center, et. al.

- Questions
  - Is a prescription for 30mg/ml of hydromorphone used in a pain pump "unreasonable on its face due to the strength"?
  - Does the fact that the pharmacist compounded and dispensed this prescription with no questions asked give rise to an actionable claim of negligence?
Pharmacist Standard of Care

• Held
  ➢ The pharmacist knew or should have known that the prescribed concentration of hydromorphone was potentially fatal, yet filled the prescription without further inquiry.
  ➢ The lack of direct patient contact does not shield a compounding pharmacist from its duty to use due and proper care.
  ➢ "The duty does not arise from a duty to warn the patient, but a duty not to fill facially unreasonable prescriptions…"

• Ruling
  ➢ The court reverses the dismissal…the case continues…

Expert Witness/Specialist

Alan D. Erickson and Monica Erickson v. United States of America Case No. 2:15-CV-95 United States District Court, W.D. Michigan Michigan 2016

For purposes of qualifying an expert witness, is a pharmacist considered to be a specialist?

Expert Witness/Specialist

• The Parties
  ➢ Plaintiff, Alan D. Erickson (patient)
  ➢ Plaintiff, Monica Erickson, Alan’s wife
  ➢ Defendant, United States (VA Medical Center)
  ➢ Defendants, Three VA pharmacists

• Questions
  ➢ Are pharmacists considered to be "specialists" under Michigan's medical malpractice law?
  ➢ If so, do the qualification requirements change for a pharmacist serving as an expert witness?

• Held
  ➢ If the professional whose conduct is at issue was not a specialist, the expert need only practice or teach in the same health profession.
  ➢ If the professional whose conduct is at issue was a specialist, the expert must have specialized in the same area and must have practiced or taught in that specialty.
  ➢ No MI court has addressed this issue – it is far from clear
  ➢ The affidavit filed was insufficient; lacked proximate cause

• Ruling
  ➢ Plaintiffs will be given an opportunity to submit a new affidavit…the case continues…

New England Compounding…


Motion to dismiss counts 1 and 2 of the indictment (Racketeer and Corrupt Organizations Act (RICO)) and to strike the second degree murder racketeering acts

Key Points

• Verifying a controlled substance prescription with the doctor is probably not enough to shield one from liability.
• Criminal acts by an injured party may not immunize you from potential civil liability.
• Understand that rounding with physicians, compounding pharmaceuticals, and providing anticoagulation services may all increase your liability exposure.
• Even though overriding computer dosage warning alerts, failing to provide medication counseling, failing to provide a measuring device, and acting cool and accusatory when contacted about an error each alone may not give rise to a level of outrageous conduct, the totality of the circumstances may get you there.
### Answers to Self-Assessment Questions

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As the delivery of healthcare changes in America, pharmacists and technicians are poised to fill new roles on the healthcare team. Are we ready to embrace the corresponding liability inherent in these new roles???

Col(r) David W. Bobb, BSPh, MA, JD
Office of the National Coordinator
U.S. Dept. of Health and Human Services
david.bobb@hhs.gov  (202) 205-4528