

# **PHARMACIST LIABILITY THEN AND NOW**

## **How has the Legal and Regulatory Landscape Changed**

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**Disclosure Information**  
**PHARMACIST LIABILITY THEN AND NOW**  
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**Srikumaran Melethil, Ph.D., J.D.**

**I have no financial relationship to disclose.**

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in my presentation.**

**Or**

**I will discuss the following off label use and/or  
investigational use in my presentation.**

# DISCLOSURE

**This presentation is solely for educational purposes. It should not be considered legal advice. If you have a legal question, you must contact a lawyer in your jurisdiction.**

# AGENDA

- 1. Expanding Professional Roles**
- 2. Theories of Liability**
- 3. The Learned Intermediary Doctrine**
- 4. Duty to Warn?**
- 5. Voluntary Assumption of Duty**
- 6. Federal Law (OBRA 90)**
- 7. Conclusions**

# **New Questions**

- 1. Should a medical error be prosecuted as a crime?**
- 2. Are pharmacist health-care providers?**

# Expanding Professional Roles

- **Monitor patient therapy and intervention (OBRA 90)**
- **Prescriptive Authority - 11 States (as of 1996)**
- **Drug Formulary Development**
- **Behind the Counter Drugs**
- **Drug Product Selection**

# **DUTY TO WARN?**

**No general duty to warn (most jurisdictions)**

- **Interference with patient-doctor relationship**
- **Learned intermediary doctrine which imposes this burden of the physician**
- **Deter patient compliance**
- **Undue burden on the practice of pharmacy**

# Legal Theories of Liability

1. Matter Of Law
2. Negligence
  - A. Duty to Warn of Adverse Effects
  - B. Voluntary Assumption of Duty to Warn
3. OBRA 90
4. Strict Liability
5. Breach of Warranty
  - A. Express Warranty Theory
  - B. Implied Warranty Theory



# Matter of Law

**PHARMACISTS ARE LIABLE FOR  
FILLING ERRORS**

# **Brown v. Marshall (MI, 1882)**

Pharmacist sold “sulphate of zinc” instead of “sulphate of magnesia”

“A druggist who delivers one medicine when another is called for, is responsible for the consequences on the ground of negligence only”

# Matter of Law (cont'd)

- **1971 - Troppi v. Scarf (MI)**
  - **“Wrongful Birth”**
  - **Rx for birth control pills filled incorrectly**
  - **Patient gave birth to a healthy baby**
  - **Court held that a pharmacist has an absolute duty to dispense the correct drug**

## **Matter of Law (cont'd)**

- **1971 - Troppi v. Scarf (MI)**
  - **What damages were awarded the patient?**

# Learned Intermediary Doctrine

Physician is “gatekeeper of drug information”

Drug manufacturer informs physician who then informs the patients of the adverse effects of the drug

# Learned Intermediary Doctrine (cont'd)

## McKee v. American Home Products (WA, 1989)

1. Rx for amphetamines correctly filled for 10 years
2. Patient sues pharmacist for failing to warn her of the drugs side effects (potential for abuse and addiction)
3. Court held that the physician had this responsibility under this doctrine

# **SMH v. Larrimore (2008 AL)**

**Jury awarded \$4 million to the estate of Larrimore, who had died of an overdose of colchicine**

**SMH appeals on the basis that pharmacist owed no duty under the learned intermediary doctrine**

**AL Supreme Court agrees**

# ELEMENTS OF NEGLIGENCE

1. DUTY

2. BREACH

3. CAUSATION

4. DAMAGES



# DUTY TO *WARN*

*When and How far?*

Highly fact-oriented

**DUTY TO WARN**

**COMMON LAW**

# Pharmacists should more than fill the prescription correctly

**Tessymond's Case**

**1 Lewin's Crown Cases 169 (1828)**

***[Cited from 45 Duq. L. Rev. 59 (2006)]***

**Jones v. Walgreen Co.**

**265 Ill. App. 308 (Ill. App. Ct. 1932)**

**Prescription:**

**Strontium Salicylate four ounces  
(Wyatt), teaspoonful in water four  
times a day**

**Pharmacist dispensed pure powder**

**Patient suffered severe diarrhea, kidney  
failure**

**Jones v. Walgreen Co.**

**265 Ill. App. 308 (Ill. App. Ct. 1932)**

**“[the] instant contention is primarily based upon the assumption that a pharmacist is obliged to fill any and all prescriptions. Such is not the law. As a chemist he may know that the physician has erred in his prescription and that to fill it might cause death or serious injury to the patient”**

**DUTY TO WARN**

**WHAT IS THE  
STANDARD OF CARE?**

# Dooley v. Everett (TN 1990)

- drug interaction (aminophylline and erythromycin)
- convulsions in 4 yr old Dooley
- pharmacist was unaware of this drug interaction
- Appeals court overruled summary judgment ruling of trial court based on affidavit of practicing pharmacist.  
Standard of care required:
  1. patient profile system
  2. review profile for interactions
  3. warning about interactions
  4. warning of toxicity symptoms

# **Lasley v. Shrake's Country Club Pharmacy, Inc (AZ 1994)**

- **patient on Doriden® and codeine for 30 years**
- **for about 10 years Shrake had mailed “one or more” of these drugs alleged to be addictive**
- **Lasely was hospitalized for addiction treatment**
- **patient claims that Shrake had a duty “to exercise that degree of care , skill and learning expected of reasonable prudent pharmacies and pharmacists . . . “**



# Lasley v. Shrake's Country Club Pharmacy, Inc (AZ 1994)

- Expert opinion (*as in Dooley*) presented which stated that the standard of care for a pharmacist:
  - “includes obligations to advise a [patient] of the highly addictive nature of a prescribed drug and of the hazards of ingesting two or more drugs that adversely interact with one another”
  - “pharmacist should also advise the prescribing doctor if it appears that the patient is taking an addictive drug in quantities inconsistent with the manufacturer’s recommended dosage guidelines”
- Trial court granted Shrake’s motion for summary judgment

# **Lasley v. Shrake's Country Club Pharmacy, Inc (AZ 1994)**

## **Appeals Court:**

- trial court confused “the concept of duty with that of standard of care”
- Shrake, during appeal, admitted that it had a duty to comply with standard of care guidelines
- Reversed lower court's holding to dismiss and remanded case for a jury trial
- Rejected arguments by Shrake that previous cases had held that a pharmacist has no duty to warn

# **Heidi Happel v. Wal-Mart Stores, Inc.**

## **IL 2002**

### **FACTS**

- **Patient's allergy towards aspirin, acetaminophen and ibuprofen was known by the pharmacy (prior visits)**
- **Prescription for Toradal<sup>®</sup> filled (alert override)**
- **Patient suffers anaphylactic shock**
- **Patient sues pharmacy for failure to warn**

# Heidi Happel v. Wal-Mart Stores, Inc.

## IL 2002

- Trial court granted summary judgment in favor of Wal-Mart
- Appeals court disagrees and presents this analysis:
- Existence of duty requires consideration of:
  - foreseeability of injury (in this case, yes)
  - likelihood of injury (“nearly certain”, here)
  - burden of duty on pharmacist (“minimal”)
  - Consequences for imposing duty (no medical judgment involved here)

# **DUTY TO WARN**

## **Regulatory Mandates**

**State Pharmacy Practice Act**

**OBRA 90**

# **OMNIBUS BUDGET RECONCILIATION ACT OF 1990 (OBRA 90)**

**Enacted as a means of cost control of  
Medicaid reimbursement**

- required states to set up drug utilization review (DUR)**
- applies only to Medicaid patients**
- failure to implement DUR program after 1/1/93 resulted in forfeiture of matching Medicaid funds**

# Horner v. Spalitto (MO 1999)

## FACTS

- Horner presented prescriptions for diazepam (50 x 10 mg, one dose q 8h) and Placidyl® (50 x 750 mg , one dose q 8h)
- Spallito checked Facts and Comparisons: Placidyl® normal dose - one 500 mg or 750 mg dose, at bedtime.
- On checking with the physician prescriber, “someone” from his office told him that “the prescription was ‘okay’ because Horner needed to be sedated throughout day”
- Spalitto then dispensed the medications (9/21/94)
- Horner is dead 6 days later; cause: drug overdose

# Horner v. Spalitto (MO 1999)

## Trial Court:

- **Family sued Spalitto alleging negligence . He**
  - “knew or should have known” that “the dosage and instructions provided therewith would expose [Horner] to unreasonable risk of great bodily harm or death”
  - did not “investigate” if Horner had a “problem or potential problem with drug abuse or chemical dependence”
  - did not warn Spalitto about adverse drug reactions of the dispensed drugs with or without other drugs
- Spalitto was granted summary judgment based on a previous MO decision ( *Kampe v. Howard Stark Professional Pharmacy, Inc, 1992* )



# Horner v. Spalitto (MO 1999)

## Appeals court

- “*Kampe* wrongly held that s a matter of law , a pharmacist’s duty will never extend beyond accurately filling a prescription.” This may be a pharmacist’s duty in particular cases, but in other cases, a pharmacist’s education and expertise will require that he or she do more to help protect their patrons from risks which pharmacists can reasonably foresee.”
- “To hold as *Kampe* did would denigrate the expertise which a pharmacist’s education provides concerning drugs and their therapeutic use. The *Kampe* holding also failed to comprehend the role a pharmacist must play in making the valuable, but highly dangerous service of drug therapy as safe and reliable as it can be”

# Horner v. Spalitto (MO 1999)

## Appeals court (cont'd)

- Then, in reversing the lower court decision, it :
- cites the practice of pharmacy act Sec. 338.010.1, RSMo 1994), where the practice of pharmacy is defined as (in pertinent part)
  - the interpretation and evaluation of prescription orders
  - consultation with patients and other health care practitioners about the safe and effective use of drugs . . .
- cites OBRA 90 requirements for establishing “standards for pharmacist counseling patients . . .” which led Mo Bd of Pharmacy to enact appropriate rules

# Cottam v. CVS Pharmacy (MA 2002)

## Facts:

- Patient suffered priapism following ingestion of Trazadone<sup>®</sup> and becomes impotent
- sues pharmacist for failure to warn
- Jury awarded Cottam \$357,000
- CVS appeals

# Cottam v. CVS Pharmacy (MA 2002)

## Appeals Court

- Generally, a pharmacist has no duty to warn its customers of the side effects of prescription drugs *(like decisions from many other jurisdictions)*

*“ . . .where the pharmacist has no specific knowledge for an increased danger to a particular customer, the pharmacist has no duty to warn that customer of potential side effects”  
(emphasis added)*

# Cottam v. CVS Pharmacy (MA 2002)

## Appeals Court

- Based on case law for many jurisdictions, the court held that generally “ a pharmacist has no duty to warn its customers of the side effects of prescriptions (of the 9 cited cases, 5 are pre-OBRA)
- However, CVS had assumed the duty to warn of all side effects (computer system )
  - long form (more detailed information) to be given with new prescriptions
  - patient testified he got only the short form which did not list priapism as a side effect; pharmacist testified she gave the long form, which lists this side effect

# Strict Liability

“A concept applied by the courts in product liability cases in which seller is liable for any and all defective or hazardous products which unduly threaten a consumer’s personal safety”

**Black’s Law Dictionary, 6<sup>th</sup> Edn. , p. 1422**

# **Coyle v. Richardson-Merrell, Inc** **584 A.2d 1383 (Pa 1991)**

## **Facts**

**Pharmacy dispenses Bendectin<sup>®</sup>, a prescription drug. Patient sues pharmacy after son is born with birth defects, alleging that the drug caused these defects.**

# Coyle v. Richardson-Merrell, Inc

Section 402A of Restatement (Second) of Torts states (in pertinent part:

- (1) One who sells any product in a defective condition unreasonably dangerous to the user . . . is subject to liability for physical harm...if**
- (a) the seller is engaged in the business of selling such product (*emphasis added*)**



# Coyle v. Richardson-Merrell, Inc (cont'd)

- **Comment (k) of Restatement**

[t]here are some products which . . . [are] quite incapable of being made safe for their ordinary and intended use. These are especially common in the field of drugs. Such a product, properly prepared, and accompanied by proper directions and warnings is not defective nor is it *unreasonably* dangerous. [Many such products], for this very reason cannot be legally sold except . . . under the prescription of a physician. . . . The seller of such product, again with the qualification that they are properly prepared and marketed, and proper warning is given,. . . is not to be held strictly liable for the unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product..... (*emphasis added*)

BREACH OF WARRANTY

(“Broken promises”)

# DEFINITIONS

## WARRANTY

**“A PROMISE THAT A PROPOSITION IS TRUE”**

### EXPRESS WARRANTY

**“A PROMISE . . . WHICH IS INCLUDED IN THE WRITTEN OR ORAL TERMS OF THE SALES AGREEMENT”**

**Black’s Law Dictionary, 6<sup>th</sup> Edn. , pp. 1586-1587**

# Rite Aid v. Levy-Gray

## 894 A.2d 563 (MD 2006)

### FACTS

Patient ingests doxycycline (for Lyme disease) with dairy products, as instructed (by manufacturer and pharmacy), when the drug caused gastric irritation. There was no improvement of disease symptoms.

Upon advise from her physician brother, she stopped consuming dairy products. A second course of doxycycline did not resolve the problem. Patient was diagnosed with post-Lyme syndrome.

One issue patient sued Rite-aid was breach of expressed warranty.

Trial court ruled in favor of patient and awarded \$250,000.

Appeals court agreed saying

“ a jury reasonably could infer Mt. Ms. Levy-Gray relied on the instruction “take with food or milk if stomach upset occurs as an affirmation that doxycycline is compatible with dairy such that it became part of the basis of the bargain . . . .”

# Are pharmacists health care providers?

No, West Virginia Supreme Court 2007

# **Are pharmacists health care providers? (cont'd)**

## **FACTS:**

**Physician writes the following directions for a colchicine prescription:**

**“take 1 tablet every hour until pain stops or diarrhea starts or nausea”**

**Larry's drive in filled the prescription as written**

**For 3 days in Feb. 2002, patient took colchicine as prescribed resulting in permanent kidney failure (dialysis)**

# **Are pharmacists health care providers? (cont'd)**

**Pharmacists seeks protection under Medical Professional Liability Act**

# Are pharmacists health care providers? (cont'd)

“Health care provider” means a person, partnership, corporation, facility . . . certified to provide health care or professional health care services, including, but not limited to, a physician, osteopathic physician, hospital, dentist, registered or licensed nurse, optometrist, podiatrist, chiropractor, physical therapist, or psychologist, or an officer, employee or agent thereof acting in the course and scope of such officer’s employee’s or agent’s employment. (emphasis added)

**W. Va. Code, 55-7B-2(c), [1986]**



# **Should medical errors result in criminal prosecution?**

**Ohio hospital pharmacist pleaded no contest to involuntary manslaughter in the death of a 2 year old girl who received her last chemo dose in 20% saline.**

**He failed to check his tech's work**

**DEFENSES WHEN YOU GOOF**

**EXCUUUUSE ME!**

# Conclusions

- **There is no general duty to warn**
- **Assuming duty to warn enhances pharmacist liability**
- **Duty to warn is fact specific**
- **Courts appear to be “reluctant” to enforce practice guidelines promulgated by state (practice acts) and federal rules (OBRA 90)**