

Is the Liability of Pharmacists Changing?



**PRESENTED AT FSHP 44TH ANNUAL MEETING
ORLANDO, FLORIDA**



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OBJECTIVES

- ❖ **Discuss rationale for potential changes to professional liability.**
- ❖ **Evaluate consequences of legal rulings.**
- ❖ **Apply case based outcomes to help decrease potential liability.**

3 Theories* of Pharmacy Liability



BREACH OF WARRANTY



NEGLIGENCE



CRIMINAL NEGLIGENCE



* Most common

1st Theory of Pharmacy Liability



BREACH OF WARRANTY

Definition – A breach of warranty involves a broken promise about a product made by either a manufacturer or a seller. Warranties can be express or implied. In an implied warranty, even though the seller may not make any explicit promises, the buyer still gets some protection. A warranty can require a product to be fit for its intended use. When a product is unable to function in its basic use the warranty is breached.


First Pharmacy Cases



MCLEOD V. W.S. MERRELL CO., 174 SO. 2D 736 (FLA. 1965)

BREACH OF WARRANTY

Q. Is an RPh who properly fills a prescription liable (in breach of warranty) if the drug has harmful effects on the purchaser?



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A. No. No warranty.

Court reasoned a druggist warrants 1) he will compound the drug prescribed; 2) he has used due care in filling 3) the compounding methods were proper; and 4) the drug was not adulterated.

First Pharmacy Cases

CONTINUED

MCLEOD V. W.S. MERRELL CO., 174 SO. 2D 736 (FLA. 1965)

Even though the Court did not find the pharmacy responsible, the **Court held:**

that a cause of action for negligence might arise when a pharmacist does not use due proper care in filling the prescription. The court did not clarify what factual circumstances the pharmacist's duty encompasses.

Initially ...

Misfill
or
Mislabeled
only



**Historically, the druggists role
was to “fill as written”**

2nd Theory of Pharmacy Liability



NEGLIGENCE

What are the elements?

2nd Theory of Pharmacy Liability



NEGLIGENCE

Definition

1. Pharmacist as a matter of law must have a legal duty to the patient (established pharmacist-patient relationship); and

2nd Theory of Pharmacy Liability



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3. That breached caused harm to the patient; and

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2. The jury must then decide if the duty was breached by falling below the standard of care of a pharmacist; and
3. That breach caused harm to the patient; and
4. The patient was indeed harmed.

1980's Cases



PYSZ V. HENRY'S DRUG STORE, 457 SO.2D 562 (FLA. 4TH DCA 1984)

Q. Does the RPh have a **duty to warn** beyond the duty to receive and fill the prescription correctly? What if the patient has been going to the same RPh for 9 years?



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A. No. The duty to warn is solely that of the prescribing physician. Also there is no duty to warn the treating physician of the customer's dependency.

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A. No. The duty to warn is solely that of the prescribing physician. Also there is no duty to warn the treating physician of the customer's dependency.

Court reasoned: It is the physician's duty to know the drug he is prescribing and monitor the patient. **However.....**

1980's Cases

CONTINUED

PYSZ V. HENRY'S DRUG STORE, 457 SO.2D 562 (FLA. 4TH DCA 1984)

Even though the Court did not find the RPh responsible, the **Court held:**

"we limit our findings to the facts of this case since we recognize that **a factual situation could exist** which would support an action for negligence against a druggist who has lawfully filled a prescription issued by a licensed physician."

1980's Liability
Changing to...

Fill, label &
Failure to
Warn

Pharmacy Department Open



**More recently the pharmacist is
responsible to also interpret and assess**

1990's Pharmacy Cases



JOHNSON V. WALGREENS CO., 675 SO.2D 1038 (FLA. 1ST DCA 1996)

Q. Is an RPh responsible if he/she accurately fills a prescription but does NOT warn or consult about potential adverse drug interactions? What if the RPh even gives bad advice causing further interactions?



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A. No. No such **duty to warn** exists.

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Q. Is an RPh responsible if he/she accurately fills a prescription but does NOT warn or consult about potential adverse drug interactions? What if the RPh even gives bad advice causing further interactions?



A. No. No such **duty to warn** exists.

Court reasoned: Relied on McLeod & Pysz stating that a druggist who sells a prescription warrants only that the prescription is accurate, has been filled with due and proper care, has not been infected with some adulterating foreign substance and has been compounded using the proper method. **However....**

1990's Pharmacy Cases



CONTINUED

JOHNSON V. WALGREENS CO., 675 SO.2D 1038 (FLA. 1ST DCA 1996)

Even though the court did not find the RPh responsible,
The **Court held** for public policy purposes it should be noted:

there is a strong public policy to support a RPh duty to warn. The FL statutes do not create a private cause of action but they do state: **1)** Dispensing includes interpreting the Rx for possible ADRs, interactions and proper dosage regimens; **2)** Certify the drug is ready for transfer; and **3)** provide counseling on proper drug usage.

s. 465.003(6), Fla. Stat.

Evolution of Pharmacy Law

Turning point of a new century



SANDERSON V. ECKERD CORP., 780 SO.2D 930 (FLA. 5TH DCA 2001)

Voluntary Undertaking/Voluntary Assumption of Duty Doctrine

Q. If the pharmacist voluntarily decides to counsel a patient, even when they are not required, could they be liable for damages?



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Court reasoned that the pharmacy advertised a promise that its computer system would detect and warn patients of adverse reactions. That system must work correctly.

Case Studies – Vol. Assumption



VOLUNTARY UNDERTAKING/VOLUNTARY ASSUMPTION OF DUTY DOCTRINE

Case 1

North Carolina 1991

RPh has no generalized duty to warn, but once he is alerted to specific facts (allergic to ASA) and voluntarily undertakes to advise, he must advise correctly.

Ferguson v. Williams, 374 S.E.2d 438 (N.C. App. 1988) appeal 399 S.E.2d 389 (N.C.App. 1991)

Case Studies – Vol. Assumption



VOLUNTARY UNDERTAKING/VOLUNTARY ASSUMPTION OF DUTY DOCTRINE

Case 2

Illinois, 1992



RPh voluntarily placed computer suggested labels on a Rx container. Duty was limited to the extent of the undertaking and not breached by attaching one correct label and not the other two.

Frye v. Medicare-Glaser Corp., 605 N.E.2d 557 (Ill.1992)

Case Studies – Vol. Assumption



VOLUNTARY UNDERTAKING/VOLUNTARY ASSUMPTION OF DUTY DOCTRINE

Case 3

Michigan, 1996

Pharmacy implemented, used and advertised a computer program that detected harmful drug interactions therefore the pharmacy voluntarily assumed duty to utilize the computer technology with due care.



Baker v. Arbor Drugs, Inc., 544 N.W.2d 727(Mich.App.1996)

Case Studies – Vol. Assumption



VOLUNTARY UNDERTAKING/VOLUNTARY ASSUMPTION OF DUTY DOCTRINE

Case 4

Illinois, 2000

RPh voluntarily listed some of the drugs side effects. The pharmacist did not assume a duty to list all possible side effects.

Kasin v. Osco Drug Co., 728 N.E.2d 77 (Ill. App. 2000)

Most Recent Pharmacy Cases (04-05)

Negligence – BW blend



DEE V. WAL-MART STORES, INC., 878 SO.2D 426 (FLA. 1ST DCA 2004)

BW – PROFESSIONAL NEGLIGENCE

Q. Could the RPh be responsible if they fill a prescription as written?



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A. Yes. The RPh can be responsible for filling a prescription as written if the prescription is not reasonable on its face.

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A. Yes. The RPh can be responsible for filling a prescription as written if the prescription is not reasonable on its face.

Court reasoned the RPh may be liable for a breach of the duty to use due care in filling a prescription when a pharmacy fills a prescription that is **unreasonable on its face** even though it is filled as written.


Most Recent Pharmacy Cases (04-05)

Negligence – BW blend



ESTATE OF POWERS V. THOBHANI, MD, YOUR DRUGGIST & THE MEDICINE SHOPPE, 903
SO. 2D 275 (FL 2005)

Q. Does the pharmacy **owe a duty** to the patient to provide for their health, safety and welfare if their prescriptions doses appear to be high and too frequent BUT were filled properly?



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A. No. Not if the prescriptions were properly filled.

Court reasoned Citing Psyzy, stating no duty to warn the patients MD about the addiction. This duty of care does not exist under FL law. BUT.....(not too fast)

Most Recent Pharmacy Cases (04-05)

Negligence – BW blend



CONTINUED

ESTATE OF POWERS V. THOBHANI, MD, YOUR DRUGGIST & THE MEDICINE SHOPPE, 903
SO. 2D 275 (FL 2005)

Even though the trial Court found the pharmacy did not owe this duty of care:

The **Appellate Court reversed the trial Court** and stated that the claim supported a negligence cause of action and sent the case back to the trial Court.

Case Studies- Negligence



NEGLIGENCE

Case 1

Pennsylvania, 1988

Pharmacy failed to warn the patient or notify the prescribing physician of obvious inadequacies appearing on the face of the prescription which created a substantial risk of serious harm to the patient.

Riff v. Morgan Pharmacy, 353 Pa. Super.21 508 A.2d 1247(1986)

Case Studies- Negligence



NEGLIGENCE

Case 2

Tennessee, 1990

A single physician wrote for 2 different prescription drugs on different days that interacted. They were filled as written by the same pharmacist on 2 different days. These facts supported a failure to warn cause of action.

Dooley v. Everett, 805 S.W.2d. 380 (Tenn.Ct.App.1990)

Case Studies- Negligence



NEGLIGENCE

Case 3

Nevada, 1993

It is not a pharmacist responsibility to second guess a licensed physician unless the circumstances would be obviously fatal.

Heredia v. Johnson, Payless Drug Stores, 827 F.Supp. 1525 (D.Nev.1993)

Case Studies- Negligence



NEGLIGENCE

Case 4

Arizona, 1994

The pharmacist had a duty to warn that the combined use of 2 addictive drugs could cause addiction or other adverse consequences. Failure to warn could breach the pharmacist's duty of reasonable care.

Lasley v. Shrake's Country Club Pharmacy, Inc., 179 Ariz. 583 P.2d 1129 (1994)

Summary of Current Civil Liability (FL)

Ministerial

- Label correctly
- Fill correctly
- Compound correctly
- Use product that is not adulterated



Discretionary

- Failure to warn
 - Controls – repeated fills
 - Drug interactions (2 diff MD)
- Vol. Assumption of Risk
 - Advertising of computer warnings
 - Auxillary labels
- Assess the Rx
 - Filling correctly but Rx is unreasonable on its face.

3rd Theory of Pharmacy Liability



**CRIMINAL NEGLIGENCE INVOLUNTARY
MANSLAUGHTER**

What are the elements?

3rd Theory of Pharmacy Liability



CRIMINAL NEGLIGENCE INVOLUNTARY MANSLAUGHTER

1. Occurs when someone who did not intend to cause death, acted so recklessly that they should have known it would have caused death; or

3rd Theory of Pharmacy Liability



CRIMINAL NEGLIGENCE INVOLUNTARY MANSLAUGHTER

1. Occurs when someone who did not intend to cause death, acted so recklessly that they should have known it would have caused death; or
2. Omission to act when there is a duty to do so; or

3rd Theory of Pharmacy Liability



CRIMINAL NEGLIGENCE INVOLUNTARY MANSLAUGHTER

1. Occurs when someone who did not intend to cause death, acted so recklessly that they should have known it would have caused death; or
2. Omission to act when there is a duty to do so; or
3. Failure to perform a duty owed; and

3rd Theory of Pharmacy Liability



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2. Omission to act when there is a duty to do so; or
3. Failure to perform a duty owed; and
4. Death results.

3rd Theory of Pharmacy Liability



CRIMINAL NEGLIGENCE INVOLUNTARY MANSLAUGHTER

1. Occurs when someone who did not intend to cause death, acted so recklessly that they should have known it would have caused death; or
2. Omission to act when there is a duty to do so; or
3. Failure to perform a duty owed; and
4. Death results.

Note that law does NOT impose criminal liability for failure to act unless a **specific duty is owed**

New Landscape...

Criminal Negligence

Early Case



•In **2001** a hospital pharmacist dispensed overdoses of 2 chemo drugs to an adult patient who **died**. The Grand Jury indicted the pharmacist for involuntary manslaughter. (Ohio)

Criminal Negligence

Error (??) – Sentenced 2009



ELIZABETH LEE WINDSOR

DECEASED, CARMEL SHELLER (72 YO)

RPh dispensed propranolol instead of prednisolone.

RPh was found guilty criminally. Sentenced to 3 months in jail and 12 months probation. Successfully appealed and was in turn given 14 days in prison and fined £300 .

Court explained that the **pharmacy** is criminally liable for the harsher sentence. **RPh** had been working a 10 hour shift without a break.

Criminal Negligence

Error 2006 – Sentenced 2009



**ERIC CROPP & RAINBOW BABIES AND CHILDREN'S
HOSPITAL (OHIO)**

DECEASED, EMILY JERRY (2 YO)

Tech mixed IV solution wrong. Case against tech was dismissed by Grand Jury.

RPh license permanently revoked in 2007. RPh found guilty of involuntary manslaughter. Served 6 months in prison, 6 months home confinement, 400 community service, \$5000 fine.

Court explained that a RPh is responsible for himself and his technician.

Details of Eric Cropp case



- **Facts of the Case:**

- Technician prepared a 23% saline solution instead of a 1% saline solution; (23x normal dose)
- Technician alerted RPh that she thought something might be wrong with her mixture.
- Concern dismissed by RPh. RPh had mixture delivered without checking it.
- Death from the error.

Details of Eric Cropp case



- Involuntary Manslaughter (criminal negligence):
 - **Occurs when someone who did not intend to cause death, acted so recklessly that they should have known it would have caused death.**
 - Omission to act when there is a duty to do so.
 - Failure to perform a duty owed.
 - **Death results.**

- Note that law does **NOT** impose criminal liability for failure to act unless a **specific duty is owed**

Outcomes of Eric Cropp case



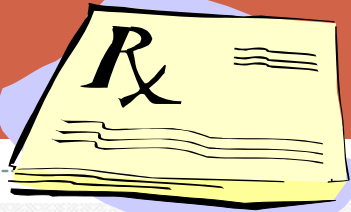
- **Results of Case Outcome:**
 - It is clear that the law allows for criminal indictment of a healthcare professional, IF....
 - ✦ If a person/patient is harmed. (death)
 - ✦ Despite no intent to harm. (act reckless)

Discussion of Eric Cropp case



- **WHY are we seeing Criminal Trends Now?**
 - Medical and pharmacy malpractice is now being focused on by prosecutors as criminal cases.
 - Victims and their families talk more publicly after a medication error.
 - When there is a death (especially that of a child) and there is extensive press coverage, local prosecutors can feel “under the gun” to do something.

Is the Liability of Pharmacists Changing? YES



**PHARMACY IS THE ONLY HEALTH CARE PROFESSION
NOW REQUIRED TO OBTAIN PERFECTION.**

DETERS THE REPORTING AND ANALYZING OF ERRORS.

CHILLING EFFECT ON RECRUITMENT EFFORTS.

**LICENSING BOARDS ARE NO LONGER THE ONLY ENTITY
EFFECTING THE PHARMACIST PRACTICE OF
PHARMACY.**

The image features several pills and capsules scattered across the page. There are two red and yellow capsules, one at the top left and one in the middle right. There are also several white oval tablets with a score line, one at the top center, one at the top right, one at the bottom left, and one at the bottom right. A small white circular pill is located in the center, just below the main title. A horizontal dashed line is positioned below the main title.

QUESTIONS?

SHARON ROBERTS, PHARM.D., J.D.
REGULATORY COUNSEL

www.healthandregulatorylaw.com