The Pharmacist’s Evolving Intellectual Duty to Warn

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Policy Justifications for Pharmacist Duty to Warn

- Patients have a right to information about prescriptions dispensed to them
- When patients are given information, therapy outcomes improve
- Pharmacists are trained and have expertise in clinical use of medicines, and in conveying relevant information
- Sophisticated computer software enables monitoring of medication use
Policy Justifications Against Pharmacist Duty to Warn

- Pharmacist warnings are an intrusion into the physician-patient relationship
- Economic costs to provide warnings
  - Personnel (RPhs) required
  - Structural changes to accommodate confidentiality
- Patient expectations of counseling by physician, with pharmacist simply dispensing
Liability Based Upon “SPECIAL KNOWLEDGE”

Facts

In August 1993, plaintiff was prescribed Toradol, a potent NSAID, for severe menstrual cramps. The doctor knew the plaintiff had drug allergies, but did not know that Toradol had cross reactivity with allergies to aspirin, despite a clear warning on the package insert.
Wal-Mart protocol required its pharmacists to ask customers if they had drug allergies, including to aspirin. Per this protocol, plaintiff’s allergy information was inputted into her computerized patient profile and was available when plaintiff’s Toradol prescription was dispensed. Plaintiff took the first dose of Toradol, and suffered anaphylactic shock. The trial court granted defendant’s summary judgment motion and the appellate court reversed.
Arguments

Plaintiffs argued that the pharmacist was negligent in not warning and dispensing a medication which was contraindicated based on noted allergies in patient’s profile. The pharmacy argued that imposing a duty to warn would have a “chilling effect” on the profession, and would discourage the gathering of relevant information about customer allergies in the future.
Decision

• Reversed summary judgment rejecting the pharmacy’s argument, noting that documenting allergy information is the standard of care. By inquiring about drug allergies, the customer can reasonably expect that contraindicated drugs would not be dispensed.

• Held that the pharmacist owed a narrow duty to warn either the plaintiff or physician of this contraindication because the patient profile includes this “special knowledge” of ASA allergy.
Analysis

• Decision is important, because it imposes a duty to warn when pharmacists obtain fact-specific patient information.

• Considering that obtaining allergy history is current standard of care, which allows check for contraindications (through computer systems), the imposition of a duty creates a precedent for a potentially broad application of the duty to warn and act in patients’ best interests.

Facts

For 6 years decedent was dispensed psychotropic drugs pursuant to valid prescriptions. Pharmacist knew and prescription patient profile documented decedent was an alcoholic. For 10 months preceding decedent’s death, 728 units of psychotropic drugs were dispensed. As a result, decedent died.
Arguments

Plaintiff’s executrix claimed that the pharmacist breached the professional standard of care by dispensing drugs contraindicated with alcohol. The pharmacy moved for summary judgment, which was granted by the trial court.
Decision

Reversed summary judgment based on the standard of care, along with the definition of “contraindications” – circumstances under which a drug must never be given, the appellate court held that a pharmacist could breach his duty if he knowingly ignored the dangers and consequences of an alcoholic ingesting medications recognized to be contraindicated.
Analysis

Although one of the first decisions to hold that a pharmacist has a duty to warn about contraindications, the breadth of this decision is limited.

- A general duty to warn is not recognized.
- Very fact-specific
- Duty/liability imposed because pharmacist had special knowledge about the patient that created a substantial risk of serious harm.
Pysz v. Henry’s Drug Store, 457 So.2d 561 (Fla. 4th DCA, 1984)

Facts and Arguments

Henry’s filled plaintiff’s prescription for Quaaludes for more than 9 years. Plaintiff alleged that pharmacist’s failure to warn of the addictive propensity of Quaaludes was negligent, and pharmacist should have known that use over extended time would cause physical and psychological dependence, and failed to advise patient or physician.
Decision

- The trial court dismissed the case, holding that the pharmacist had no duty to refuse to dispense a lawfully prescribed medication, nor was obligated to warn of the drug’s addictive propensities.

- In upholding dismissal, the appellate court stated that although a pharmacist might possess greater knowledge than a physician of the adverse effects of drugs, “it is the physician who has the duty to know the drugs that he is prescribing and to properly monitor the patient.”

- A pharmacist, who had properly filled a lawful prescription, had no duty to warn.
Analysis

• This opinion amplifies the then prevailing view that the pharmacist’s role was secondary to that of the physician.

• Although the possibility of a pharmacist’s negligence in failing to warn a patient in special circumstances remains, the circumstances were not present herein.

• Presumption that pharmacist does not have a duty to warn absent special circumstances.
Voluntary Undertaking

Facts

In 1986, Stephen Frye underwent surgery and post-operatively was prescribed Fiorinal. The pharmacist dispensed the prescription exactly as prescribed, and the physician did not instruct that any warning be given. However, the pharmacist placed 2 auxiliary warning labels on the vial, one of which was a “Drowsy Eye” warning label.
The pharmacist disregarded the pharmacy’s computer software program, which suggested an auxiliary warning label against consumption of alcohol, because she was afraid it might offend people with alcoholic tendencies.

Plaintiff argued that although defendants did not have a duty to warn, they voluntarily undertook the duty, did not do so fully and were thus negligent.
Decision

Under the voluntary undertaking theory, the duty of care imposed is limited to the extent of the defendant’s undertaking. Affixing the “Drowsy Eye” label on the prescription vial did not constitute an undertaking to warn about all side effects and contraindications. The Supreme Court concluded that consumers should principally look to their physician for appropriate warnings.
Analysis

This case directly addresses the policy considerations relevant to a limited application of the voluntary undertaking theory of liability, concluding that when the pharmacist undertakes a responsibility, these actions impute a duty to act reasonably. The ruling only holds the pharmacist accountable for the specific warnings provided, and not for those excluded.
**Facts**

Plaintiff was prescribed Trazodone for depression in 1994. Upon dispensing prescription at CVS, the pharmacist only provided the “short form” warning listing the most common side effects, which did not include the risk of priapism, which befell plaintiff and caused his injury. The “long form warning,” a more comprehensive warning list which included priapism, was required to be dispensed under CVS corporate policy for all new prescriptions.
Plaintiff developed a persistent erection for 30 hours before seeking medical attention, requiring emergency surgery, which caused permanent impotence.

A jury held the pharmacy 51% negligent, plaintiff 49% culpable.
**Issue and Decision**

Issue: Whether a pharmacy had a duty to warn of all risks and side effects of medications dispensed.

- Concluded that there was no general duty to warn.
- Since CVS had voluntarily assumed the duty to warn about some of the side effects of Trazodone, a patient could reasonably assume that it was a complete list. By voluntarily assuming the duty to warn, CVS was negligent in only providing a partial list.
Analysis

• Court carefully distinguished the Illinois Frye decision, where only 2 auxiliary labels were attached. Here, CVS provided the consumer with a list of warnings which a patient could assume was comprehensive.

• Even though a general duty to warn is not imposed, once the duty is assumed, it must be done completely.

• As most pharmacies dispense "short form" warnings with each prescription generated through computer software, the imposition of a duty to provide comprehensive warnings is a distinct possibility in the future.
Expert Testimony: Pharmacist Breached the Standard of Care
Dooley v. Everett, 805 S.W.2d 380 (Tenn. Ct. App. 1990)

Facts

The 3 year-old plaintiff was hospitalized for pneumonia and was prescribed theophylline. Theophylline was also dispensed by the pharmacy between September and December 1987. During this time, the physician also prescribed erythromycin, which was dispensed at the same Revco pharmacy. Plaintiff suffered seizures as the result of toxic levels of theophylline.
The package insert for erythromycin stated that patients who concomitantly received high doses of theophylline had an increased potential for theophylline toxicity. The pharmacist denied knowing that erythromycin could adversely interact with theophylline and did not warn plaintiff as such. The trial court held that the pharmacist had no duty to warn and granted defendant’s summary judgment motion.
Decision

Reversed summary judgment imposing on pharmacists “the responsibility of relating information as required concerning such drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease.”
Plaintiff’s expert testified that it was common in Tennessee pharmacy practice for pharmacies to maintain a patient profile system, for pharmacists to review to determine if the prescription interacted with others the patient was taking, and to call the physician or advise the patient if an interaction was found.
• Computer technology existed to help pharmacists identify drug interactions in general and the erythromycin/theophylline interaction in particular.

• Held that a question of material fact existed as to whether the professional standard of care encompassed the duty to discover and warn consumers of potential drug interactions. SJ overturned.

• The significance of Dooley lies in its shift from focusing on the pharmacist’s duty to focusing on pharmacy standard of practice.

**Facts**

From 1960 to 1990 George Lasley was prescribed Doriden and codeine, controlled substances for sleep and pain. Over 10 years, Lasley had most of these prescriptions filled at Shrakes CC Pharmacy while in Arizona as a snowbird in winter. At times, prescriptions were mailed to his residence in another state.
• As a result of his extended use, plaintiff required in-patient detoxification and psychiatric treatment for addiction, and clinical depression.

• The trial court granted defendant's sj motion, and plaintiff appealed.

• On appeal, defendant argued that pharmacists do not have a duty to warn of a drug’s dangerous propensities or a duty to keep track of a customer’s reliance on drugs legally prescribed by a physician.
Decision

- The Court carefully distinguished between the duty owed by a pharmacist, and plaintiff’s argument that defendant breached the applicable standard of care.

- Summary judgment reversed. The Court found that the pharmacist had a duty, but whether the standard of care included the duty to warn was one of first impression in Arizona.
Analysis

• A pharmacist’s warning about a drug’s adverse effects is a professional standard of care issue and not a duty question, and thus a question of fact for the jury, subject to expert opinion testimony.

• The Court did not carve out a narrow, fact-based exception limiting a pharmacist’s duty, but rather rejected the no-duty argument, and allowed the case to proceed.
Public Expectation Based Upon Pharmacy Representation
Facts

Decedent’s doctor prescribed Parnate for depression after an attempted suicide in October 1989. Parnate is a monoamone oxidase (“MAO”) inhibitor and has potential interactions with other medications and foods.

In 1992, decedent developed a cold and saw another physician. Decedent informed the doctor that he took Parnate. Prescribed Ceftin (an antibiotic) and Tavist-D (a decongestant), which were dispensed at Arbor Drugs.
• Though Arbor Drugs had pharmacy computer software to detect potential drug-drug interactions, including the well-known one between Tavist-D and Parnate, the pharmacist did not see this interaction warning on the computer.

• The pharmacy advertised that their sophisticated computer software was able to render better pharmaceutical care.
• Patient suffered a stroke, caused by the concurrent ingestion of Parnate and Tavist-D.

• Plaintiff contends that the pharmacy’s negligence in failing to detect this drug-drug interaction proximately caused the injury. Defendant granted SJ by trial court.
Decision

- Plaintiff submitted evidence that the pharmacy implemented, used and advertised its sophisticated software, to assist in rendering pharmaceutical care.

- Held that the defendant voluntarily assumed the duty to utilize the software correctly. The prior summary judgment was overturned.
Analysis

Michigan Appellate Court considered sophisticated software as an integral component of modern day pharmacy practice, which was specifically held out as a marketing tool to instill confidence that prescriptions were being properly monitored for drug interactions.
• The utilization and promotion of this system invite customers to rely on pharmacists beyond their dispensing role.
• If pharmacists promote their professional capabilities and patients rely upon these representations, liability may attach for not meeting the expanded obligation being assumed.
OBRA ’90
The Forgotten Statute
Moore v. Memorial Hospital of Gulfport, 825 So.2d 658 (Miss. 2002)

Facts

A pregnant patient with a history of hypertension was prescribed Aldomet, dispensed at Winn-Dixie Pharmacy from February - July 1997. In May 1997, another physician added Diovan, a combination ACE inhibitor and diuretic for hypertension, which was also dispensed at Winn-Dixie.
Four days after delivery the neonate became acutely ill and experienced renal failure requiring a kidney transplant. The trial court granted, and the appellate court sustained, defendant’s summary judgment motion.

Plaintiff sued Winn-Dixie claiming negligence in dispensing a drug which had a black box warning as contraindicated in pregnancy because of potential fetal harm.
Decision

The Supreme Court dismissed claims against the pharmacy based on the learned intermediary doctrine, refusing to impose a duty to warn. Although aware of several exceptions where the learned intermediary doctrine would not shield a pharmacy from liability, i.e., if the patient provided specific medical information, those exceptions are fact-specific and do not apply here.
Analysis

• The Court was not swayed by the statutory obligations enumerated in the Mississippi Pharmacy Act, which incorporated OBRA ‘90.

• Ruling was largely influenced by a decision issued before the implementation of OBRA 90.

• Concurring opinion accurately addressed the State Pharmacy Act to recognize the modern pharmacist, as “experts in pharmacology, unlike doctors who only know perhaps a handful of drugs.” Therefore, shielding a pharmacist under the learned intermediary doctrine goes against regulatory provisions.
Horner v. Spalitto, 1 S.W.3d 519 (Mo. Ct. App. 1999)

Facts

• In Sept. 1994, a pharmacist dispensed 2 prescriptions, and the patient died of a drug overdose 6 days later. One of the prescriptions for Placidyl, a hypnotic, was ordered for 3 times the usual dose. The pharmacist was initially concerned about the high dosage and called the prescriber’s office, and was told by “someone in the office” that the prescription was okay.

• The trial court granted the pharmacist’s sj motion finding that the pharmacist was under no duty to warn.
**Decision**

Reversed summary judgment finding “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. We must leave to a fact-finder what this duty requires of a pharmacist in a particular case.”
Analysis

• The Court was partially swayed by recently enacted OBRA requirements adopted in Missouri. OBRA requires a pharmacist to “offer to counsel” each customer about the safe and appropriate use of the medication jointly based on the pharmacist’s review of available patient information. This was not done.

• Horner was one of the first cases to directly address OBRA, and setting a pharmacist standard of care, based upon practice in the profession and regulatory mandates.