Pharmacist Liability

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Objectives:

- Define negligence and tort law.
- Review limits of liability, including defenses to a negligence claim, and relate to pharmacy practice.
- Describe practical ways to avoid complaints, liability

Limits of pharmacist liability in WA

- See RCW 18.64.275: limits liability of pharmacist who dispenses a prescription product *in the form produced by the manufacturer*:
  - Prescription drug as manufactured by pharmaceutical company—no alterations
  - Compounds: liability *not* limited under this statute. See WAC 246-878-020 (Compounded Drug Products-Pharmacist)

Limits of pharmacist liability in WA (cont'd)

- In this situation, pharmacist can be liable only if:
  - Negligent
  - If pharmacist makes an "express warranty" about drug
  - If pharmacist either conceals information or intentionally misrepresents facts about drug (thus the importance of avoiding statements that seem fraudulent or deceptive).

Tort law

- The body of law encompassing negligence is tort law.
- Definition of a tort: violation of a duty imposed by law on an individual based upon a relationship to another individual.
  - Duty owed: health care professional to patient.
  - No duty owed: passerby to injured person. (Good Samaritan statutes, see RCW 4.24.300)

Elements of a tort claim

- Duty
- Breach
- Causation
- Damages (or harm)

Defining pharmacist's duty

- Traditional view encompasses a technical responsibility to fill prescriptions accurately:
  - Correct drug, strength, directions
  - Label complies with requirements of RCW 18.64.246, WAC 246-869-210
  - Drug within manufacturer's expiration date (easy to overlook!!)
  - Drug dispensed to correct patient

Traditional view of duty

- Consistent with this traditional view is the duty of the pharmacist to verify, or refuse to fill, a prescription that contains patent or obvious errors on its face.
- Also consistent with this technical view is the duty of the pharmacist to clarify illegible or poorly written prescriptions.

Expanding the definition of pharmacist's duty

- An expansion of pharmacist duties from the non-discretionary standard of technical accuracy to a discretionary standard which requires pharmacists to perform professional functions.
- Move is from technical model to pharmaceutical care model.

Case law on pharmacist's duty in Washington

- *McKee v. American Home Products,* 782 P.2d 1045 (Wash. 1989). Washington Supreme Court held that although pharmacist had duty to take corrective measures when filling a prescription containing an obvious or known error, RPh had no "duty to question a judgment made by the physician as to the propriety of the prescription or to warn customers of the hazardous side effects associated with a drug."

McKee (cont'd)

- Significance of holding: pharmacist who accurately filled prescription from licensed prescriber has no duty to warn patient of potential hazards associated with the drug prescribed.
- Although this holding not specifically overruled by the Court, this is no longer "good law" in Washington.

OBRA 90: a federal standard for pharmacy care

- The Omnibus Reconciliation Act of 1990 (OBRA 90) established minimum standards of care for pharmacists.
- Although individual states were given latitude for implementation, the effect of OBRA 90 was to expand duty to include:
  - monitoring of patient's drug therapy;
  - intervention when problems are detected; and,
  - provision of drug information to patient prior to dispensing prescription.

Expanding the definition of pharmacist's duty

- Washington pharmacist's duty codified in WAC 246-863-095 (Pharmacist's professional responsibilities):
  - Receipt of new verbal prescription from MD
  - Consultation with prescriber and patient regarding prescription itself and/or information contained in the patient medication record.
  - Independent review and assessment of patient medication record (allergies, effect of chronic conditions, potential therapeutic duplications or drug interactions)

Washington pharmacist's duties

- Ultimate responsibility for all aspects of the completed prescription and assumption of liability for prescription as filled.
- These duties are only delegable to an intern. Note language regarding liability for final Rx.
- NOTE: Because of the controversy with RPh refusal to dispense and the conditions under which that would be permitted, WAC 246-869-095 is currently being redrafted (see 11/29 reading, BOP website).

Part of Duty: Patient Counseling

- Washington law also requires the pharmacist to provide patient information (WAC 246-869-220)

Pharmacist conduct and the "standard of care"

- Consistent with the revised view of duty is the application of a professional standard to pharmacist conduct. Conduct must comply with the "standard of care" of a reasonable and prudent pharmacist.
- Standard of care assessed within the "relevant community"; comparison is between similarly situated practitioners (e.g. hospital pharmacists compared to each other, practitioners in the same community).

Ask the Expert:

- What would a reasonable and prudent pharmacist with similar education, training, and experience would do under the same set of circumstances?
- A pharmacist expert would be responsible for testifying as to the standard of care of another pharmacist.

Burden of Proof at Trial in Civil Liability Cases

- *Burden of proof* is on the plaintiff to prove each and every element of the alleged case. *Degree of proof* is preponderance of evidence or "more likely than not" (51%).

Breach of duty (cont'd)

- P can show negligence *per se* if pharmacist violated a statute or regulation. For example, failure to provide patient information is a violation of WAC 246-869-220 and is negligence *per se*. If established, P only needs to prove causation and damages.

Causation

- Actual vs. proximate cause
- Actual cause: prove that D-Ph's conduct was a *substantial factor* in P's harm
- Issues with actual cause, may require expert testimony:
  - E.g. prescription error stipulated, patient actually ingested wrong drug. Now burden is on P to show that this drug caused the harm alleged rather than some other factor (another drug or disease state).

Causation (cont'd)

- Proximate cause limits the scope of liability by breaking the chain of causation between D-Ph's act and P's harm.
- Test is foreseeability. Unforseeable event ("superceding cause") breaks the chain:
  - Chain continued: medical treatment for harm, even if treatment is negligent
  - Chain broken: misuse of drug by patient

Damages: Actual or economic

- Economic damages (WA): objectively verifiable monetary damages, including medical expenses, lost wages, loss of employment, loss of business or opportunity cost. Judgment for these damages can restore P to where s/he would have been "but for" the negligence.
- Relatively easy to prove, not "capped" in Washington.

Damages: Non-economic

- Noneconomic damages (WA): subjective, non-monetary losses, including emotional injury, "pain and suffering", disability or disfigurement, loss of society and companionship.
- Difficult to establish, because award of these damages is designed not so much to restore P to previous situation, but to make the consequences of the harm bearable.
- Legislative attempt to "cap" ruled unconstitutional in WA.

Damages (cont'd)

- Punitive damages: designed to make an example of D-Ph
- Awarded in these situations:
  - D-Ph shows "wanton and reckless disregard" for P's rights
  - D-Ph demonstrates morally culpable conduct
- Washington law allows for punitive damages only as established by statute, no provision for medical negligence.

Defenses:

- Contributory negligence: P's negligence completely bars recovery (e.g. failure to seek medical attention, failure to wear a seat belt in an automobile PI case), or;
- Comparative fault: damages awarded are reduced by the degree of fault that P contributed to the harm. Washington law.

Defenses (cont'd)

- Statute of limitations: claim must be filed within a certain window of time. Purpose is to prevent "stale" claims.
- Many states have a "discovery rule", modifying statute to reflect date of discovery of the injury.
  - RCW 4.16.350: must file claim within 3 years of act/omission or within 1 year of discovery, whichever expires later. (However, no claim may be filed more than 8 years after act/omission).

Civil Procedure

- Lawsuit initiated by summons and complaint (by plaintiff or P): allege elements of harm (complaint) and give notice to other party that suit has been initiated (summons).
- Answer (by defendant or D): rebut or acknowledge each and every allegation in P's complaint.
- Discovery: parties exchange information through interrogatories, request for production, and depositions (potential for abuse).

Civil Procedure (cont'd)

- Mediation (required before trial in Washington for health care malpractice)
- Pre-trial and preliminary motions: defendant can move to have action dismissed
- Trial: can be bench (judge) or jury in a civil proceeding depending upon the motions of the parties in pre-trail
- Announcement of verdict/judgment: settlement can occur any time prior to this.

Board of Pharmacy Disciplinary Action

- Pursuant to RCW 18.130.180, "unprofessional conduct" of any license holder can be the basis for disciplinary action by the Board. "Unprofessional conduct" includes "Incompetence, negligence, or malpractice which results in injury to a patient or creates an unreasonable risk that a patient may be harmed."
- Note that complaint of "unprofessional conduct" can trigger investigation by BOP (RCW 18.130.080)

Board of Pharmacy Disciplinary Action (cont'd)

- Disciplinary action follows procedure described in Uniform Disciplinary Act (RCW 18.130). Since penalties can be warnings, fines, probationary period, and license suspension or revocation, wise to hire an attorney to interface with the Board of Pharmacy.

How to Stay out of Trouble: Avoid Common Sources of Liability, Complaints

- Use "systems approach" to evaluate work areas for sources of potential error
- Don't cut corners: watch for and appropriately assess allergies, drug-drug interactions, drug-disease interactions.
- Don't cut corners II: effectively counsel patients on their medications so they are used appropriately. Also, many errors are caught "at the window".

If an error occurs, patient communication is critical!

- Listen carefully to patients' complaints and concerns.
- Give patient simple explanation of error if determined. May follow up with more detailed explanation if situation warrants it.
- Reassure patient that efforts will be made to prevent these types of errors in the future, and follow up to inform patient of remedial measures.