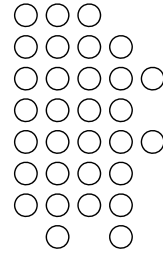


# Pharmacist Liability

With thanks to

Martha Dye-Whealan, R.Ph., J.D.



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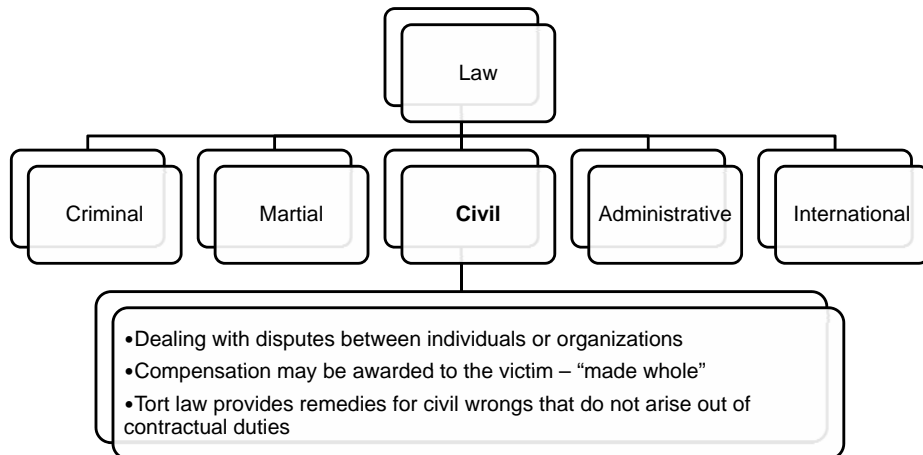
## Objectives:

- 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



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## ... recall



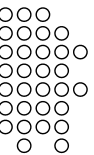
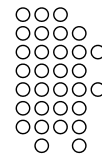
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## Tort law

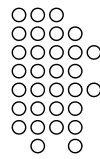
- The body of law encompassing negligence is tort law.
- Definition of a tort: violation of a duty imposed by law on an individual based upon a relationship to another individual.
  - Duty owed: health care professional to patient.
  - No duty owed: passerby to injured person. (Good Samaritan statutes,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

<http://apps.leg.wa.gov/rcw/default.aspx?cite=4.24.300>

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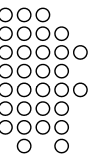
## Elements of a tort claim



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

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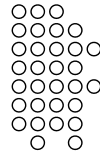
## Defining pharmacist's duty



- 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!!—some drug are actually toxic past their expiration dates)
  - Drug dispensed to correct patient

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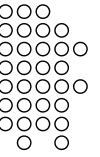
## Traditional view of duty



- Duty of the pharmacist to verify, or refuse to fill, a prescription that contains obvious errors
- Duty of the pharmacist to clarify illegible or poorly written prescriptions

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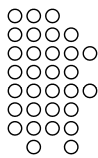
## Expanding the definition of pharmacist's duty



- 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.

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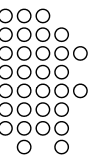
## Case law on pharmacist's duty in Washington



- *McKee v. American Home Products*, 782 P.2d 1045 (Wash. 1989).
- Washington Supreme Court held
  - RPH has duty to take corrective measures when filling a prescription containing an obvious or known errors
  - 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.

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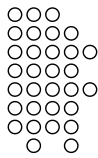
## McKee (cont'd)



- 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.
- Revisions to practice act following ruling

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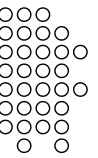
## OBRA 90: a federal standard for pharmacy care



- 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.

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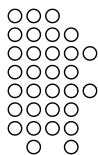
## Expanding the definition of pharmacist's duty



- Washington pharmacist's duty codified in WAC 246-863-095 (Pharmacist's professional responsibilities):
  - Receipt of new verbal prescription from MD (refills ok)
  - 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)
  - Decision to not dispense lawfully prescribed drugs or devices or to not distribute drugs and devices

12

## Washington pharmacist's duties



- Ultimate responsibility for all aspects of the completed prescription and assumption of liability for prescription as filled:
  - accuracy of drug,
  - strength, labeling,
  - expiration date,
  - proper container
  - other requirements.
- These duties are only delegable to an intern. Note language regarding liability for final Rx.

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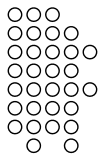
## Washington Pharmacist's Professional Duty -- revised.



- Pharmacist should refuse to fill prescriptions that contain errors or might otherwise endanger the patient.
- “unprofessional conduct”
  - (a) Destroy unfilled lawful prescription;
  - (b) Refuse to return unfilled lawful prescriptions;
  - (c) Violate a patient's privacy;
  - (d) Discriminate against patients or their agent in a manner prohibited by state or federal laws
  - (e) Intimidate or harass a patient.

14

## Part of Duty: Patient Counseling

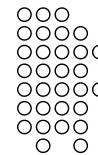


- Washington law also requires the pharmacist to provide patient information (WAC 246-869-220)
  - (1) directly counsel the patient or patient's agent on the use of drugs or devices.
  - (3) determine the amount of counseling ... necessary ... [for] safe and effective administration ... and facilitate an appropriate therapeutic outcome

effective 3/8/01

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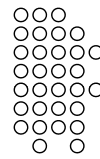
## Ask the Expert:



- 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.

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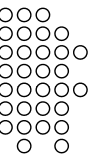
## Burden of Proof at Trial in Civil Liability Cases



- *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%).

17

## Breach of duty (cont'd)



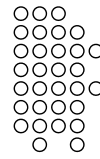
- Plaintiff can show negligence *per se* if pharmacist violated a statute or regulation.
- For example, failure to provide patient information is a violation of WAC 246-869-220 and is negligence *per se*. If established, plaintiff only needs to prove causation and damages.

### Elements of Tort

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

18

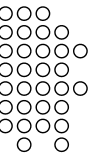
## Causation



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

19

## Causation (cont'd)

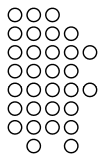


- Proximate cause limits the scope of liability by breaking the chain of causation between defendant RPh's act and plaintiff's harm.
- Test is foreseeability. Unforeseeable event (“superceding cause”) breaks the causality chain:
  - Chain continued: medical treatment for harm, even if treatment is negligent
  - Chain broken: misuse of drug by patient

**Proximate cause:** event sufficiently related to a legally recognizable injury to be held the cause of that injury (Wikipedia)

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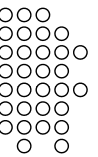
## Damages: Actual or economic



- 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.

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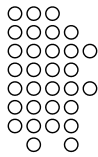
## Damages: Non-economic



- 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 plaintiff to previous situation, but to make the consequences of the harm bearable.
- Legislative attempt to “cap” ruled unconstitutional in WA.

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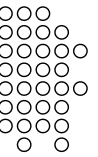
## Damages (cont'd)



- Punitive damages: designed to make an example of defendant RPh
- 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.

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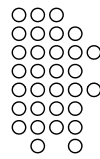
## Defenses:



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

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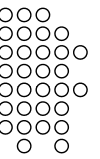
## Defenses (cont'd)



- 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).

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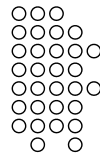
## Board of Pharmacy Disciplinary Action



- 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)

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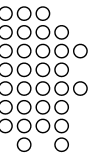
## Board of Pharmacy Disciplinary Action (cont'd)



- 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.

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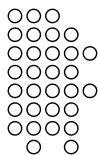
## How to Stay out of Trouble: Avoid Common Sources of Liability, Complaints



- Use “systems approach” to evaluate work areas for sources of potential error. Workflow can be effective, or can actually promote errors.
- When job shopping: look at the technology your employer uses. Script-Pro may be nice, but a computer system that takes away “busy work”/distractions (e.g. processing refills) is even better.
- Execute your professional duties!!: watch for and appropriately assess allergies, drug-drug interactions, drug-disease interactions.

28

## More ways to stay out of trouble..



- Execute your professional responsibilities: effectively counsel patients on their medications so they are used appropriately. Also, many errors are caught “at the window”.
- Avoid “unprofessional conduct”. Always treat every patient and every situation in a consistent way. If your company does not have a policy to handle, e.g. questionable narcotic prescriptions, set one up.
- AVOID THE APPEARANCE OF DISCRIMINATION!!!

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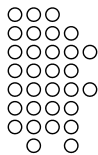
## Limits of pharmacist liability in WA



- 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)

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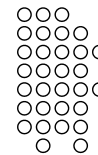
## Limits of pharmacist liability in WA (cont'd)



- 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).

31

## Maintain an atmosphere of professional conduct

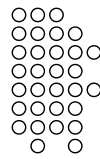


- Discipline staff who engage in inappropriate conversation, especially comments that could be heard by patients and be interpreted as either a violation of privacy or discrimination.
- Every employee, pharmacist and technician, should have a working understanding of HIPAA and Washington Privacy law and should understand the penalties for violating the law.

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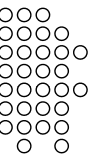
## If an error occurs, patient communication is critical!



- Do not delegate assessment of a possible error to technical staff
- Take time away from workflow to listen carefully to patients' complaints and concerns.
- Document the error as specified by your employer
- Give patient simple explanation of error if determined. May follow up with more detailed explanation if situation warrants it.

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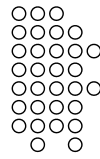
## Error management



- Thank the patient for pointing out the error.
- 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.
- Make the patient feel like he/she is part of the quality improvement process.

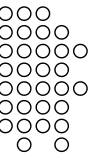
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## QUESTIONS



35

## Emphasis



- What is a tort
- 4 elements
- Professional responsibilities → negligence
- Staying out of trouble

36