The Pharmacist's Duty to Warn

Detroit, MI

October 30, 2008
3:30 PM – 4:45 PM
Session 6: The Pharmacist’s Duty to Warn

Learning Objectives

- Define the 4 required components of a lawsuit alleging pharmacist negligence.
- Explain the effect of recent case law decisions involving a pharmacist’s duty to warn.

Faculty

Paul M. Garbarini, JD, RPh
Attorney, Private Practice
Northampton, Massachusetts

Mr Garbarini is an attorney in private practice in Northampton, Massachusetts. His practice concentrates on the area of representation of health care professionals in administrative hearings, legislative matters, and other civil and criminal matters. He is also a licensed registered pharmacist.

Mr Garbarini earned a bachelor’s degree in biology from the Rochester Institute of Technology, Rochester, New York, in 1985, as well as a bachelor’s degree in pharmacy from the Massachusetts College of Pharmacy in Boston in 1985. He earned a doctor of jurisprudence degree from the Suffolk University School of Law in Boston in 1992 and was admitted to the Massachusetts Bar in December 1992. He is a former member of the Massachusetts Pharmacist Association board of directors, having served from 1997 through 2000. He is General Counsel to the Massachusetts Independent Pharmacist’s Association and the Massachusetts Pharmacist Association. He is adjunct faculty at Bouve College of Pharmacy, Northeastern University, Boston, Massachusetts where he teaches pharmacy jurisprudence.

Mr Garbarini has lectured extensively on the topic of pharmacy law, including the pharmacist’s duty to warn, negligence, state and federal pharmacy law, state and federal pharmacy legislation, the Omnibus Budget Reconciliation Act (OBRA) ’90, the Health Insurance Portability and Accountability Act (HIPAA), drug purchasing, 340B eligibility, and other related matters.

Faculty Financial Disclosure Statement

The presenting faculty reported the following:
Mr Garbarini has no relationships to disclose.

Drug List

<table>
<thead>
<tr>
<th>Generic</th>
<th>Trade</th>
</tr>
</thead>
<tbody>
<tr>
<td>indomethacin</td>
<td>Indocin</td>
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<tr>
<td>colchicine</td>
<td>various</td>
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<tr>
<td>diazepam</td>
<td>Valium</td>
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<tr>
<td>ethchlorvynol</td>
<td>Placidyl</td>
</tr>
<tr>
<td>fentanyl patch</td>
<td>Duragesic</td>
</tr>
</tbody>
</table>

Suggested Reading List


Horner v Spalitto, 1 S.W. 3d 519 (1999).


The Pharmacist’s Duty to Warn

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Negligence - What is the legal meaning?

- Definition
  “The failure to use such care as a reasonably prudent person would use under similar circumstances.”

- Negligence Generally
  - Plaintiff accuses provider of substandard practice
  - What must a plaintiff prove to prevail in a negligence action?

* Black’s Law Dictionary

Negligence - Duty

- What is a duty?
  - Definition
    “An obligation, to which the law will give recognition and effect, to conform to a particular standard of conduct to another.”

* Black’s Law Dictionary

Negligence - Violation

- Plaintiff must prove violation of the duty
  - What evidence proves violation of duty?
  - Are experts always needed to prove violation of a pharmacist’s duty?
  - Mechanical pharmacy errors
  - Intellectual pharmacy errors
  - Statutory standards - OBRA, etc.

Negligence - Duty

- Plaintiff must prove existence of duty
  - An act or omission required
  - Types of duties
  - Legal v. moral duties
  - To whom is the duty owed?

Negligence - Required Elements of Negligence

- Duty
- Violation
- Causation
- Harm

* Black’s Law Dictionary
Negligence - Causation

- Causation
  - Plaintiff must prove that violation of duty was the proximate cause of harm
  - Types of Causation
    - But for cause = Not legal causation
    - Proximate (Direct) Cause = Legal Causation
e.g. my poor driving
  - Proximate (Direct) Cause = Legal Causation
e.g. intoxicated cement truck operator

Negligence - Harm

- Harm
  - Plaintiff must prove that Harm was a foreseeable result of Defendant’s action
  - Plaintiff need not prove that the extent of harm was foreseeable
e.g. Thin-Skulled Plaintiff Rule
  - Type of Thin-Skulled pharmacy plaintiff
e.g. drug allergy, pharmacy shopper, elderly

Negligence - Self-Assessment

Which of the following is true regarding a lawsuit alleging pharmacist negligence?

1.) All pharmacy errors require expert testimony from pharmacists to prove a plaintiff's claim.

2.) The harm suffered need not be foreseeable to impute liability.

3.) All pharmacy errors constitute legal negligence.

4.) The harm suffered must be the direct result of the violation of the duty owed.

Negligence - Duty

- What Duty is owed by a pharmacist to a patient?
  - Fulfilling every patient’s/clinician’s expectations?
  - Duty to fill Rx correctly pursuant to practitioner’s valid prescription or order
  - Duty to satisfy minimum standards of conduct required by regulations (OBRA)
  - Do pharmacists have a duty to warn of all possible harmful effects of drugs they dispense?
  - Should one be imposed?

Duty to Warn - Where does it come from?

The Duty to Warn is a creation of which of the following?

1.) Required by State law since 1993 as a result of the enactment of OBRA ’90

2.) Board of Pharmacy Best Practices

3.) Food and Drug Act

4.) Case law or judge-made law

Duty to Warn - Where does it come from?

- Statutory Law
  - No Federal laws or regulations impose it
  - No State laws or regulations impose it

- Licensing Boards
  - No Board of Registration policy imposes it

- Case Law
  - The Duty to Warn is a creation of case law
Duty to Warn (continued)

Case Law
- Traditional View
  - see Andreota v. Gaeta, 260 Mass. 105 (1927)
  - No duty other than filling Rx properly
  - No duty to warn
- Recent View
  - Learned Intermediary Doctrine (LID) - MD Issue
  - LID - Marriage of patient-specific and drug-specific needs
  - Evolution of Duty to Warn

Ferguson v. Williams, 339 S.E. 389 (1991)
- Pre-OBRA 90
- Patient treated for gout with colchicine and indomethacin
- Patient inquiry re drug allergy
- Thin-skulled plaintiff
- No Duty to Warn
- Pharmacist voluntarily assumes Duty to Warn, must act reasonably to avoid liability based on negligence

Hypothetical
- Patient presents prescriptions for two potent CNS depressants simultaneously
- One has an unusual sig- RPh consults Facts and Comparisons and is not satisfied
- RPh contacts prescriber to verify RXs and dosing
- Physician- "both RXs are OK because patient needs to be sedated throughout the day"
- Patient dies of drug overdose- Pharmacist Liability???

Horner v. Spalitto, 1 S.W. 3d 519 (Mo. Ct. of App. 1999)
- #50 Diazepam 10mg, 1po q8h
- #50 Ethchlorvynol 750mg , 1po q8h
- Literature and prescriber consulted
- RXs filled after consultation
- Prior Case law in MO- no liability for pharmacist who fills RX correctly- no other duty owed

Horner v. Spalitto, 1 S.W. 3d 519 (Mo. Ct. of App. 1999)
- At trial, defendant files motion for summary judgment (no facts in dispute, entitled to judgment as matter of law)
- Trial court allows motion, dismisses lawsuit
- Plaintiff appeals, appellate court cites OBRA 90 and new responsibilities of RPhs
- Reversed and remanded to lower court
- RPhs happy with this result???
Duty to Warn (continued)

Hooper v. Thrifty-Payless, Slip Op No C037465 (12/17/02)
• Patient treated for depression with sertraline
• Prescriber issues prescription for trazodone
• Patient refuses Offer of Counsel, gets Rite-Aid handout
• Patient suffers notorious effect
• Alleges negligence, citing Board of Pharmacy Regs
• Holding: Once offer refused, no further

Duty to Warn (continued)

Hypothetical
• Can a pharmacist follow the law and be found negligent?
• Patient has surgical procedure, given narcotic Rx for pain control
• RX not filled at time of issuance
• Patient suffers painful injury 4 months later
• Pharmacist fills RX 4 months after date of issuance
• Patient death due to overdose
• Pharmacist Liability?

Duty to Warn (continued)

• Patient has C-section, receives fentanyl prescription
• Patient suffers broken ankle 4 months later
• Pharmacist fills RX 4 months after date of issuance
• Patient death due to fentanyl overdose
• Negligence action filed against pharmacist dismissed
• Dismissal reversed- If filling is unreasonable on its face, even though lawful, negligence (fact issue) action may be maintained

Duty to Warn (continued)

• Does counseling = Duty to warn of all potential adverse side effects?
• Patient claims Board of Pharmacy regulations impose such a Duty
• Court applies Learned Intermediary Doctrine
• Court- Board regulations impose duty to warn only of common side effects

Duty to Warn (continued)

Hypothetical
• Patient receives numerous controlled substance prescriptions from same MD and pharmacy over an extended period of time
• Pharmacist occasionally verifies legitimacy of Rx, Diagnosis and Prognosis at the initiation of therapy
• Later Rxs are filled for patient without much intervention
• Patient becomes addicted to medication
• Pharmacist liability?
Duty to Warn (continued)

Plante v. Lambiano, 2005 WL 1090198 Conn. Superior 3/31/05

- Patient (addict) sues pharmacist for injury from prescriptions filled
- Patient alleges that pharmacist has liability under extended learned intermediary theory
- Court: No duty to warn of dangers, including addiction, to prescriptions filled

Negligence Self-Assessment

Regarding recent case law decisions, which of the following is true?

1.) Any time a patient suffers harm from using a properly prescribed drug the cause of harm is negligence on the part of a pharmacist.
2.) All patients must be counseled per OBRA ’90 prior to receiving a prescription.
3.) A pharmacist must warn of all possible side effects.
4.) Absent a pharmacist voluntarily assuming a Duty to Warn a court of law will usually not impose one.

Duty to Warn - Advice

What does this all mean?
- Dynamic area of Law
- Duty to Warn is fact specific
- Reasonable attempts to obtain patient specific info must be performed during intake and recorded
- Adequate malpractice coverage - extremely important
- Higher prescription volume = less time spent on/with each prescription/order/patient
- Greater exposure for pharmacists
- Is current standard of care too high or low?