HAVE YOU RECENTLY MOVED? PLEASE NOTIFY US.

In this lesson, we review recent court cases that have impacted upon pharmacy practice. The goal is to describe the increased duty to warn that pharmacists face. This lesson provides 3.00 hours (0.3 CEUs) of credit, and is intended for pharmacists in all practice settings.

The program ID # for this lesson is 707-000-03-001-H03. Pharmacists completing this lesson by January 31, 2006 may receive full credit.

To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

Upcoming topics for continuous participants: See Page 10.

If you have any comments, suggestions or questions, contact us at the above address, or call toll free 1-800-323-4305. (In Alaska and Hawaii phone 1-847-945-8050). Please write your ID Number (the number that is on the top of the mailing label) in the indicated space on the quiz page (for continuous participants only).

The objectives of this lesson are such that upon completion the participant will be able to:

1. List the legal duties of pharmacists beyond those of accurate order processing.
2. Describe the influence of the OBRA 90 standards on the legal responsibilities of pharmacists.
3. Discuss recent cases in which pharmacists have been held to a high standard of care.
4. Describe the “superior knowledge” requirement applied to pharmacist legal duties.
5. Discuss the responsibilities of pharmacists that result from voluntary assumption of a duty.
6. List the actions pharmacists are required to take when they detect an obvious inaccuracy on the face of a prescription.
7. Describe the appropriate use of drug information leaflets in the education of patients by pharmacists.

All opinions expressed by the author/authors are strictly their own and are not necessarily approved or endorsed by W-F Professional Associates, Inc.

Consult full prescribing information on any drugs or devices discussed.
INTRODUCTION

Pharmacists traditionally have occupied the important role of accurate order processors, assuring that patients receive the correct drug, in the correct strength, with the correct directions. The vast majority of pharmacist malpractice cases are based on the failure by a pharmacist to meet the responsibilities imposed under this “accuracy mandate.” It is an important role, and pharmacists will not be relieved of it, even as the profession matures beyond a focus on dispensing. Pharmacists are certain to continue their legal responsibility to assure order processing accuracy, although pharmacy system design improvements and the use of technology will facilitate the expansion of the profession into new areas of clinical care.

In addition to the accuracy mandate, pharmacists must meet a “safety mandate.” Pharmacists are responsible for assuring that errors in prescribing are detected and rectified prior to a medication being dispensed to a patient. The complexity of modern therapeutics makes it impossible for one person to assure the prevention of errors, so the health care community has recognized a system of overlapping responsibilities to protect patients from harm. Pharmacists have a duty to recognize a prescription that has been issued in error and to consult with the prescriber to correct the error.

As if this were not enough, pharmacists also have an “efficiency mandate” that they must meet. The high costs of drug therapy, and the ready availability of equivalent, but less expensive, generic products, have led to a demand for pharmacist switching of patients from a costly prescribed product to a less costly equivalent product. Pharmacists have an important role in deciding when and for whom to make such a substitution. Although state and federal laws provide useful rules and guidelines, ultimately it is the responsibility of the pharmacist to assure that patients are protected during the switching of products.

Finally, contemporary pharmacists are faced with a “quality mandate.” The focus of the health care community on outcomes of care has led to an expectation that pharmacists will provide consultation when their expertise may improve the quality of a patient’s care. This expertise is recognized as valuable, not simply to prevent bad outcomes, but to produce good outcomes as well.

In this lesson, recent court cases are reviewed to examine how pharmacists are legally required to participate in important decisions about drug therapy. The responsibilities of pharmacists to their patients are expanding, and the courts describe in these cases how those responsibilities have been recognized over the past several years.
Case One: Riff v. Morgan Pharmacy

Any discussion of expanded pharmacist responsibilities must begin with the case of *Riff v. Morgan Pharmacy*. Decided in 1986, the lessons of the Riff case have reverberated through litigation over the past 16 years. The Riff case was the first to hold that a pharmacist has responsibilities that extend beyond order processing accuracy.

**Background**

One morning the plaintiff in this case awoke with a headache. She went to her mother’s home, and the family physician was summoned. While visiting the patient on a house call, the physician prescribed 12 Cafergot suppositories, with instructions to insert one every four hours for headache. The defendant pharmacy filled the prescription exactly as it was issued, but did not provide any warnings regarding the potential hazards of exceeding 2 suppositories per headache and 4 suppositories per week. This limitation on use was clearly stated in the package insert and was well known in the pharmacy community.

The patient, not knowing the limitation on use of Cafergot, used either 5 or 6 suppositories to treat her headache, always inserting one every 4 hours as she had been instructed. She suffered ergotamine toxicity as a result. She was initially advised by her doctors that she was likely to die. Fortunately, she survived, but she suffered permanent damage to her feet due to diminished blood circulation, and nerve damage following the Cafergot overdose.

**Result**

In defending the lawsuit brought against it by the patient, the pharmacy claimed that its duty was simply that of order processor, and that the physician was the only person who could have prevented this error from occurring. This was an argument that had been effective in defending pharmacists up until that time, and rejection of it would require the recognition of a new legal precedent.

In establishing new precedent, the court had this to say:

"In the instant case the pharmacy had a legal duty to exercise due care and diligence in the performance of its professional duties. Sufficient credible evidence was presented to establish that Morgan Pharmacy breached that duty by failing to warn the patient or notify the prescribing physician of the obvious inadequacies appearing on the face of the prescription which created a substantial risk of serious harm to the plaintiff."

To emphasize the source of this newly recognized responsibility of pharmacists, the court said:

"If the consensus of the medical community is that a safety net of overlapping responsibilities is necessary to serve the best interests of patients, it is not for the judiciary to dismantle the safety net and leave patients at the peril of one man’s human frailty."

Although this is expansive language, the duty it recognizes is a limited one. Under the ruling of the Riff case, pharmacists are not responsible for all aspects of a patient’s drug therapy. They are simply required to speak up and find a solution to an error that is blatantly obvious on the face of a prescription. The ruling in this case is recognized as a first exception to the general rule of “no duty to
warn" for pharmacists. As we will soon see, the exceptions to that rule have become so numerous that they are on the verge of becoming the rule.

Case Two: Horner v. Spalitto

The Riff case preceded the adoption of OBRA 90 standards by the United States Congress and the eventual implementation of those standards by virtually every state. The promise of the Riff case to expand pharmacists' responsibilities was stimulated by the passage in 1990 of provisions in the Omnibus Budget Reconciliation Act that mandated an offer of patient counseling, maintenance of patient medication records, and the review of each prescription to detect and rectify potential problems with drug therapy. It seemed likely following OBRA 90 that the legal expectations of pharmacists would expand at a rapid rate, but it was not until the Horner case from Missouri in 1999 that firm recognition of that expansion occurred.

Background

Mr. Horner brought two prescriptions to his pharmacy in September of 1994. One of them was for a quantity of fifty Placidyl in the 750 mg. strength. The physician had instructed on the prescription to take one every eight hours. The other prescription was for 10 mg. diazepam, number 50, with instructions to take one dose every eight hours. Before filling these prescriptions, the pharmacist noted in a reference book that the normal dose of Placidyl is one capsule at bedtime. He contacted the physician's office to express concern, and was told that the prescription was “okay” because the patient “needed to be sedated throughout the day.”

Six days later, the patient was found dead. The cause of death was listed as “adverse effects of multiple medications (drugs), especially Placidyl (ethchlorvynol), which was near the toxic range.” In their subsequent lawsuit against the pharmacist, the patient's survivors claimed that the pharmacist should be held liable for failing to counsel the patient regarding the potential side effects or adverse reactions of the drugs when prescribed in this way. The pharmacist filed a motion to dismiss the case, contending that a pharmacist never has any duty beyond accuracy in order processing, relying on a ruling by the Missouri courts, known as the Kampe case, that had earlier held a pharmacist not liable despite his failure to warn.

Result

The Court of Appeals of Missouri had this to say:
“Kampe wrongly held that, as a matter of law, a pharmacist’s duty will never extend beyond accurately filling a prescription. This may be a pharmacist’s only duty in particular cases, but in other cases, 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.”

The court then added:
“To hold as Kampe did would denigrate the expertise which a pharmacist's education provides concerning drugs and their therapeutic use. The Kampe holding also failed to comprehend the role a pharmacist must play in making the valuable, but highly dangerous, service of drug therapy as safe and reliable as it can be.”
Relying on the standard established by the OBRA 90 legislations, the court concluded with the observation that:

"Pharmacists have the training and skills to recognize when a prescription dose is outside a normal range. They are in the best position to contact the prescribing physician, to alert the physician about the dose and any contraindications relating to other prescriptions the customer may be taking as identified by the pharmacy records, and to verify that the physician intended such a dose for a particular patient. We do not perceive that this type of risk management unduly interferes with the physician-patient relationship. Instead, it should increase the overall quality of health care."

Case Three: Cottam v. CVS

The Supreme Court of Connecticut took yet another step toward recognition of an expanded pharmacist duty to patients, in the case of Cottam v. CVS, decided in March of 2002. In this case, the expansion of law was based not on an error in the prescription or on the OBRA 90 standards, but on a finding that the defendant pharmacy had voluntarily undertaken to provide expanded services to the patient. Under the law, a duty voluntarily assumed must be performed with due care.

Background

In May of 1994, the defendant pharmacy implemented a computer system designed to provide its patients with written information about the risks and side effects of prescription drugs. The computer produced this information in one of two ways: a short, condensed form or a longer and more inclusive form. Although the pharmacy’s computers automatically generated the short form unless the computer operator hit a key to print the long form, corporate policy required the pharmacists to distribute the long form when dispensing new prescriptions. Corporate policy also required pharmacists to review the information on both the long and short forms with the patient.

The patient in this case was prescribed trazodone to treat depression. When his prescription was filled at the defendant pharmacy, he testified that he received only the short form. The pharmacist insisted that she had provided the patient with the long form, although the pharmacist admitted that she had not verbally counseled the patient. The patient suffered adverse effects of priapism, the risk of which was noted in the long form but not in the short form. In his lawsuit, he alleged that the pharmacy was liable for failing to warn him of the risk of priapism by providing the long form as its own rules required.

Result

The court reviewed prior case law, noting that pharmacists have no general duty to provide all warnings of all side effects to all patients. This responsibility would be unduly burdensome and counterproductive. However, under the facts of this case, the court held that a duty to warn existed. The court said:
A pharmacy, like any other person or entity, may voluntarily assume a duty that would not otherwise be imposed on it, and thus may voluntarily assume a duty to provide information, advice or warnings to its customers."

Turning to the allegations of the patient in this case, the court said:

"Where, as here, the patient could reasonably interpret the warning form as a complete and comprehensive list of all known side effects, it is appropriate to impose on the pharmacy a duty commensurate with what it appeared to have undertaken."

A judgment in the amount of $357,000 against the pharmacy was upheld. This is a narrow holding, but a wide opening into the duty of a pharmacist. Although pharmacists are potentially liable only when they undertake to provide services, pharmacists increasingly are providing such services. To take a step backward from the provision of services is impracticable in the pharmacy profession. Thus, the profession seems to be defining its own role through the voluntary assumption of responsibilities that become legal duties. The best risk management tool under such circumstances is to assure that patients have realistic expectations of their pharmacy. Pharmacists should not over-promise and disappoint patients who expect more than is reasonable. They should over-deliver on realistic promises. And their realistic promises should be spelled out in writing to patients. To make sure a patient is not led to believe that a brief list of side effects is an all-inclusive list, pharmacies should note clearly on such lists that the information is incomplete and that expanded information is available upon request.

**Case Four: Happel v. Wal-Mart**

A second case decided in March of 2002, this one by the Supreme Court of Illinois, provided still another reason to expand pharmacist legal responsibilities. In this case, the court reasoned that a pharmacist who has "special knowledge" of a risk to the patient, has a duty to prevent the occurrence of that risk.

**Background**

The patient in this case called her physician on August 4, 1993, complaining of severe menstrual cramps. She sought a more effective pain reliever, and her physician prescribed ketorolac. His office telephoned the prescription to the defendant pharmacy. This physician had been treating the patient since December 1992, and he knew that the patient was allergic to aspirin. He stated later that at the time he prescribed ketorolac, he did not know it was contraindicated for patients with allergies to aspirin. If he had known this, he would not have prescribed it for this patient.

Prior to this time, the patient had been to the defendant pharmacy about six times to have other prescriptions filled. Each time she went, the pharmacy personnel asked her if she had any drug allergies, and each time she told them she was allergic to aspirin, acetaminophen, and ibuprofen. This information was in the pharmacy’s computer system, and was available to the pharmacist when the patient’s prescription was filled. According to policy at the pharmacy, a drug interaction warning would have flashed across the computer screen when this prescription was filled. At that time, the pharmacist would call the physician with notification of the contraindication. However, the pharmacist who filled the prescription could not produce any documentation indicating that she had made such a call.
The patient's husband went to the pharmacy to pick up the prescription, before it had been filled, and a pharmacy staff member asked him about the patient's allergies. He explained that the patient was allergic to aspirin, ibuprofen, and acetaminophen.

The patient received no information about the contraindication. She took the first dose of ketorolac at about 4 pm on August 4, and within 40 minutes she began to experience respiratory problems including tightness in her chest. She began a breathing treatment with a nebulizer, and called the pharmacy to ask if she could be having a reaction to ketorolac. Her call was disconnected. She called again, and was told that there should be no drug reaction problem. The patient then called a friend who was a pharmacist and was aware of her allergies. He told her to begin a nebulizer, if she had not already done so, and to go to the emergency department if her condition worsened. She went to the emergency department, and was found to be experiencing an acute hypersensitivity reaction to ketorolac. As a result of taking ketorolac, the patient experienced more frequent asthma attacks, as well as seizures and a worsening of her multiple sclerosis.

The patient filed a lawsuit against both the physician and the pharmacy. The physician settled with her, but the pharmacy denied liability, arguing that it had no legal duty to warn the patient of the contraindication.

Result

The court focused on the special knowledge of the pharmacist in this case, and concluded that the defendant pharmacy owed a duty of care to this patient, including the duty to warn of the contraindication. The court said:

"It is undisputed that, at the time Heidi's prescription was filled on August 4, 1993, Wal-Mart was aware not only of Heidi's drug allergies, but also that the drug prescribed by Dr. Lorenc, Toradol, was contraindicated for persons such as Heidi who are allergic to aspirin. Given this superior knowledge on the part of Wal-Mart, and particularly given the nature of the knowledge, i.e., that Toradol was contraindicated, it was reasonably foreseeable that a failure to convey this knowledge might result in injury to Heidi. Both the likelihood and the reasonable foreseeability of injury here were great. These factors thus favor the imposition of a duty on Wal-Mart."

Responding to the contention that a requirement for a warning would be burdensome, the court had this to say:

"The burden on defendant of imposing this duty is minimal. All that is required is that the pharmacist telephones the physician and informs him or her of the contraindication. Alternatively, the pharmacist could provide the same information to the patient. Since this burden of warning about a contraindication is extremely small, this factor also favors the imposition of a duty here."

The court then summarized the pharmacy's responsibility in this way:

"We think that, given the circumstances in this case, Wal-Mart had a duty to warn and that this duty is encompassed within the pharmacist's duty of ordinary care. As noted, Wal-Mart was aware not only of Heidi's drug allergies, but also that Toradol was contraindicated for persons with such allergies. A contraindication is a serious limitation on a drug's use, necessarily implying grave consequences if it is
ignored. As one court has noted, a contraindication refers to ‘a circumstance under which the drug
must never be given.’ Taking into account the potentially severe consequences of a failure to warn in
this case, we conclude that imposing on Wal-Mart a duty to warn is clearly proportionate to the danger
involved.” Based on this rationale, the court ruled against the pharmacy on its motion to dismiss the case, and the
case was sent back to the trial court for further proceedings against the pharmacy.

CONCLUSION

The rule of “no duty to warn” continues to be the general rule for pharmacists, but the exceptions
to the general rule are many. In fact, the exceptions have become so numerous and so significant that
they threaten to engulf the general rule. First, there is the exception that pharmacists must warn patients
when there is an obvious error on the face of the prescription. This is the exception noted by the Riff
case. Second, there is the exception that pharmacists must warn patients when regulatory standards,
such as those implemented under the authority of OBRA 90, recognize an expanded responsibility for
pharmacists. This is the exception noted by the Horner case. Third, there is the exception that
pharmacists must warn patients when they have voluntarily undertaken to provide some sort of brief
warning, but allegedly have not provided as complete a warning as the patient was led to believe was
being provided. This is the exception noted by the Cottam case. Fourth, there is the exception that
pharmacists must warn patients when they have “special knowledge” of potential harm to the patient,
such as the cross-allergenicity between two drugs. This is the exception noted by the Happel case.

These four exceptions provide sample opportunity for courts to recognize expanded duties of
pharmacists, despite the absence of clear standards establishing an expanded duty as a matter of
law. Pharmacists are understandably concerned about the legal expectations of them, but each of the
exceptions that recognize a duty of care corresponds with pharmacist knowledge or action consistent
with a duty of care. The judicial expectations of pharmacists are derived from expanding
professionalism in pharmacy. The law may be slow to adapt to changes in practice, but eventually
legal standards are modified to reflect changes in practice patterns.

UPCOMING TOPICS IN 2003

Osteoporosis
Cystic Fibrosis
Lipid Management
Ulcer Management
COPD
Fill in the information below, answer questions and return Quiz Only for certification of participation to:
CE PRN®, 400 Lake Cook Road, Suite 207, Deerfield, IL 60015.

NAME___________________________________________________________________________(1st line on label)
ADDRESS____________________________________________________________________CITY________________________STATE_________ZIP____________
CHECK IF NEW ADDRESS ☐ COMPANY WHERE EMPLOYED___________________________

LESSON EVALUATION
Please fill-out this section as a means of evaluating this lesson. The information will aid us in improving future efforts.
Please rate each of the following from 1 to 7. Circle your choices. (1 is the lowest rating; 7 is the highest).

<table>
<thead>
<tr>
<th>1. Relevance of topic to practice.</th>
<th>Poor</th>
<th>Average</th>
<th>Excellent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>2. Author’s ability to communicate.</td>
<td>Poor</td>
<td>Average</td>
<td>Excellent</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. Author’s knowledge of topic.</td>
<td>Poor</td>
<td>Average</td>
<td>Excellent</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. Appropriateness of topic.</td>
<td>Poor</td>
<td>Average</td>
<td>Excellent</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

5. Do you have any further comments about this lesson? _______________________________________________________________
_____________________________________________________________________________________________________________________

Please Select the Most Correct Answer

1. What is the “take home” message for pharmacists from the Cottam case?
A. Never talk to patients
B. Never provide information leaflets to patients
C. Always warn patients of every possible side effect
D. Follow policies adopted for quality patient care

2. Which legal mandate reflects the emerging requirement that pharmacists focus on improving outcomes for patients?
A. Accuracy
B. Safety
C. Efficiency
D. Quality

3. According to the Riff case, what is the basis of a pharmacist’s duty to warn?
A. An obvious error on the face of the prescription
B. The OBRA 90 standards
C. The voluntary assumption of a duty
D. Special knowledge

4. According to the Horner case, what is the basis of a pharmacist’s duty to warn?
A. An obvious error on the face of the prescription
B. The OBRA 90 standards
C. The voluntary assumption of a duty
D. Special knowledge

5. Regarding available knowledge on Cafergot dosing & toxicity, where did the court turn in the Riff case?
A. The curricula of colleges and schools of pharmacy
B. Internet resources
C. The USP
D. The package insert

6. What pharmacist responsibility was described in the Horner case?
A. Making drug therapy as safe as it can be
B. Guaranteeing therapeutic efficacy
C. Guaranteeing zero error
D. Guaranteeing avoidance of side effects

7. Which legal mandate reflects the traditional pharmacist role of order processor?
A. Accuracy
B. Safety
C. Efficiency
D. Quality

8. If a pharmacist knows that a patient is allergic to penicillin, and if penicillin has been prescribed for the patient, on what basis would the court in the Happel case find a duty to warn the patient?
A. Special knowledge of the pharmacist
B. The package insert
C. Curricula in schools and colleges of pharmacy
D. Medical testimony

9. What can fairly be said about the “exceptions” to the pharmacist no duty to warn general rule?
A. There are no exceptions
B. The exceptions are minor
C. The exceptions are trivial
D. The exceptions are large enough to engulf the general rule

10. How should a pharmacy assure that patients know a brief list of side effects is not all inclusive?
A. Always use the long form
B. Always use the package insert
C. Always counsel verbally
D. Note clearly that the list is incomplete & that expanded info is available on request
Contributing Author
David D. Brushwood, RPh, JD
Professor, Healthcare Administration
University of Florida College of Pharmacy
Gainesville, FL

Executive Editor
William J. Feinberg, BS Pharm, MBA

CE PRN® is a publication of W-F Professional Associates, Inc.
This program is in printed format.

W-F Professional Associates, Inc. is approved by the American Council on Pharmaceutical Education (ACPE) as a provider of continuing pharmaceutical education.

Providers who are approved by ACPE are recognized by the following states: Alaska, Arizona, Arkansas, California, Connecticut, Delaware, District of Columbia, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin and Wyoming.

Pharmacists completing this course by January 31, 2006 may receive full credit. This program has been approved by the State Boards of Pharmacy in Alabama and Oklahoma.

This lesson furnishes 3.00 hours (0.3 CEUs) of credit.

Program ID #707-000-03-001-H03.