

The Pharmacist's Duty to Counsel

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Home Study Monograph



THE PHARMACIST'S DUTY TO COUNSEL

Activity Overview

This monograph considers the importance of the patient education role in the pharmacy profession, and the legal responsibility of the pharmacist for the failure to counsel patients. The monograph distinguishes between the non-recognition of a general duty to counsel on all possible adverse effects, and recognition of a specific legal duty to counsel when a pharmacist has special knowledge of a particular adverse effect. Legal case studies are used as pertinent examples.

TARGET AUDIENCE

The target audience for this activity is **pharmacists** and **pharmacy technicians** in hospital, community, and retail pharmacy settings.

LEARNING OBJECTIVES

After completing this activity, the **pharmacist** will be able to:

- List elements of the pharmacist's duty to warn
- Discuss the evolution of pharmacist patient education responsibilities.
- Describe the importance of documentation in a duty to warn case

After completing this activity, the **pharmacy technician** will be able to:

- Discuss characteristics of a prescription for which patient education is necessary.
- Describe the importance of patient education in pharmacy practice.
- List the factors that may create a duty to counsel patients.

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The Pharmacist's Duty to Counsel

Klasch v. Walgreen Co.....	5
The Empty Offer.....	12
The Voluntary Undertaking Rule.....	15
Adequate Directions for Use.....	15
Patient or Prescriber?.....	18
DiGiovanni v. Albertson's	20
Keffer v. Lorenz.....	23

The Professional Role

Over the past several decades, the public perception of the pharmacist has changed from that of product seller to service provider. The primary service pharmacists provide is patient education.

Patient education is a responsibility that is reserved for pharmacists and cannot be delegated to pharmacy technicians. It is a valued professional service that places a pharmacist and a patient in physical proximity with each other, with the opportunity for personal interaction. It promotes informed medication use by patients who can modify their behaviors to improve therapeutic outcomes.

From a pharmacy perspective, the patient education role is important because it demonstrates to the public the skills and knowledge possessed by pharmacists. Patient education identifies pharmacists as experts in medication use. It shows patients that they can rely on pharmacists for accurate and useful information to enhance their experience with drug therapy.

In many professions, such as accounting, financial advisement, medicine, and law, most clients identify a particular person as the individual on whom they rely for professional service. This happens less often in pharmacy, where patients are more inclined to identify a pharmacy business as the source of their professional services, rather than an individual pharmacist. Some patients report that they are unable to distinguish pharmacists from the other people who are busily working behind the counter at their pharmacy. The identification issue presents a challenge for pharmacists to promote recognition by patients that pharmaceutical products and services are provided by a pharmacist and not by a pharmacy.

Patient education is an opportunity to establish with patients a professional relationship that identifies their pharmacist as an essential health care professional. Immunizations, medication therapy management, and collaborative practice under

protocol are derivative of the patient education role. Under some circumstances, the role of patient education by pharmacists is legally recognized as a duty.

Is It Really “Counseling”?

The educational activities conducted by pharmacists are often referred to as “patient counseling.”

Patients are sometimes asked by technicians whether they need “counseling” by the pharmacist. The physical layout of pharmacies often includes an area designated as the “counseling” area. Although the meaning of this word within a pharmacy context is clear to pharmacists, it may be less clear to patients. “Counseling” often connotes assistance in dealing with emotional concerns or with other personal difficulties. Some patients may not understand what is being offered to them when pharmacist “counseling” is made available, or they may feel uncomfortable admitting that they need “counseling.” There may be an expectation that the pharmacist can provide support of a kind that exceeds the scope of pharmacy practice. The words “consultation” or “education,” or the phrase “medication review” may better describe the services of pharmacists.

Exemplary Case: Klasch v. Walgreen Co.

The pharmacist’s duty to counsel is recognized under the law when there are special circumstances under which a pharmacist has knowledge of a specific risk to a specific patient. The law generally provides that there is no legal duty for a pharmacist to warn patients of potential problems that could arise for any patient who uses a prescribed medication. There must be something special about the patient, or the patient’s prescription, that raises concerns for a pharmacist, and that leads to a duty to warn the patient about the special something. In the alternative, a warning to the prescriber is usually considered sufficient.

Most pharmacy “duty to warn” cases consider the issue of the “learned intermediary doctrine.” Under this doctrine, pharmaceutical manufacturers have no duty to warn patients of risks directly, because prescribers know patients individually and are better positioned to provide medication-related warnings. The doctrine sometimes works to relieve pharmacists of liability, when a warning has not been provided to a patient, placing the responsibility for that omission on the prescriber’s shoulders alone.

All language in italics below is quoted directly from the court’s opinion. Names are not redacted as they are a matter of public record in a legal case.

Factual Summary By The Court

In December 2005, Helen Klasch visited Dr. Fredrick Tanenggee, M.D., for the first time. While filling out paperwork concerning her medical history, Klasch indicated that she might have a sulfa allergy. People with sulfa allergies generally experience minor skin rashes when exposed to sulfa, but in a small number of cases, the sulfa exposure may cause a toxic reaction in the person's skin, potentially leading to death. Although still largely unpredictable, people who have experienced a past allergic reaction to sulfa are at a heightened risk for suffering this toxic reaction in the event of future sulfa exposure. After some further discussion with Dr. Tanenggee's assistant, this possible sulfa allergy was recorded on Klasch's medical chart with a question mark ("Sulfa?").

In July 2006, Klasch returned to Dr. Tanenggee's office, complaining of "abdominal fullness." After performing routine tests, Dr. Tanenggee diagnosed her with a urinary tract infection. Dr. Tanenggee told Klasch that under normal circumstances, her infection could be treated most effectively with Bactrim, a sulfa-based antibiotic. Given the notation in her chart, however, Dr. Tanenggee asked Klasch to clarify how certain she was of her sulfa allergy. After some further discussion, Klasch downplayed the previous notation and asked Dr. Tanenggee to write her a prescription for Bactrim. Dr. Tanenggee complied, and Klasch

dropped off the prescription at Walgreens Pharmacy on her way home from Dr. Tanenggee's office.

Later that same day, Klasch's caretaker returned to Walgreens to pick up the prescription. Upon asking a pharmacy employee to release the prescription, the employee told the caretaker that Klasch's prescription had been "flagged" by Walgreens' computer system while it was being filled. Walgreens maintains a "patient profile" for each of its customers, which its pharmacists use to identify any potential allergic reactions, harmful interactions with other medications, or adverse side effects that a customer may have to a particular medication. The employee told Klasch's caretaker that the prescription had been flagged because Klasch's patient profile indicated that she was allergic to sulfa-based drugs. The caretaker then asked the employee to call Klasch and to speak with her directly. A Walgreens employee called Klasch and conveyed that her prescription had been flagged because of her sulfa allergy. In response, Klasch reportedly indicated that she had taken Bactrim in the past and that she had not experienced any adverse reaction to it. Satisfied with this clarification, a pharmacist then manually overrode the computer system's flag, and the prescription was released to Klasch's caretaker.

Later that day, after taking the medication, Klasch complained that she felt "itchy." The following day, Klasch called Dr. Tanenggee's office and left a voice mail in which she stated that she was wrong about not having a sulfa allergy. Klasch's condition continued to worsen, and she was taken to the emergency room. After being diagnosed with SJS/TEN, Klasch was transferred to a burn center, where she eventually lapsed into a coma and passed away. At the time Klasch was removed from life support, she had burns covering 40 to 50 percent of her body.

The Allegations

Klasch's two children (the Klasches) brought a wrongful-death action against Walgreens, alleging that its pharmacist breached the duty of care owed to their mother. Specifically, the Klasches contended that Walgreen's pharmacist breached her duty of care by failing to adequately warn Klasch of the prescribed medication's risks in light of her allergy to it or, alternatively, by failing to call Dr. Tanenggee to clarify whether he really meant to prescribe a medication to which she was allergic.

Although this court has not previously considered the learned-intermediary doctrine, the issues raised in this appeal compel us to consider its applicability and scope. In so doing, we first adopt the learned-intermediary doctrine in the context of pharmacist/customer tort litigation and hold that pharmacists have no duty to warn of a prescribed medication's generalized risks.

We next consider whether the learned-intermediary doctrine likewise insulates a pharmacist from liability when he or she has knowledge of a customer-specific risk. Following the modern trend of case law, we conclude that the learned-intermediary doctrine does not foreclose a pharmacist's potential for liability when the pharmacist has knowledge of a customer-specific risk. Instead, under these circumstances, a pharmacist has a duty to exercise reasonable care in warning the customer or notifying the prescribing doctor of the risk.

Traditionally, the learned-intermediary doctrine has been used to insulate drug manufacturers from liability in products-liability lawsuits. Under the learned-intermediary doctrine, a drug manufacturer is immune from liability to a patient taking the manufacturer's drug so long as the manufacturer has provided the patient's doctor with all relevant safety information for that drug. It is then up to the patient's doctor--who has the benefit of knowing the patient's specific situation--to convey to the patient any information that the doctor deems relevant.

Jurisdictions adopting the learned-intermediary doctrine in the context of pharmacist/customer tort litigation have put forth a similar rationale: that between the doctor and the pharmacist, the doctor is in the best position to warn the customer of a given medication's generalized risks. Or, viewed more pragmatically, the doctrine prevents pharmacists from constantly second-guessing a prescribing doctor's judgment simply in order to avoid his or her own liability to the customer. 11 In this sense, the learned-intermediary doctrine preserves the pharmacist's role as a conduit for dispensing much-needed prescription medications.

Because we believe that these public-policy considerations are sound, we adopt the learned-intermediary doctrine in the context of pharmacist/customer tort litigation. Accordingly, Nevada pharmacists have no duty to warn their customers of the generalized risks inherent in the prescriptions they fill.

The Result

Having adopted the learned-intermediary doctrine, we next define its scope.

Consistent with what we perceive to be the modern trend of caselaw, we hold that the learned-intermediary doctrine does not insulate a pharmacist from liability when her or she has knowledge of a customer-specific risk. Instead, when a pharmacist has such knowledge, the pharmacist has a duty to warn the customer or to notify the prescribing doctor of the customer-specific risk.

By insulating pharmacists from liability for failing to warn their customers of a medication's generalized risks, the learned-intermediary doctrine prevents pharmacists from interfering with the doctor-patient relationship. Because the public-policy considerations behind this doctrine are sound, we adopt it in the context of pharmacist/customer tort litigation. These public-policy considerations are less persuasive, however, when a pharmacist has knowledge of a customer-specific risk with respect to a

prescribed medication. Accordingly, in such circumstances, the learned-intermediary doctrine does not insulate a pharmacist from liability, and the pharmacist instead has a duty to exercise reasonable care in warning the customer or notifying the prescribing doctor of this risk

Take-Home Message

This interesting (and somewhat surprising) case raises the issue of the sufficiency of a warning. The patient in this case was aware of the risks, yet she apparently accepted the risk that she under-appreciated.

The pharmacy's "no duty to warn under any circumstances" argument was unpersuasive to the court. Perhaps a "no duty to warn under these circumstances" argument would have been more favorably received. As the court's language suggests, circumstances matter. Under most circumstances, when a pharmacist lacks specific information indicating that a patient is at risk of harm, the pharmacist has no duty to warn of an unknown risk. It makes sense. You can't warn somebody about something that is unknown to you. On the other hand, when a risk is known, or should be known, the pharmacist has a duty to warn the patient. Does this approach mean that every pharmacist has a duty to warn every patient of every risk that may occur with every drug? No. Absolutely not. In fact, it is just the opposite. The duty to warn applies to specific risks of specific drugs prescribed for specific patients. And this case goes one step further to suggest that when a patient obviously does not appreciate the significance of a known risk, efforts must be made to explain that risk more thoroughly to the patient.

The OBRA-90 Standard

The Omnibus Budget Reconciliation Act of 1990 (OBRA-90) established a requirement that states participating in the federally funded Medicaid program expand their standards of practice for pharmacists. Most states implemented this standard rather than lose federal Medicaid funding, although there are minor variations among the states in the specifics of the implementation. Prior to the enactment of OBRA-90, many states had statutes or regulations that mandated patient education by pharmacists, with wide variations in the content and process of that mandated activity. The OBRA-90 legislation standardized the pharmacist's patient education mandate across the states. Here is the language of the federal law:

"The pharmacist must offer to discuss with each individual receiving benefits under this title or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:

- The name and description of the medication.
- The route, dosage form, dosage, route of administration, and duration of drug therapy.
- Special directions and precautions for preparation, administration and use by the patient.
- Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.
- Techniques for self-monitoring drug therapy.
- Proper storage.
- Prescription refill information.

- Action to be taken in the event of a missed dose.”

Note that the OBRA-90 standard requires an offer to “discuss,” which suggests a two-way exchange of information rather than a one-way transfer of information. The standard defers to the pharmacist’s professional judgment in determining what matters are significant, based on the patient’s need for information rather than the characteristics of the drug itself. The listed types of information that can be discussed are not an exhaustive list of factors that may be considered significant by a pharmacist. They are representative of the type of conversation that may occur.

The Empty Offer

It is quite obvious from the express language of the OBRA-90 standard that there is no mandate for patient education by pharmacists. The mandate in the OBRA-90 standard is that an offer to discuss medications be made by the pharmacist to the patient or the patient’s agent. Patients or agents to whom an offer is made are free to decline the offer and “waive” their opportunity to discuss the medications they are using.

In some pharmacies, the unfortunate result has been a gaming of the system to make the offer of discussion so unappealing that it is almost always declined. Patients may be asked, “Do you have any questions for the pharmacist?” without being told any drug-related information that might give rise to questions. Some pharmacies have patients sign a registry documenting the waiver of a discussion with the pharmacist, although the patients often don’t know what they are declining. Pharmacy systems have generally not been redesigned to promote discussions between pharmacists and patients.

“Pharmacy systems have generally not been redesigned to promote discussions between pharmacists and patients.”

Learned Intermediaries

Pharmaceutical manufacturers are generally considered to be the best experts about the drugs they distribute. Manufacturers have an obligation to share information about their drugs with those who use them. This sharing of information is generally done through the drug package insert.

Patients who have been harmed by drug use will occasionally sue the manufacturer alleging the failure by the manufacturer to warn the patient of a risk that the patient would like to have known prior to deciding to use the drug. These lawsuits are almost always unsuccessful because the manufacturer's duty to the patient is to warn the "learned intermediary" and not the patient. Most courts consider the prescriber to be the key "learned intermediary," although some courts include the pharmacist within that category. When an adequate warning is given by a manufacturer to a "learned intermediary," the manufacturer's duty to the patient has been met.



The manufacturer's duty is to provide warnings to the learned intermediary.

Risk Assessment And Risk Management Information

Pharmacists may become concerned that the information they provide to patients will not be useful or may even be harmful. As a general rule, pharmacists can distinguish between two types of information that may be delivered through patient education. The two types are risk assessment (RA) information and risk management (RM) information.

RA information relates primarily to whether a drug should be used at all. This information discloses unmanageable risks that can be avoided only by not using the drug and instead choosing an alternative therapy. RA information is generally best



Risk Management information relates to how a drug can best be used.

disclosed to patients by the prescriber, who has the option of selecting from available alternatives should the patient object to the chosen therapy. An example of RA information would be an adverse effect that cannot be avoided if the drug is used.

RM information relates primarily to how a drug can best be used, given that the decision to use the drug is not being reconsidered. RM information discloses manageable risks that can be avoided by changing lifestyle while using a drug. This type of information is very appropriately disclosed by a pharmacist when dispensing medication to a patient. An example of RM information would be not to drive an automobile while using a drug, or not to spend long hours in direct sunlight. The risks disclosed through RA and RM information are equally as important, but they are of differing types.

Special Knowledge Of The Pharmacist

While some courts have recognized a legal duty for pharmacists to routinely engage in patient education activities, other courts have been reluctant to adopt what they consider a new responsibility for pharmacists. Yet even in the jurisdictions that adhere to a “no general duty to warn” approach, there is recognition that there can be circumstances in which a pharmacist has “special knowledge” creating an exception to the general rule.

*“Special knowledge
is often not so
special.”*

The pharmacist’s “special knowledge” can lead to a duty to warn a patient of drug risks. And special knowledge is often not so special; it is the kind of knowledge that pharmacists usually have in the ordinary course of providing pharmaceutical products and services. The exception has, in many situations, become the rule.

So-called “special knowledge” can be apparent on the prescription itself where the prescriber has ordered a dosage that would harm any patient who used it. It can be apparent from the patient’s computerized medication record that discloses a potential drug-drug-interaction. It can become known when a patient discloses a risk (“I am allergic to drug X, is it

okay for me to take this?”). Pharmacist responsibilities are situational, depending on what they know.

The Voluntary Undertaking Rule

There is a principle of law that requires a person to perform well the services the person provides, even though the person may not be required to provide the services at all. This is called the “voluntary undertaking” rule. For example, a business may not be under a legal obligation to provide security services for its clients, but having undertaken to provide security services, the business may be liable for harm caused to clients through the provision of negligent security services. The business cannot escape legal liability by saying, “Hey, we didn’t have to do that to begin with.”



Having undertaken to provide services, it must be done well.

Some courts have applied this rule to pharmacies that engage in patient education activities. Even though there may be a legal requirement to educate patients only to a limited extent, a pharmacy that undertakes to provide more extensive patient education is legally obligated to do so accurately. This rule can be daunting to pharmacies, and can cause a reluctance to voluntarily expand pharmacy services. The better solution is to provide high quality expanded services.

Adequate Directions For Use

Pharmacists have a responsibility to provide patients with adequate directions for using medications dispensed to them by pharmacists. Usually there are adequate directions within the sig provided by the prescriber, and the correct transcription of those directions on the label provided to the patient will suffice to meet the pharmacist’s responsibility. But that is not always the case.

When there is a complex set of directions, such as a corticosteroid taper or an anticoagulant that is taken in different alternating doses over a three-day rotation, courts have held that pharmacists have failed in their educational responsibility if the patient is not provided thorough directions for using the medication.

The sig “as directed” is particularly problematic for pharmacists, who must assure that patients understand what they have previously been directed to do.

Under some circumstances, patients may need to be told that taking one tablet twice daily does not mean at 8am and 10am, but instead means spaced evenly through the day.

Specific verbal directions (with accompanying printed diagrams) showing how to instill eyedrops, insert rectal suppositories, and effectively use an inhaler can make the difference between successful and unsuccessful drug therapy.



Complex directions should be explained to patients.

Taking several seconds to repeat directions to patients at the time medications are picked up from the pharmacy provides an opportunity to stress that medications need to be used as directed. And it is also a good time to self-check the accuracy of order processing.

Side Effects

Patients are interested in knowing the side effects that may occur from using prescribed medications. They also are interested in knowing the likelihood that side effects will occur and the magnitude of potential harm should side effects occur.

The OBRA-90 standard places confidence in the professional judgment of pharmacists to determine the significance of information provided to patients. One way in which this can be done is to provide the patient with written information that contains numerous substantiated side effects that may be experienced by any patient, and to also emphasize verbally those far fewer side effects that are particularly relevant to the specific patient. A significant side effect would be one that is relatively likely to occur and is harmful when it does occur. A side effect caused by exposure to UV radiation while the drug is used would be more significant for a young person in the summer, and less significant for an elderly long-term-care resident in the winter.

“The OBRA-90 standard places confidence in the professional judgment of pharmacists.”

Pharmacists can know the age and sex of patients, as well as the other therapies being used by patients. Often this is sufficient to determine drug side effects that are potentially significant to a specific person and that need to be warned of.

Drug-Drug Interactions

One of the greatest challenges for pharmacists is filtering through the many alerts provided by computer programs and determining which alerts are important. The alerts that provide warnings of drug-drug interactions are among the most frequent and difficult to manage. Particularly challenging are the drug-drug interactions where two different prescribers have ordered the two problematic drugs, and it is not clear that each knew what the other has prescribed.

Courts have often viewed potential drug-drug interactions as a patient education responsibility for pharmacists, because patients can be told of the need to clarify with each prescriber the appropriateness of using the two prescribed drugs together.

In litigation against pharmacists, the presence of a seemingly ignored computer alert is very problematic for the pharmacist. When there appears to have been no effort made to resolve a problem, pharmacists find themselves in a difficult defense posture.

Written information for patients often includes a list of drugs that a patient should disclose to prescribers if the drugs are being used by the patient.

When potential drug-drug interactions at the highest level of risk are discovered, pharmacists have a clear responsibility to educate the patient regarding the nature of the risk and the consequences of using the two medications together.

Limits On The Pharmacist's Educational Responsibility

The patient education responsibility that courts and regulatory agencies have recognized for pharmacists is not unlimited. Nobody expects pharmacists to educate patients to the extent that patients become as expert as health care professionals. And patients wouldn't want that.

One significant limit on pharmacist responsibility is the foreseeability of harm to the patient. Courts have consistently ruled that if a risk to the patient is not reasonably foreseeable, then there is no duty to educate the patient about the risk.



Nobody expects pharmacists to educate patients to the extent that patients become as expert as health care professionals.

A second significant limit is interference with the physician-patient relationship. Patients rely on their physicians to provide safe and effective medications, and it would be contrary to the collegial nature of the pharmacist's role in health care to provide a warning that would sabotage that relationship. Obviously, the patient's best interests are paramount, so under some circumstances a patient must be educated regarding major risks despite implications this may have for the patient's relationship with the prescriber.

The economic costs of patient education are a concern of courts considering whether to recognize a pharmacist duty to warn about drug risks. Courts are prepared to do a cost/benefit calculation. However, many of the economic costs of patient education by pharmacists have already been paid, and the recognition of an educational responsibility for pharmacists often does not increase those costs.

Patient Or Prescriber?

Pharmacists may have the option of solving a therapeutic problem either through patient education or through consultation with the prescriber. The advantage of patient education is that patients are accessible. Prescribers can be difficult, if not impossible, to locate. And when prescribers can be located, they may not be in a position to give their full attention to a pharmacist consultation.

Courts have generally recognized a responsibility for pharmacist consultation either with the prescriber or with the patient, but not with both. The exception to this alternative approach is situations when a prescription has been issued in a way that indicates a knowledge deficit on the part of the prescriber, or when there is a clear error in the prescription. Under these circumstances, the prescriber must be consulted.

"Courts have generally recognized a responsibility for pharmacist consultation with either the prescriber or with the patient, but not with both."

There may also be a situation in which a patient has adopted medication use behaviors (stockpiling of medication and unauthorized dose escalations, for example) that the pharmacist

identifies and that the patient refuses to modify despite educational efforts by the pharmacist. When this happens, consultation with the prescriber is necessary.

Drug Product Liability Duty To Warn

Some failure to warn cases brought against pharmacists have alleged the provision to the patient of a defective product; the defect being an inadequate warning. This is not a professional negligence case. It is a type of case that is usually brought against a manufacturer, but it may also be brought against a pharmacist. Almost always the pharmacist who did nothing more than dispense a manufacturer's prepared product will win these cases.

One example of such a case is the long line of litigation alleging the failure to warn that the pregnancy antiemetic Bendectin (now off the market) may cause birth defects. The absence of any scientific evidence did not dissuade the plaintiffs who filed these cases, but the courts were uniformly unsympathetic to their claims. The resolution of these cases in favor of pharmacists leaves a confusing history of sensible "no duty" judicial rulings that conflict with other rulings finding a duty for pharmacists under a negligence theory of liability.

When the pharmacist is a compounder or otherwise acts like a manufacturer, the product liability action may be successful, otherwise pharmacists will be dismissed from the product liability case.



Drug product liability is not negligence.

Court Case: DiGiovanni v. Albertson's

Are there circumstances in which a specific risk to a specific patient for a specific drug is known to a pharmacist, and yet the pharmacist fails to warn the patient and bears no responsibility when the risk materializes? Yes. Absolutely yes. The case reviewed here is one such case.

This is a drug-drug interaction case, which is one of the most frequent types of pharmacist failure to warn cases. In this case, the pharmacists did not warn the patient. But the pharmacist who dispensed the original supply of medication consulted with the prescriber regarding the potential drug-drug interaction, and received assurance from the prescriber that the prescriber would monitor the patient to determine whether the drug-drug interaction had materialized.

The pharmacist who dispensed the refill supply of medication relied on documentation of the conversation between the original pharmacist and the prescriber.

Under these circumstances, it is the prescriber who must accept responsibility when an adverse effect occurs. Pharmacists cannot guarantee good outcomes from drug therapy.

Summary of the Court's Opinion

The decedent, Laverne DiGiovanni, was a longtime patient of defendant, Dr. Sachidananda D. Shastri. For 10 years, he had prescribed lithium to Laverne for her probable manic depressive psychosis. On January 16, 2003, Dr. Shastri prescribed a drug called Tenoretic to treat Laverne's high blood pressure. The prescription for the Tenoretic was filled on January 20, 2003, at Osco. However, prior to filling the prescription, the pharmacist called Dr. Shastri. According to the pharmacist, Dr. Jonathan Huynh, the pharmacy computer indicated that there would be an interaction between lithium and Tenoretic. The interaction between the two drugs could cause lithium toxicity. When Dr. Huynh called Dr. Shastri to inform him of the interaction, Dr. Shastri told Dr. Huynh to fill the prescription and that he would monitor the patient. The conversation was memorialized in a note and placed in Laverne's file. However, when Dr. Shastri was questioned during his deposition about a conversation with Dr. Huynh, he indicated that he had no recollection of the conversation.

A prescription for lithium was subsequently issued by Dr. Shastri for Laverne, which was filled on January 27, 2003, by another Osco pharmacist, John Glowacki. Prior to filling the prescription, Glowacki noticed the handwritten note in Laverne's file indicating that the doctor was going to monitor the patient after receiving notice of the interaction between lithium and Tenoretic. Glowacki did not call Dr. Shastri prior to filling the lithium prescription. Laverne became ill and was subsequently hospitalized on February 3, 2003. She later died, allegedly from lithium toxicity.

The Estate filed a wrongful death action against his wife's longtime doctor, Dr. Shastri, Gericare, Ltd. (Gericare), and Osco. The Estate alleged, in part, that Osco failed to warn of the interaction between Tenoretic and lithium.

Here, Laverne's longtime physician, Dr. Shastri, prescribed Tenoretic to treat high blood pressure while she was already taking lithium for manic depression. The two drugs were apparently known to have a negative interaction, and the computer indicated so when the

Tenoretic prescription was being filled. The record indicates that the pharmacist called the physician prior to filling the prescription regarding the potential interaction, and the physician indicated that he would monitor Laverne. Making a notation in the file, the pharmacist filled the prescription for the Tenoretic. When the lithium prescription was refilled, the pharmacist saw the note regarding notification to the physician about the interaction and that the physician would monitor the patient. We find that the pharmacist properly filled the prescriptions that the physician wrote, took notice of the warning in the system regarding a possible interaction between the two drugs, and notified the physician of the potential interaction prior to filling the prescription. The physician then indicated that he would monitor the usage, so the pharmacist filled the prescription and made a notation. Under these circumstances, we find that the pharmacist was under no duty to warn the customer of the possible interaction between the two drugs under the learned intermediary doctrine. To hold otherwise would impose a greater duty on the pharmacist than on the drug's manufacturer, as the duty of extending warnings to patients concerning prescription drugs belongs with physicians.

What This Case Teaches

Please consider the significance of the first pharmacist's documentation in this case, and the of the reliance placed by the second pharmacist in this documentation. It is a huge deal. Undocumented consultations with prescribers are difficulty to prove; perhaps even impossible. They can result in an argument about who said what to whom and when. But a notation in a patient care record is golden.

The failure to warn a patient of a potential adverse event, such as a drug-drug interaction, can be forgiven under the law, when a pharmacist's documentation establishes that the prescriber took responsibility for managing the drug-drug interaction.

The value of documentation does not support having pharmacists become primarily journalists as opposed to health product and service providers. But it does support taking a brief moment to memorialize a conversation with a prescriber who has acknowledge a consultation with a pharmacist and who has accepted responsibility for a potentially adverse outcome to the patient. Documentation can shift responsibility from the pharmacist to the prescriber.

Court Case: Keffer v. Lorenz

This is another drug-drug interaction case, with a different result. The case is a ruling on a motion submitted by the pharmacy, requesting that the court dismiss the litigation without even considering what the facts might eventually show has occurred. The pharmacy defendant is arguing that there is no set of facts in which the plaintiff could win against the pharmacy, because as a matter of law pharmacists never have any duty to warn a patient of potential risks such as drug-drug interactions.

Only two decades ago, this motion would likely have been granted, because courts were consistently ruling that pharmacists who had processed a prescription accurately could rely on the prescriber's expertise to select the correct drug. Consistent with that way of thinking, if a patient was harmed by a drug-drug interaction, and the pharmacist processed the prescriptions accurately, then the prescriber alone was held liable. The pharmacist was untouchable.

That approach has changed. This case reflects the change.

As you read this court's opinion that is excerpted below, pay particular attention to the "general risks v. specific risk" analysis.

Summary of the Court's Opinion

Mr. Keffer, the decedent, was a CVS patient from 2009 until his death in January 2011. From 2010 to January 2011, one of Mr. Keffer's physicians had prescribed Cymbalta and Vyvanse. Cymbalta and Vyvanse, when taken together, are known to cause serious adverse effects in some patients. CVS simultaneously filled both of these prescriptions for Mr. Keffer. CVS's pharmacy personnel used a computerized prescription system (the "CVS system") that informed them of Mr. Keffer's prescription history, that he had been prescribed both Cymbalta and Vyvanse, and that he was filling both medications simultaneously. In addition, the CVS system notified CVS's personnel that they should not fill the two prescriptions without first contacting Mr. Keffer's physicians to confirm that they wanted him to take both medications at the same time. CVS never told Mr. Keffer about the drug interaction before it dispensed the Cymbalta and Vyvanse, nor did CVS contact any of his physicians to obtain confirmation. After simultaneously taking Cymbalta and Vyvanse for several months from 2010 to 2011, Mr. Keffer suffered sudden heart failure and died on January 17, 2011.

Defendant CVS argues that it is entitled to dismissal of the claim against it because: (1) it had no duty to warn Mr. Keffer of known contraindications, as its only duty was to accurately fill the prescription; and (2) relying on the learned intermediary doctrine, any other duty rested upon decedent's physician. Plaintiff counters that dismissal is not warranted as there was a duty to warn, particularly in the face of known contraindications, and that the learned intermediary doctrine does not apply for policy reasons.

The general rule is that a pharmacist has no duty to warn a patient of the potential risks of a given medication, but there is a significant body of authority that stands for the proposition that a pharmacist does have a narrow duty to alert his or her patient or the prescribing physician when the prescription is contraindicated for the patient. If a pharmacist does not have a duty to warn under those circumstances, it may be argued that warning of the existence of a known, adverse drug interaction may fall within the

pharmacist's broader duty of ordinary care. At this stage it may fairly be said that CVS had a duty to warn because Mr. Keffer was at risk of a specific, defined, and foreseeable harm about which the pharmacists knew or should have known.

What This Case Teaches

The pharmacy may be able to win this case. But to do so, the pharmacy will have to explain why the failure to warn had a solid justification in science and/or in clinical practice. The law cannot protect a pharmacist under these circumstances, but the standards of the profession can.

A key element of the case is what the court referred to as the possibility of "foreseeable harm about which the pharmacists knew or should have known." Foreseeability is an open question, as is pharmacist knowledge. They are essentially questions of fact and not of law. Medical evidence, and perhaps expert testimony, will be required to inform the jury's interpretation of the facts. The facts will be evaluated from the perspective of professional standards of practice in pharmacy.

Not all drug-drug interactions warrant consultation with the prescriber or a warning to the patient. An explanation by a pharmacist as to why medications with an established drug-drug interaction were dispensed may be judged as perfectly adequate. That explanation will have to be made. Dismissal of this type of "duty to warn" case, based on the law of decades ago, is no longer available to pharmacists. It is facts and professional standards that matter now.

Exam Questions

1. Which of the following words or phrases may make a patient feel uncomfortable about talking with a pharmacist?
 - a. Counseling.
 - b. Consultation.
 - c. Education.
 - d. Medication review.
2. Under the “learned intermediary” doctrine, who is generally considered in the best position to provide medication-related warnings to patients?
 - a. The FDA.
 - b. The manufacturer.
 - c. The prescriber.
 - d. The nurse.
3. What law established a requirement that states participating in the federally funded Medicaid program expand their standards of practice for pharmacists?
 - a. The Affordable Care Act.
 - b. The Internal Revenue Code.
 - c. HIPAA.
 - d. OBRA-90.
4. What type of information about drugs relates primarily to how a drug can best be used, given that the decision to use the drug is not being reconsidered?
 - a. Risk Assessment.
 - b. Risk Management.
 - c. Risk Adversity.
 - d. Risk Integrity.
5. What principle of law requires a person to perform well the services the person provides, even though the person may not be required to perform the services at all?
 - a. Specific performance.
 - b. Duty to perform.
 - c. Voluntary undertaking.
 - d. The rule of law.

6. Which of the following signs is particularly problematic for pharmacists who must assure that patients understand what they have previously been directed to do?
 - a. Take one tablet daily.
 - b. Take two tablets daily.
 - c. Take three tablets daily.
 - d. Take as directed.
7. Who expects pharmacists to educate patients to the extent that patients become as expert as health professionals?
 - a. The FDA.
 - b. The DEA.
 - c. The AMA.
 - d. Nobody.
8. Under what circumstances might a product liability (as opposed to negligence) lawsuit against a pharmacy be successful?
 - a. Drug-drug interaction.
 - b. Compounding.
 - c. Technician supervision.
 - d. Wrong patient.
9. In the *DiGiovanni v. Albertson's* case, alleging an interaction between Tenoretic and lithium caused harm to the patient, what evidence supported the conclusion that the pharmacist had consulted with the physician?
 - a. A notation in the file.
 - b. A really good memory.
 - c. Video cameras.
 - d. Patient participation.
10. Foreseeability and pharmacist knowledge are open questions in a failure to warn case. What type of questions are they?
 - a. Constitutional law questions.
 - b. Statutory law questions.
 - c. Regulatory law questions.
 - d. Fact questions.

Please submit your final responses on [freeCE.com](https://www.freeCE.com). Thank you.