

THE PHARMACIST'S EVOLVING DUTY TO WARN: A VIEW FROM THE COURTS¹

The vital role played by pharmacists as members of the health care team, in ensuring that medications are used appropriately in order to optimize patient care, is by now so firmly ingrained in the pharmacy culture that it is difficult to imagine that not long ago pharmacists were viewed as nothing more than glorified retailers. As recently as 1985, one prominent state court jurist compared the role of a pharmacist to that of an ordinary hardware store clerk:

[I]n the marketing of prescription drugs by retail druggists, as in the marketing of automobiles and other consumer products, the sale aspect predominates over any incidental service provided to the consumer * * *

* * * the retail druggist's role is similar to that of a clerk in an "ordinary" retail store . . . the average hardware store clerk probably devotes as much or more time counseling customers on the applications and proper use of the items offered for sale by the store.¹

Now, less than twenty years later, it is widely known and accepted that a pharmacist is much more than a glorified retailer. As every licensed pharmacist in this country knows (or should know), before filling any prescription, a pharmacist is required to review the prescription order for potential drug therapy problems. Since 1990, every state in the country has passed laws or regulations requiring pharmacists to perform a drug utilization review ("DUR"), which requires pharmacists to screen prescription drug orders for potential problems such as therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect dosages or duration of treatment, drug allergies, and clinical abuse or misuse of the prescribed medication.² In addition, every state has passed some form of patient counseling law. In some states, the law requires the pharmacist or his designee to make an offer to counsel patients on their medications. Other states affirmatively require counseling, not just an offer to counsel, on all new and refilled prescriptions presented to the pharmacy.

These "new" duties and responsibilities are clearly understood by all pharmacists. If a pharmacist fails to perform DUR, or, depending on the state law, fails to offer to counsel or affirmatively counsel a patient, the pharmacist is subject to discipline by the state board of pharmacy. What is less clear to pharmacists, however, is whether a pharmacist can be held civilly liable in a court of law when his or her failure to perform DUR, or to counsel a patient about his or her prescription medication, results in an injury to a patient. This article reviews several recent state court decisions addressing that very issue. In what might come as a surprise to pharmacists, these cases demonstrate that although a pharmacist is recognized as a member of the health care team, with very direct and unambiguous patient care responsibilities, courts have for the most part been reluctant to hold pharmacists liable when their failure to perform their responsibilities results in patient harm. Courts have taken the view that it is the doctor, and not

¹ This article discusses general principles of law, and is not intended as legal advice. Pharmacists should consult their own attorneys for specific advice concerning any legal issues that might arise in connection with their practice of pharmacy.

the pharmacist, who has the responsibility for deciding the appropriateness of a patient's drug therapy, and for discussing with patients the side effects and potential risks associated with the use of their prescription medications.

Although most courts have refused to impose a generalized duty to warn, recent cases have recognized that there are exceptions to the general "no duty" approach. First, courts have held that even though pharmacists have no general duty to warn, if it does provide warnings, it must do so properly. These courts take the view that if a pharmacist warns of a potential problem with the patient's drug therapy, but does so negligently, the pharmacist can be held liable.

Other courts have recognized another, perhaps more significant exception to the "no duty" approach. These courts have held that when a pharmacist has actual knowledge of a patient's health condition, and has knowledge that as a result of that condition, the medication prescribed by the doctor is contraindicated, the pharmacist will have a duty to act on the information it has, by warning either the doctor or the patient of the potential problem. As will be discussed, this exception may be big enough to overcome the general rule.

Pharmacy Law 101: The Law of Negligence

In order to better understand the various approaches taken by courts when analyzing a pharmacist's duty to warn, it is important to have some understanding of the basic law of negligence. When a person is injured as a result of the inadvertent or accidental conduct of another party, the injured person (the "Plaintiff") has a potential cause of action for negligence. If the claim is successful, the party causing the injury (the "Defendant") would be required to pay money damages to pay compensate the Plaintiff him for his injuries. For example, suppose a person is driving his car down the street, but is distracted because he is using his cell phone. He inadvertently fails to slow down or stop at a traffic light, and as a result, his car strikes the rear of a more attentive driver, who was properly stopped at the traffic light. If the driver of the second car is injured, he can file a lawsuit seeking to hold the negligent cell phone user liable for the damage to his car, and for any physical injuries he sustained as a result of the collision.

In order to win this lawsuit, the Plaintiff would be required to prove four elements. First, he would be required to prove that the Defendant owed him a duty of care to drive carefully and in such a manner as to avoid causing an accident. Next, assuming that the law recognizes such a duty, the Plaintiff would be required to prove that the Defendant breached that duty. If a duty and breach are shown, the Plaintiff would still be required to show that he was injured or damaged in some way, and that the Defendant's breach caused his injuries. These four elements, duty, breach, causation and injury, comprise the law of negligence.

When an injury is caused by the negligent conduct of a health care professional, such as a doctor or pharmacist, the cause of action is typically referred to as malpractice. However, the four elements that must be proven by the Plaintiff - duty, breach, causation and injury - are the same. Take, for example, the facts of an actual pharmacy malpractice case involving a misfilled prescription. In *Harco Drugs v. Holloway*,³ the doctor prescribed Tamoxifen®, an anti-cancer drug, but the pharmacist misread the prescription, and instead dispensed Tambacor®, a cardiac drug. It is undisputed that a pharmacist has a duty to fill prescriptions correctly.⁴ By misfilling

the prescription, it is clear that the pharmacist has breached that duty. If the patient can also prove that she consumed the incorrect medication, and sustained some injury or damage as a result, the four elements will have been proven, and the pharmacist would be held liable for money damages to compensate the patient for her injuries. However, if the patient left the pharmacy with the medication, but caught the error before consuming any of the Tambacor®, then there would be no injury, and no causation, and the Plaintiff would have failed to prove her case, and there would be no liability. Similarly, if the patient took the medication, but could not prove that she was injured in any way, there would be no liability, even though the pharmacist failed in his duty to fill the prescription correctly. Again, all four elements must be proven in order for a Plaintiff to prevail.

Three of the four required elements, breach, causation and injury, are decided by a jury or, if the case is tried before a judge without a jury, by the judge in his role as fact finder. The fourth element, however, is always decided by the judge as a matter of law. In a negligence action, the duty owed by one person to another is often described as “ordinary care”. “Ordinary care” is commonly defined as that degree of care which a prudent and competent person engaged in the same line of business or endeavor should exercise under similar circumstances.⁵ Taking again our example of a hypothetical automobile accident case, the duty owed can be described as taking that amount of care that is required so as to avoid accidents. The amount of care required is based upon how a “reasonably prudent person” would act under the same or similar circumstances. Although the use of cell phones by car drivers is commonplace, the hypothetical “reasonably prudent person” would nevertheless pay attention to the world around him while driving and talking, so that he could see that the traffic light had turned red, and that traffic had stopped in front of him, and slow and eventually stop his vehicle before colliding with another car.

In deciding how a reasonably prudent person would act, courts have taken a variety of approaches. One very well respected federal court judge attempted to define duty in the form of a mathematical formula. In a case decided in 1947, Justice Learned Hand introduced the “Hand Formula”, which stated that whether a particular course of conduct was reasonable was a function of three variables:

(1) The probability [of the accident’s occurrence]; (2) the gravity of the resulting injury . . . ; (3) the burden of adequate precautions. . . . [I]f the probability be called P; the injury L; and the burden, B; liability depends on whether . . . $B < PL$.⁶

In other words, according to Justice Hand, if the probability of an injury occurring as a result of the conduct at issue multiplied by the seriousness of the resultant injury outweighs the burden that would be imposed in preventing the accident from occurring, then a duty exists, and if breach causation and injury is proven, there would be liability. If a driver is using a cell phone in a manner that would distract him from paying attention to traffic flow and traffic signals, there is a good probability that an accident could occur. An injury resulting from a car accident could potentially be very serious, particularly if the driver strikes a pedestrian. If the burden is defined as simply requiring a driver to pay attention, even if he is using his cell phone, clearly the first two factors would outweigh that burden, and a court could conclude that a duty to drive carefully exists – whether or not the driver is using a cell phone.

Although this formula is useful in terms of understanding the interaction of the variables – probability of injury occurring as a result of the Defendant’s, the potential harm that could result from the conduct, and the burden of preventing the accident, since there is no real way to quantify these variables mathematically, the usefulness of the Hand Formula is dubious at best. However, the general principles are still followed by courts throughout the country to this day. In a recent case that will be discussed in detail later in this article, the Illinois Supreme Court stated:

In determining whether a duty exists, courts look to certain relevant factors. These include: (1) the reasonable foreseeability that the defendant’s conduct may injure another, (2) the likelihood of an injury occurring, (3) the magnitude of the burden of guarding against such injury, and (4) the consequences of placing that burden on the defendant.⁷

This widely held view of duty restates the Hand “formula”, but clarifies it is not enough for a court to look simply at the specific case before it when determining the duty of care owed by a Defendant. In addition to analyzing the probability of an injury occurring, the gravity of the injury, and the burden placed on the Defendant to prevent the accident, the court will also examine the consequences that would result from imposing liability on the Defendant.

In pharmacy malpractice cases alleging negligence based on the pharmacist’s failure to warn of a potential risk associated with the use of the prescribed drug, courts have voiced concerns about the consequences of imposing a generalized duty to warn that would, if breached, subject the pharmacist to malpractice liability. This continues to be the prevailing view even though state pharmacy laws require pharmacists to perform these functions. It is not that the courts fail to recognize the role of the pharmacist in patient care. Rather, it appears that courts are concerned that imposing a generalized duty to warn will create a health care environment in which pharmacists, out of fear of civil liability, will second guess the prescribing decisions of doctors.

Applicability of the Learned Intermediary Doctrine

The most commonly cited reason for refusing to impose a generalized duty to warn on pharmacists is that to do so would violate the “learned intermediary doctrine”. The learned intermediary doctrine recognizes that prescription drug manufacturers have no duty to directly warn consumers of the side effects associated with the use of their products. Rather, manufacturers provide warnings to the prescribing physician, who acts as a “learned intermediary” between the manufacturer and the patient. This doctrine recognizes that the doctor has unique and specialized knowledge of the medical condition of the patient. That specific knowledge, along with knowledge of the prescribed drug, places the doctor in the best position to convey warnings to the patient.

Courts have relied on the learned intermediary doctrine when refusing to impose a generalized duty to warn on pharmacists. These courts have taken the view that to impose a duty to warn would require the pharmacist to become interjected into the doctor-patient relationship, and could serve to “compel the pharmacist to second guess every prescription a doctor orders in

order to escape liability.”⁸ Moreover, these courts fear that although pharmacists might, in many cases possess greater knowledge than a physician of the adverse effects of a drug,⁹ pharmacists may not have all of the information concerning the patient’s idiosyncrasies, or even of the patient’s medical condition, to be able to make decisions concerning the appropriateness of the prescribed drug, or of what warnings should be conveyed. For example, in *Fakhouri v. Taylor*,¹⁰ the family of a deceased patient alleged that the pharmacy was negligent in failing to warn that the dosage of imipramine prescribed by the doctor was in excess of the manufacturer’s recommended limits. The court, relying on the learned intermediary doctrine, refused to impose liability upon the pharmacy, holding:

To impose a duty to warn on the pharmacist would be to place the pharmacist in the middle of the doctor patient relationship, *without* the physician’s knowledge of the patient. Furthermore . . . the duty of the manufacturer runs to the physician, not the patient. Therefore, it is illogical and unreasonable to impose a greater duty on the pharmacist who properly fills a prescription than is imposed on the drug’s manufacturer.

The majority of courts that have considered the issue have applied the learned intermediary doctrine to effectively shield pharmacists from liability based on the failure to warn. As will be discussed, however, recent cases suggest that the learned intermediary doctrine will not apply where the pharmacist has actual knowledge about a contraindication, or other specific knowledge that use of the drug as prescribed would harm the patient.

Duty to Warn: The View from the Courts

Many practitioners believed that the imposition of a duty to warn on pharmacists would be a natural consequence of the federal OBRA 90 mandate. That has not proven to be the case. Courts have taken three general approaches to the issue. First, the majority of courts have refused to impose a generalized duty to warn. Next, some courts have held that even though pharmacists have no general duty to warn, they can assume a duty by providing warnings voluntarily, and be held liable if those warnings prove to be inadequate. Finally, courts have recognized exceptions to the general “no duty” rule, and have imposed a duty in cases where the pharmacist has specific knowledge concerning the patient’s health condition.

Assuming a Duty to Warn

In *Cottam v. CVS Pharmacy*¹¹, a patient brought a negligence action against a pharmacy arising out of the pharmacy’s alleged failure to warn a customer about a prescription antidepressant drug’s potential side effect of priapism. Priapism is a serious condition that if not promptly treated, could lead to irreversible damage and impotence.

The patient’s psychiatrist prescribed Trazadone® to treat depression. The patient had the prescription filled at a CVS pharmacy. A few months prior to the date that the prescription was filled, CVS had implemented a computer system that was designed to provide customers with information about risks and side effects associated with prescription drugs. The computer system could produce either a short form that discussed more common side effects, or a longer

form that was more comprehensive, and included warnings that were not included in the short form. It was CVS's policy to distribute the long form when a prescription was first filled.

The parties disputed whether the long form or short form was given to the patient, but the pharmacist did admit that she did not verbally warn the patient of the side effect of priapism. In addition, the manufacturer's package insert provided. Both the CVS long form, and the package insert, included warnings about priapism. However, the patient's treating psychiatrist testified that he had warned the plaintiff that priapism was a potential side effect before prescribing the medication.

The patient took the first dose of Trazadone® at night, and awoke the next morning with an erection that persisted throughout the day. The erection became uncomfortable later that evening. The plaintiff did not contact his doctor, deciding to wait until the next day when he had an appointment with his primary care doctor. He took an additional dose of Trazadone® before going to bed that evening. The next day, his doctor immediately referred him to an urologist, who diagnosed priapism, and scheduled him for emergency surgery. The surgery left the plaintiff permanently impotent.

At trial, the jury found in favor of the plaintiff, and found the pharmacy to be 51% liable for the plaintiff's injury, and the plaintiff 49% comparatively at fault. CVS appealed, and on appeal the court affirmed the jury's verdict. Initially, the court held that the pharmacy had no generalized duty to warn patients of the side effects of the drugs dispensed by the pharmacy pursuant to a prescription. However, the court found that since CVS had provided some warnings, in the form of the counseling form that was provided to the patient, it had voluntarily assumed a duty to warn. The court held that since the pharmacy provided a detailed list of warnings, the patient could reasonably assume that the warnings provided were comprehensive. Since those warnings did not include any warnings about priapism, or of the need to seek prompt treatment if that side effect developed, the warnings were inadequate.

It is important to note that the court's reasoning in this case has been rejected by other courts that have reviewed the issue. In *Kasin v. Osco Drug, Inc.*¹², a pharmacy customer and his brother, whose kidney had been transplanted into the customer, sued the pharmacy for negligence, alleging that, in dispensing a prescription drug, the pharmacy had negligently advised the customer of the drug's side effects, including possible kidney failure. The pharmacy filled a prescription for Daypro®, and provided the plaintiffs with an information sheet that addressed several issues concerning the use of the drug. The sheet a section titled "Are There Any Side Effects" which stated "Very unlikely, but report: Eye/ear problems, change in urine color, bloody stools, difficulty breathing, mental changes." There was no discussion of any potential risk of kidney damage or renal failure.

The plaintiffs argued that even if the pharmacy had no duty to warn of any side effects initially, by providing the information sheet it had voluntarily assumed a duty, and was therefore required to warn of all side effects. The court disagreed, finding that the duty assumed by the pharmacy was limited to the extent of its undertaking. According to the court, the pharmacy chose to warn of only certain, more common side effects, did not create a duty to warn of all side effects:

By voluntarily undertaking to list some of the drug's side effects, Osco did not assume a duty to list all possible side effects. Concluding otherwise would ignore the public policy considerations . . . and would deter pharmacies from providing any information at all. Illinois case law has consistently held that public policy considerations may be taken into account by a court when determining if a duty has been voluntarily undertaken.

The court granted summary judgment in favor of the pharmacy, and dismissed the case. In doing so, the court recognized that holding that the provision of any warnings would create a duty to provide all warnings would set a dangerous precedent, in that pharmacies would be reluctant to provide any warnings at all.

Application of the Learned Intermediary Doctrine

As previously stated, the view taken by the majority of courts continues to be that pharmacists have no generalized duty to warn. The following cases discuss the application of the learned intermediary doctrine to shield pharmacists from liability for failure to warn.

In *Hooper v. Thrifty Payless*,¹³ a California case decided in December, 2000, the court reviewed another case alleging that the pharmacist failed to warn of that Trazadone® could cause priapism. When the patient had his prescription filled, he was asked whether he had any questions concerning the Trazadone®, which had been prescribed by his psychiatrist as a “sleep aid”. The patient claimed that he refused the offer to counsel, because he thought a sleep aid could not be a very powerful drug, since in his experience, sleep aids were available without a prescription even at convenience stores such as the “7-Eleven.” The pharmacy documented the refusal of the offer to counsel, and provided the medication to the patient. The facts also showed that although it was company policy to include with the medication a written handout that discussed potential side effects, no handout was provided to the patient in this case.

The patient used the Trazadone® at bedtime for the next several nights, and priapism. The patient was not treated for three days, and sustained a permanent injury. The patient sued, alleging that the pharmacy “knew or should have known of the serious and foreseeable side effects” of Trazadone®, and that it “negligently and carelessly failed to warn or advise [him] of the known and serious side effects of the drug.”

Thrift moved for summary judgment, which is a motion that is filed when the facts of the case are not in dispute, and the case can be decided by the court as a matter of law. The pharmacy argued that it had satisfied its legal duty to their patient when it made the offer to counsel, which the patient declined. Further, the pharmacy argued that under the learned intermediary doctrine, it was the doctor, and not the pharmacist or pharmacy, that had the responsibility to warn the patient of side effects associated with a drug.

The court recognized that the majority of the courts in the country that had reviewed the issue of the pharmacist's duty to warn had applied the learned intermediary doctrine and held that no duty exists. It then adopted the majority view, reasoning that “it would be illogical and

unreasonable to impose a greater duty on the pharmacist who properly fills the prescription than on the drug manufacturer,” which has a duty to warn only the physician.

A similar result was reached by the Texas Court of Appeals in *Morgan v. Wal-Mart Stores, Inc.*¹⁴ In *Morgan*, a physician prescribed Desipramine® to the plaintiffs’ twelve year old child for treatment of Attention Deficit Hyperactivity Disorder (“ADHD”). The child used the medication for two years before developing chest pains, numbness in one of his arms, and eventually large, dark bruising on his legs. Despite consulting with numerous physicians, including specialists, the cause of the child’s problems could not be determined. Sadly, the child died, and only then was it determined that he suffered from hypereosinophilic syndrome, an extremely rare blood disorder. The plaintiffs’ expert witness, a specialist in the field of immunology, opined that the condition was caused by a hypereosinophilic reaction to Desipramine®. Plaintiffs filed suit against a number of health care providers, including Wal-Mart pharmacy. The theory against the pharmacy was negligent failure to warn of the side effects of Desipramine®.

The case proceeded to trial, where a jury found Wal-Mart 15% at fault for the child’s death. On appeal, Wal-Mart argued that as a matter of law, pharmacists had no duty to warn of the potential dangers of Desipramine®, because that duty rested with the prescribing physician. The court agreed, holding that the learned intermediary doctrine prohibited holding a pharmacist liable.

The court specifically considered the effect of Texas’ pharmacy practice laws and regulations, which imposed on pharmacists a duty to perform DUR and to warn of “common severe side effects or adverse effects” associated with the drugs they dispense. The court held that while these regulations demonstrate that pharmacists are trusted professionals with varied and important responsibilities, they cannot be reasonably read to impose a legal duty to warn. The court reasoned that to impose a generalized duty to warn “would unnecessarily interfere with the relationship between physician and patient by compelling pharmacists seeking to escape liability to question the propriety of every prescription they fill.”

The court also raised concern that faced with an overwhelming number of warnings from the pharmacist, patients may decide not to take a medication prescribed by a physician, who has greater access to and knowledge of the patient’s complete medical history and current condition compared to the pharmacist. The court noted that although pharmacy practice rules act as final auditors of the technical accuracy of the prescription, and its appropriateness with respect to a patient’s known condition and medication record, “they do not possess the extensive knowledge of a physician with respect to a patient’s complete medical history and are thus not legally obligated to warn a patient of adverse drug reactions.” Accordingly, the court held that “in light of the learned intermediary doctrine . . . we hold that pharmacists have no generalized duty to warn patients of potential adverse reactions to prescription drugs absent some special circumstances not present here”.

The Mississippi Supreme Court has also relied upon the learned intermediary doctrine to hold that pharmacists have no generalized duty to warn. In *Moore v. Memorial Hospital of Gulfport*,¹⁵ a pregnant woman was being treated for labile hypertension and anemia. Her doctor prescribed Diovan®, which was filled by the defendant pharmacy. Allegedly as a result of the

mother's ingestion of Diovan®, her child developed end stage renal failure shortly after her birth.

The family filed a lawsuit against the doctor, the hospital, and the pharmacy that dispensed the Diovan®. The complaint alleged that the pharmacy was negligent by dispensing a drug that was contraindicated for pregnant women.

The court recognized that other courts had found exceptions to the learned intermediary doctrine where it was undisputed that the patient had advised the pharmacist of health problems that contraindicated the use of the drug, and where the pharmacist filled prescriptions in quantities inconsistent with the recommended dosage guidelines. Finding that neither exception applied in the case before it, the court granted summary judgment in favor of the defendant pharmacy, holding that the learned intermediary doctrine applied.

Exceptions to Learned Intermediary Doctrine

As discussed by the Mississippi court in *Moore*, as well as the Texas appellate court in *Morgan*, the learned intermediary doctrine may not apply where special circumstances exist. Specifically, courts have held that where the pharmacist has specific information about a condition, the existence of which creates a contraindication to the use of the prescribed drug, the learned intermediary doctrine may not apply. The Illinois Supreme Court recently considered such a case.

In *Happel v. Wal-Mart Stores, Inc.*,¹⁶ the plaintiff sued the pharmacy after experiencing anaphylactic shock from a prescription for a non-steroidal anti-inflammatory (“NSAID”) drug. The facts of the case were undisputed. The Plaintiff's physician called Wal-Mart pharmacy with a prescription for Toradol® after the Plaintiff called him with complaints of menstrual cramps. The Plaintiff, Heidi Happel (“Happel”) had been to the Wal-Mart pharmacy on six prior occasions to have prescriptions filled. Each time that she went, the pharmacy staff asked her whether she had any drug allergies, and each time she told them that she was allergic to aspirin, acetaminophen, and ibuprofen. Wal-Mart's manager testified in his deposition that at the time that this prescription was filled, Wal-Mart had a policy that required the pharmacy staff to obtain this type of information before dispensing any medication, and that the reason for this was to alert the pharmacist to any drug interactions or allergies that could cause harm to the patient.

Both of the pharmacists who were on duty on the day of the incident testified that Happel's allergy information was in the pharmacy's computer system and available to pharmacists on the day that the prescription was filled. The pharmacist who filled the prescription testified that at the time that she filled the prescription, she was aware that Toradol® was contraindicated for patients who were sensitive to aspirin and ibuprofen. It was also undisputed that if the Toradol® information was in the pharmacy's computer, a “drug interaction” warning would have flashed across the screen, halting the prescription process for patients with a noted sensitivity to NSAID's. The pharmacy policies and procedures would then require the pharmacist to call the doctor to notify him of the contraindication.

The pharmacist who filled the prescription had no specific recollection of filling the prescription, but admitted that had she called, there would have been a notation on either the prescription or in the computer to that effect. It was undisputed that there was no such record

If after being made aware of the contraindication, the physician wanted the prescription filled anyway, the pharmacist would be required to override the computer by entering a special code. It was also undisputed by the parties that to override the computer without first calling the physician would be a deviation from the standard of care applicable to pharmacists.

Finally, it was undisputed that when Happel's husband came to the pharmacy to pick up his wife's prescription, a pharmacy employee asked him about Happel's allergies. He advised the employee that his wife was allergic to aspirin, ibuprofen and acetaminophen. Nevertheless, the medication was dispensed, and Happel consumed one dose of the Toradol®.

Within forty minutes of taking the drug, Happel began to experience respiratory distress. She began a breathing treatment with a nebulizer and called the pharmacy to ask whether she might be having a reaction to Toradol®, but her call was cut off. She eventually went to the emergency room, and was found to be experiencing anaphylactic shock. She survived the episode, but claimed that as a result of the incident, she experienced more frequent and severe asthma attacks, seizures, and a worsening of her multiple sclerosis.

Happel filed suit against Wal-Mart, alleging that its pharmacists were negligent for failing to warn that Toradol® was contraindicated in patients who were allergic to aspirin and ibuprofen. Wal-Mart moved for summary judgment, and the trial court granted the motion. Happel appealed, and the appellate court reversed, concluding that Wal-Mart had a duty to warn. Wal-Mart appealed the reversal, and asked the Illinois Supreme Court to affirm the trial court's holding that a pharmacist has no legal duty to warn.

The Supreme Court framed the issue on appeal very narrowly, stating that “[t]he central issue in this appeal is whether a pharmacy has a duty to warn about a known drug contraindication where the pharmacy is aware of a customer's drug allergies and knows that the medication prescribed by the customer's physician is contraindicated for a person with those allergies.” It then proceeded to analyze the issue of whether a duty to warn exists:

A duty to warn exists where there is unequal knowledge, actual or constructive [of a dangerous condition], and the defendant, possessed of such knowledge knows or should know that harm might or could occur if no warning is given.

Next, the court set out the four factors that it was required to consider in determining whether a duty exists: (1) foreseeability that the defendant's conduct may injure another, (2) the likelihood of an injury occurring, (3) the magnitude of the burden of guarding against such injury, and (4) the consequences of placing that burden on the defendant. Applying these factors, the court found that a duty did exist.

First, it was undisputed that Wal-Mart had actual knowledge of Happel's drug allergies, as well as knowledge that the use of Toradol® was contraindicated in persons with such allergies.

Accordingly, it was reasonably foreseeable that a failure to convey this knowledge might result in an injury to Happel. Both the likelihood and reasonable foreseeability of injury were great, thus favoring the imposition of a duty to warn.

Next, the court found that the burden of imposing a duty on the pharmacy was minimal, since all that was required would be to telephone the doctor and inform him of the contraindication, or alternatively, to provide the warning to the patient. This factor therefore also favored the imposition of a duty to warn.

Finally, the court considered the consequences of imposing such a duty. Here, the court distinguished prior precedent, which held that the consequences of imposing a duty would be to interject the pharmacist into the doctor-patient relationship. The court found that under the facts of the case before it, defendant was not being asked to render a medical judgment, or to second guess the judgment of the doctor. Instead, all the pharmacy was being asked to do was to pass along information that was already known.

The pharmacy, relying on a string of Illinois cases that had previously held that no duty to warn exists, made several arguments that the court rejected out of hand. First, it argued that the consequences of imposing a duty to warn would be to create a “chilling effect” on pharmacies. The pharmacy argued that since the duty to warn was premised on the pharmacy’s knowledge of a customer’s allergies, imposing such a duty might discourage pharmacies from obtaining that type of information in the future. In other words, to avoid being held responsible for providing warnings, the pharmacy would simply not obtain any information that might give rise to such a duty.

The court soundly rejected the pharmacy’s argument:

The consequence of accepting Wal-Mart's "chilling effect" argument would be to sanction the status quo, where pharmacies solicit allergy information from their customers but are under no obligation to follow through with a warning, even where the pharmacy knows that the drug being prescribed is contraindicated for the individual customer. ***The difficulty with this approach is that the status quo is unacceptable.*** (Emphasis added.)

The court went on to say that it did not disapprove of the practice of pharmacies’ collecting information about a patient’s allergies and putting it in the computer. However, it made it very clear that when a pharmacy does this, it is required to act on that information when necessary to prevent harm to a patient:

if a pharmacy chooses to engage in such a practice, it must also warn of known contraindications. The alternative, as noted, would place the customer at serious risk. We therefore conclude that any negative consequences of recognizing a duty to warn here are far outweighed by the substantial reasons favoring such a duty.

Next, the court considered the pharmacy's argument that the learned intermediary doctrine shielded the pharmacy from liability, which had been adopted in Illinois. However, the court found that the reasons for refusing to impose a duty to warn based on the learned intermediary doctrine did not apply in this case, where the pharmacy knew of the patient's allergies, as well as the contraindication. According to the court, to impose a duty to warn under such circumstances would not require the pharmacist to learn the patient's condition and monitor her drug usage, since the pharmacy already had the information it needed to give an effective warning. The court found that "this is not a case in which the plaintiff is asking the pharmacist to exercise any modicum of medical judgment or to interject himself into the doctor-patient relationship." In so finding, the court distinguished cases such as *Fakhouri*, where the doctor had prescribed a drug in an excessive dosage. The court recognized that where dosing of a drug, or quantities prescribed was the issue, imposing a duty to warn would potentially require the pharmacist to exercise medical judgment since, "a prescription which is excessive for one patient may be entirely reasonable for the treatment of another." However, when the issue is a known contraindication, the drug should not be given, and all that is required is to simply notify the physician or patient of the contraindication. Conveying such a warning would require no medical judgment.

Based on its view of the case, and of the applicability of the learned intermediary doctrine, the court held that "a narrow duty to warn exists where . . . a pharmacy has patient-specific information about drug allergies, and knows that the drug being prescribed is contraindicated for the individual patient." In such instances, according to the Illinois Supreme Court, "a pharmacy has a duty to warn either the prescribing physician or the patient of the potential danger."

Will the Exceptions Swallow the Rule?

If the learned intermediary doctrine does not apply in cases where the pharmacist has actual knowledge of a contraindication, and of the likelihood of harm to the patient if the contraindicated drug is consumed, it is reasonable to ask whether there is any scenario where the doctrine should apply. After all, since pharmacists have a duty to learn about a patient's medical condition before dispensing any medication, if they are doing their jobs properly, wouldn't pharmacists routinely have the type of information that the *Happel* court stated must be acted upon if a potential problem arises? Moreover, applying the concepts of reasonable foreseeability and burden that factor into the decision of whether a duty to warn exists, will the exception to the learned intermediary doctrine expand to areas other than allergies, such as drug interactions?

Similarly, in those states that have held that by providing any drug information, a pharmacist may assume a duty to warn that otherwise would not have existed, it would appear that all pharmacists are exposed to potential liability. Nearly all pharmacies provide patient information, and state counseling laws require that at least an offer to counsel must be made whenever a prescription is filled and medication is dispensed. It is not practical for a pharmacist to take the view that, for fear of being exposed to liability, he will refuse to provide any drug information to his patients. Nor would such an approach be consistent with the role of the pharmacist as a health care provider.

Although it is difficult to predict what a court will do in any given case, it seems that based on cases like *Morgan*, which involve a rare side effect, it is unlikely that most courts would impose a duty to warn. Further, as stated by the court in *Happel*, a duty to warn should not exist in cases involving excessive dosages or quantities of a medication, since what is excessive for one patient might be entirely reasonable for another. Those issues are prescribing decisions that are best left to the doctor, and it is likely that courts that have adopted the learned intermediary doctrine will continue to refuse to impose a duty to warn on pharmacists in those cases.

Notwithstanding the issue of what a court might or might not do in any given case, however, pharmacists must remember that their primary obligation is to the patient. If a pharmacist practices good pharmacy, with an eye toward ensuring that medications are used properly, and positive outcomes are achieved for their patients, the issue of civil liability should be a non-issue. The best technique for avoiding liability is to practice good pharmaceutical care.

¹ *Murphy v. E. R. Squibb & Sons, Inc.*, 40 Cal.3d 672, 221 Cal.Rptr. 447; 710 P.2d 247 (1985).

² In 1990, the federal Omnibus Budget Reconciliation Act of 1990 (“OBRA 90”) took effect, requiring that all states pass laws or regulations requiring drug utilization review and patient counseling by pharmacist. 42 U.S.C.A. §1396r, *et seq.*

³ *Harco Drugs v. Holloway*, 669 So.2d 878 (Ala. 1995). In *Harco*, the issue was not whether the pharmacist was negligent, but rather, whether the pharmacy owner could be held directly liable, and subject to punitive damages, for failing to institute adequate controls in the workplace so as to prevent errors from occurring.

⁴ *See, e.g., DeCordova v. State*, 878 P.2d 73 (Colo. 1994). In *DeCordova*, the defendant pharmacy argued that, because it can be predicted that a certain percentage of errors will occur in filling pharmacy orders, and because not all errors are negligent, the jury could have reasonably inferred “that the mistake made by the University’s pharmacy was the type of calculation error that was due not to negligence, but rather to a statistical error rate that cannot be eliminated.” The court rejected that argument as disingenuous. Although the court agreed that some negligence in the course of human endeavors is predictable, it ruled that the just because a certain percentage of errors in the pharmacy are inevitable, that does not support the argument that an error on a particular occasion was free of negligence. The court held: “To err is human. To forgive divine. To be responsible for injuries caused by undisputed negligence is the law of this state.”

⁵ *Warner v. Kiowa County Hospital Authority*, 551 P.2d 1179 (Okla. Ct. App. 1976).

⁶ *United States v. Carroll Towing Co.*, 159 F.2d 169 (2nd Cir. 1947).

⁷ *Happel v. Wal-Mart*, 199 Ill. 2d 179, 766 N.E.2d 1118 (2002).

⁸ *Jones v. Irvin*, 602 F. Supp. 399 (S.D. Ill. 1985).

⁹ *See, Pysz v. Henry’s Drug Store*, 457 So.2d 561 (Fla. Dist. Ct. App. 1984).

¹⁰ *Fakhouri v. Taylor*, 248 Ill. App. 3d 328, 618 N.E.2d 518 (1993).

¹¹ *Cottam v. CVS Pharmacy*, 436 Mass. 316, 764 N.E.2d 814 (2002).

¹² *Kasin v. Osco Drug, Inc.*, 312 Ill.App.3d 823, 728 N.E.2d 77 (2nd Dist. 2000).

¹³ *Hooper v. Thrifty Payless*, No. 99AS01792 (Cal. Super Ct., Nov. 15, 2000), *aff’d*. No. C037465 (Cal. Ct. of App., Dec. 17, 2002).

¹⁴ *Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.2d 455 (Tex. App. Ct. 2000).

¹⁵ *Moore v. Memorial Hospital of Gulfport*, 825 So.2d 658 (Miss. 2002).

¹⁶ *Happel v. Wal-Mart Stores, Inc.*, 199 Ill.2d 179, 766 N.E.2d 1118 (2002).