



Pharmacy Malpractice: Understanding, Mitigation, and Prevention

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- Upon successful completion of this article, the pharmacist should be able to:
1. Identify trends in medication misadventures.
 2. List the elements necessary for a malpractice claim to succeed.
 3. Identify a variety of methods that can mitigate malpractice claims or minimize losses.
 4. Describe potential techniques currently utilized to prevent malpractice claims.
 5. Understand how malpractice case outcomes are relevant to contemporary pharmacy practice.

People entrust not only their health, but also their very lives, to their pharmacist. While good health outcomes are a goal of pharmacy practice, occasionally an event takes place which results in a negative patient outcome. Sometimes, this is based on a therapeutic failure. Other times, such an outcome may be based on a pharmacist's failure to comply with standards of practice. Clearly, a pharmacist's lack of care may prove harmful or even fatal. In the area of pharmacy practice and application of the pharmacist's knowledge, literally no room exists for error. In the patient's view, the pharmacist is responsible for preventing the patient from being exposed to dangers associated with medication consumption.

These dangers include prescription preparation, drug-drug interactions, abuse, overuse, underuse, failure to receive a drug warning, drug allergies interactions, therapeutic duplica-

tion, and incorrect drug dosage or duration of treatment, just to name a few. The public's view of the responsibility of a pharmacist for providing care has changed over time. Today, the perception and reality is that a pharmacist is an integral component of the health care team, assuming risks for any medication issues that may result in patient harm.

UNDERSTANDING

A pharmacist might be held responsible for deficient professional actions in a variety of ways. Over the years the most likely negligence-based cause of action centered upon the prescription misfill, in which the pharmacist dispensed an incorrect drug. Other actions against pharmacists included dispensing the wrong strength of the correct drug or providing incorrect directions for use on the prescription container, commonly known as the mislabeling of a drug.

The pharmacist's duty of care encompasses not only properly compounding a prescription in the appropriate dosage and labeling it correctly, but also includes a duty to warn the consumer of known dangers connected with the product dispensed. This duty to warn emanates from federal regulations that have trickled down to the states. Corresponding regulations in virtually every state now require pharmacists to counsel patients, or to offer counseling, in order to optimize drug therapy and, likewise, share with the patient information regarding common severe side effects, adverse effects, interactions, and therapeutic contraindications which may accompany the use of a particular medication. Failure to comply with the state provisions, the purpose of which is to protect the health, safety, and welfare of patients, may be deemed an act that falls below the required standard of practice for the pharmacist.

DATA TRENDS

An Institute of Medicine (IOM) study identified medication errors as the most common type of error in health care, and attributed several thousand deaths annually to medication-related errors. Such preventable errors harm at least 1.5 million people each year. Another study found that among outpatient Medicare patients, 530,000 adverse drug events occurred each year. Regardless of whether one considers errors of commission or omission, error rates for various steps in the medication-use process, adverse drug event rates in various care settings, or estimates of the economic impact of drug-related morbidity and mortality, medication safety clearly represents a serious cause of concern for both health care providers and patients. Numerous studies have been conducted on medication error rates.

In one national observational study of the accuracy of prescription dispensing in community pharmacies, the error rate was 1.7 percent—equivalent to about 50 million errors during the filling of three billion prescriptions each year in the United States. In 1997 drug researchers estimated that the annual cost of drug-related illness and death in the ambulatory care setting in the United States was approximately \$76.6 billion. Using the same approach, this cost was estimated to be \$177.4 billion in 2000.

These figures are staggering. As greater numbers of prescriptions are filled on an annual basis, the risk of medication misadventures increases along with the potential for pharmacist liability.

THE NEGLIGENCE CAUSE OF ACTION

The law imposes an obligation on all persons to use prudence in their actions so others will not suffer bodily injury or property damage. Failure to do so gives the injured party a right of action against the wrongdoer (tort-feasor) for damages.

Negligence is the act of an unreasonable and imprudent person. What society expects of the pharmacist as well as what self-imposed standards the pharmacy profession may place on its members sets the standard of “reasonableness.”

In the case of a pharmacist, negligence often results from simple carelessness or a thoughtless action, but it may also result from forgetfulness, ignorance or simply bad judgment.

Res Ipsa Loquitor

In a negligence case, ordinarily the injured patient bears the burden of proof that claims the pharmacist failed to exercise reasonable care of a professional nature. However, if the facts justify a reasonable inference of negligence, the courts may decide to lift that burden by applying the common law doctrine of *res ipsa loquitor* (“the thing speaks for itself”). Under this doctrine a legally sufficient case of negligence can be established and referred to the jury if the defective object caused the plaintiff’s injury, the injury could not have occurred without the defendant’s negligence, and the defendant controlled the object causing the injury. These conditions establish presumed negligence.

However, this type of claim is rarely used. Its application could be useful if the plaintiff was unable to prove the pharmacist’s negligence, but the resulting injury could only have happened as a result of the pharmacist’s negligence.

ELEMENTS OF THE NEGLIGENCE CASE

Four essential elements constitute a negligent act, and each is essential before a court will award damages. These elements include a legal duty to protect the injured party; a breach of that duty; an injury to the patient’s person, property, legal rights or reputation; and a reasonably close causal relationship between the breach of duty and the patient’s injury.

Duty

A pharmacist, in undertaking the filling of a prescription, is held to the duty of exercising the highest possible degree of care and diligence and of employing the most reliable and exact safeguards consistent with reasonable conduct of the business of pharmacy. The pharmacist’s extreme duty of care exists in order to ensure that human life not be exposed to danger from his or her actions. Violation of the pharmacist’s duty of exercising the highest degree of care can result in liability for damages. The pharmacist, who fails to fulfill his/her duty of care in filling a prescription, will not be relieved of

liability merely because the physician who wrote the prescription also breached a duty of care. If the dosage of drug prescribed by a physician appears to be unusual, the pharmacist has a duty to make inquiry of the physician to ensure no error has occurred.

Breach of Duty

A pharmacist might breach the duty of care in numerous situations. The pharmacist could negligently dispense an incorrect drug, add or substitute an incorrect ingredient into a compound, incorrectly label physician instructions to the patient or dispense an incorrect dosage of a drug. Any mislabeling of a drug may give rise to liability for negligence. In one example, a court held that the patient was entitled to recover from a pharmacist for injuries sustained when she ingested a prescription drug, prepared for another person and placed in a container bearing that person's name, but mistakenly placed by the pharmacist in a bag bearing the customer's name. The injured patient having been prescribed Percodan, an analgesic, went to the drug counter, picked up her prescription bag, noticed her name as well as her doctor's name on the bag, and paid for the prescription.

The evidence disclosed that the medicine contained in the bag was actually Meticorten, a steroid, and that the patient took the drug for three days until her niece observed that the label on the prescription container bore the name of another person. One study has indicated that 8 percent of all malpractice claims are of this type in which the right prescription is placed in the wrong bag.

A pharmacist's duty of care encompasses not only properly compounding a prescription in the appropriate dosage with the correct labeling, but also includes a duty to warn the consumer of known dangers connected with the medications dispensed. Providing appropriate counseling and supplemental information in the form of written information leaflets, pictogram labels, and video programs can fulfill this duty. Absent adequate warnings and contribu-

tory negligence on the part of the patient, the pharmacist may be held liable for injuries resulting from his negligent failure to warn the patient of common adverse events associated with specific medications.

Damages

Bodily injury liability includes liability for losses a person may incur because of harm to his or her body or mind. Such losses include payments for medical bills, loss of income, rehabilitation costs, loss of services (household as well as marital), pain and suffering, loss of life, and punitive damages.

Pain and suffering damages are designed to compensate the injured party for the pain endured due to the negligent behavior of the defendant pharmacist. These damages, considered noneconomic damages, are often greater than economic losses, such as loss of income and medical expenses.

Punitive damages may be assessed when the court deems that the pharmacist has acted in a grossly negligent manner, which is viewed as a reckless disregard for the life of the patient. Punitive damage awards are possible when a negligent act happens that deserves to have an example made of the behavior so as to discourage others from acting in the same or similar manner. For example, an award of punitive damages was sustained against a pharmacist who permitted his son (who was not a pharmacist) to fill prescriptions, with the result that the purchaser of supposed aspirin actually received suppositories containing barbiturates.

Causation

As well as proving that the pharmacist failed to fulfill the requirement of providing a high degree of care in filling a prescription, an injured patient must also demonstrate a causal link between the pharmacist's improper filling of the prescription and the damages alleged. Without such a proven connection, liability will be denied by the court. A negligent action may possibly cause some, but not all, of a patient's injuries.

In one case a pharmacist mislabeled a prescription, and the patient ingested an overdose of digoxin. The patient died five months later. The trial court ruled that the pharmacist's error had caused the patient's death. The appellate court, however, limited liability to those damages suffered during the two to three days after

the overdose. Even though the pharmacist had made a mistake and the patient ultimately died, the pharmacist's action was held not to have been the cause of the patient's death. In other words, the causal link between the pharmacist's error and the patient's ultimate death was not firmly established.

STANDARDS OF PRACTICE

Determining whether a pharmacist has breached his legal duty requires that a jury consider whether the pharmacist has deviated from a standard of performance or care as required of the profession. For those holding themselves out to be pharmacists, the public expects to be in competent hands because of the professional qualifications of the individual and because the pharmacist will follow professionally required standards. A pharmacist needs to comply with established standards of practice to fulfill his/her duty. Obviously, each pharmacist must follow the law.

Many states have enacted minimum practice standards that require the pharmacist to perform certain acts. These acts include accurate prescription dispensing, patient counseling, documentation of relevant information (such as allergies, age, idiosyncrasies, and current medications taken), and required recordkeeping of filled prescriptions. These basic acts are intended, for the most part, to protect patients. Depending on the jurisdiction, a violation of such an act may be deemed *per se* violations and be considered a strict liability offense. If such is found, then meeting the standard of the four elements in a negligence case as outlined previously is negated with proof of the illegal behavior being sufficient to impose liability.

Professional organizations may also set forth recommendations and guidelines with the intention to give the pharmacist requirements to provide safe patient care. While these guidelines may not be legally binding, lawyers may use expert testimony to describe the expectation of the professional as viewed by the guidelines. After such testimony is received, the jury must determine what the professional pharmacist would have done under the same or similar circumstances. Jurors, not pharmacists, at the judgment phase of trial make the final determination regarding the action of the pharmacist and whether or not professional practice standards define the action as acceptable.

While some local pharmacy practice standards may be relevant, current trends are to hold medical profession-

als, including pharmacists, to a national practice standard, one which holds all pharmacists to the highest degree of care necessary in order to prevent injuries from the use of drugs. As a result, pharmacists must continually seek to determine the latest practice standards and take the necessary steps to conform to these standards.

MITIGATION

A pharmacist can adopt a multitude of methods to reduce malpractice claims or to lower the risk of loss. These methods include past error identification, use of defenses to malpractice claims, giving an effective apology, insurance, and asset protection methods.

Error Identification

Certainly once an error has been detected, the pharmacist should take all necessary steps to rectify it promptly. More appropriately, however, proactive procedures can head off medication errors. According to the IOM, much of the harm suffered because of medication errors is preventable. The first step in error prevention involves allowing and encouraging patients to take a more active role in their own medical care. Pharmacists should encourage patients to keep careful records of their medication and take greater responsibility for monitoring those medications by, for example, double-checking prescriptions from pharmacies and reporting unexpected changes in medication size, shape, or color or any unexpected changes in how they feel after starting a new medication. (See Table 1, page 39)

Pharmacists should also find ways to practice in a distraction-free environment. They must minimize interference with the ability to concentrate in order to reduce errors and liability. Busy community pharmacies essentially demand that pharmacists multitask to deliver prescriptions to patients in a timely manner.

Many resources are available to pharmacists which provide suggestions in error reduction. The Institute for Safe Medication Practice (ISMP) provides useful information that can alert

Table 1: Methods to Minimize Medication Problems

- Utilize a consistent counseling routine that ascertains the patient's understanding of drug therapy (including the "three prime questions": What did the doctor tell you the medication is for? How did the doctor tell you to take the medication? What did the doctor tell you to expect?).
- Open each vial or package to allow the patient to make a visual connection between the drug and the information provided during the counseling session.
- Encourage the patient to ask questions or contact the pharmacy about any uncertainty or confusion.
- * Provide written information that emphasizes the major patient counseling points.
- In the case of refills, provide an opportunity for the patient to verify that the drug, strength, dosage form, and quantity are consistent with their original prescription.

pharmacists to error-prone situations. These resources include error-prone abbreviations, symbols, dose designations, and confused drug names. The Food and Drug Administration's (FDA) Division of Medication Errors and Technical Support includes a medication error prevention program staffed with pharmacists and support personnel. The FDA and the ISMP have launched a national education campaign to eliminate the use of ambiguous medical abbreviations frequently misinterpreted and leading to mistakes that result in patient harm.

DEFENSES

Contributory/Comparative Negligence

While a pharmacist may breach the duty of care with regard to a patient, the patient or patient's caregiver may act in such a way as to assume some responsibility for the ensuing injury, thereby negating or modifying the pharmacist's negligence. The defenses that a pharmacist may use in such cases are known as either contributory or comparative negligence, depending on the jurisdiction. If the patient could have avoided the consequences of the pharmacist's negligent actions by ordinary care, yet the patient's actions contributed in some manner to the resulting harm, then under the theory of contributory negligence, recovery of damages is completely barred, even if the patient's action was slight and the pharmacist's negligent action was

great. This type of outcome has resulted in unfair verdicts because of the patient's minor negligence. Because of such verdicts, the doctrine of comparative negligence in many states has replaced the defense of contributory negligence.

Under comparative negligence statutes or doctrines, negligence is measured in terms of percentage, and any damages allowed are diminished in proportion to the amount of negligence attributable to the patient for whom injury, damage, or death has resulted. Where concurrent negligence exists and contributes to injury as determined by the jury, recovery is not barred under such a doctrine. Most jurisdictions permit recovery under "modified" comparative negligence, in which the patient recovers

whatever percentage of the damages corresponds with the pharmacist's percentage of fault, provided that the patient is less than 50 percent at fault. If the court deems the patient's negligence is greater than 50 percent, then under this legal theory, no recovery is possible.

Contributory or comparative negligence may arise when the patient develops symptoms related to the negligent act and continues to use the drug despite the fact that a reasonably prudent person would have sought medical advice about the drug-induced symptoms. Similar legal results may follow when a patient takes too high a dosage or takes a drug intended for another patient. In one case a father permitted, without inquiry, the administration of a medication which he knew differed in character, dose, and frequency of dose from that which the attending physician said he prescribed, to a dangerously ill child three months of age. The court ruled, as a matter of law, that the father was guilty of contributory negligence and barred from recovering for the death of the child even though the pharmacist had committed a negligent act in furnishing the medication.

Statute of Limitations

A statute of limitations defense is based on laws which prescribe the period within which a legal action must be brought or such actions will be barred by time. The time limits vary from state to state. Drug-related injuries may occur slowly over time. The person injured by the pharmacist's negligence in filling a prescription may wait some time before consulting an attorney, possibly even until long after the purchase of the medicine. The ques-

tion then arises as to when the time begins to accrue on the negligence-based cause of action. The traditional rule is that the statute of limitations starts to run at the date of the transaction or, as the case may be, on the date that the patient received the medication. However, situations exist in which patient harm may not be discovered until some time after the actual medication dispensing. A contemporary view in many states is that the cause of action does not accrue until the date on which the patient discovers the injury. This is known as the “discovery rule.”

How this “discovery rule” works in the favor of the patient becomes clear in the following case. Six months after a patient had an eye ailment diagnosed as steroid-induced glaucoma, she filed a lawsuit. The pharmacy affected by this action requested that the court rule the statute of limitations barred this action. In fact, the patient had originally received the medication three years prior to the suit, and Georgia law provided that personal injury actions must be brought within two years of the time that the cause of action accrues. The patient, however, claimed that the doctrine of “continuing tort,” which is when the negligent action continues past the original wrongful act, placed on hold the statute of limitations until the injured patient made the discovery. The court agreed in this situation, ruling that the statute of limitations did not begin to run until the patient had knowledge of the existence of the injury.

USE OF THE APOLOGY

One of the most profound human interactions is the offering and accepting of apologies. Apologies have the power to remove the desire for vengeance and to generate forgiveness on the part of offended parties. During the course of a career, the professional pharmacist may have multiple opportunities to say “I’m sorry” or “I apologize,” yet may never do so. Though these phrases may appear benign on the surface, fear of the apology being used as an admission of guilt might prevent pharmacists from openly and freely offering one. Many defense lawyers would certainly have legitimate concerns about recommending an apology except under those circumstances where liability was not an issue.

In recent years certain states, including Texas, Massachusetts, and California, have enacted legislation prohibiting the introduction of apologetic expressions of sympathy into evidence. The legislation adopted by these states protects only “partial” apologies and expressions

of remorse—that is, statements that do not admit liability or fault. Anecdotal reports reveal that use of the apology in medical establishments may mitigate the medical incident and resolve conflict. While the apology is certainly not expected to be a panacea in every situation, in the appropriate case, pharmacists should consider the apology as a clear option.

When an error occurs, the patient needs to hear three specific comments: 1) an explanation of what happened; 2) an apology from whoever is responsible; and 3) an assurance that changes have been made to prevent the error from occurring again. The pharmacist’s goal should be to alleviate patient fears and rebuild a relationship of trust with the patient. While not solely replacing the need for patient compensation for a medication misadventure, the apology may serve to heal the hurt feelings and provide an avenue for resolution of a situation of patient-pharmacist conflict.

INSURANCE

Professional liability insurance, like any other form of casualty insurance, spreads the financial consequences of risk over a large group and, thereby, decreases the potential financial impact on each member of the group. Liability insurance for the profession of pharmacy is no different. Such policies, which are legal contracts, provide relatively inexpensive pharmacy malpractice insurance. In these policies the insurer promises to reimburse the insured for losses suffered during the term of the agreement. This policy serves as a risk mitigation tool for the pharmacist and may protect the pharmacist’s business and personal assets. Because the insuring agreement is a contract, the pharmacist should place the policy, once received, in a secure location and carefully attach any supplemental agreements to the original policy.

Insurance policies typically require that the insured meet certain conditions in order for coverage to initiate. Such a requirement might include a clause that requires the pharmacist to notify and cooperate with the insurance com-

pany in the event a claim is filed. Clauses may also require the pharmacist to cooperate by providing evidence and attending hearings and trials. Failure of the pharmacist to comply with the policy requirements may result in coverage being denied due to a breach of the insuring agreements. Pharmacists should be aware that for the insurance company to legally be required to provide legal defense and possibly settle a claim, the provisions of the policy must be in effect—that is, the policy must be paid up.

Over the course of time, two unique types of policies have evolved. One policy, known as an occurrence policy, covers any claims brought against the pharmacist for any incident covered under the policy that occurs during the time the policy is in effect. The second type of insurance is claims-made policy.

Under the occurrence policy, if a claim is made against the pharmacist even many years after the incident, the fact the policy had lapsed does not matter; what is significant is that the pharmacist had the policy in effect at the time of the incident which resulted in the claim. This means even if the pharmacist no longer held the policy, and the claim was brought against the pharmacist for an act that occurred when the pharmacist did hold the insurance policy, the pharmacist is covered by the policy.

In contrast, for a claims-made policy to be legally protective, the insurance must be in effect during the time that the claim is filed. To be protected, the pharmacist must continue coverage with this type of insurance. Because claims can be brought years after an incident, if the pharmacist retires, changes insurance, or moves to another state where similar coverage is unavailable, the pharmacist should purchase a single-premium tail coverage of the claims-made policy. This type of coverage is available and can be purchased upon termination of a claims-made policy. This coverage will then extend coverage to claims or suits filed after expiration of the policy.

ASSET PROTECTION

Attorneys typically will tackle a malpractice

action if, after deliberation, the risk of financial reward is outweighed by the risk of financial loss. One method for the pharmacist to reduce the risk of litigation is to protect assets in such a manner so that any plaintiff's gaining access to the assets appears difficult. Without asset protection planning, the pharmacist subjected to potential liability or an actual judgment could lose all assets not exempted from attachment by state law. A well-designed asset protection plan builds a protective fort around the pharmacist's estate and helps guard family wealth both for today and in the future from external creditor attack and frivolous lawsuits.

While insurance should serve as a primary mitigating-loss tool, the prudent pharmacist should have a competent attorney perform an asset risk-analysis to determine what steps, if any, he/she should implement in order to provide additional risk reduction. A sharp dividing line exists between valid asset protection planning and criminal actions to defraud creditors. Hence, having an attorney serve as a guide through the entire asset planning process is essential. Once assets are effectively protected, the pharmacist gains substantial leverage in negotiating a reasonable settlement of a creditor's claim in the event of inadequate or nonexistent insurance coverage. The presentation of limited pharmacist assets along with some psychological trickery, giving the appearance that judgment collection will be difficult, is useful as a mitigation component of the pharmacy malpractice claim.

PREVENTION

CQI/QA

Pharmacists never intend to cause an error which results in patient harm. Nevertheless, accidents still happen. While some errors may result from a pharmacist's knowledge deficit or a performance deficit, other errors result based on a "processing" deficit, or a weakness in the mechanical completion of prescription filling. These system failures upon which malpractice claims are based must be fixed to prevent future claims.

A current approach to risk management of the prescription-filling process is known as continuous quality improvement (CQI). CQI builds upon traditional quality assurance methods by emphasizing improvements in the organization and systems approach to prescription completion, focusing on the "process" as opposed to the individual, and promoting the need for objective data to analyze and

improve prescription processing methods. CQI avoids fear and defensiveness that typify many traditional quality assurance activities because of the assumption that errors are the result due to system weaknesses instead of individual incompetency or irresponsibility.

The principles of CQI and pharmaceutical care are compatible. In fact, CQI provides an objective, fact-based method for implementing quality pharmaceutical care and, by doing so, reduces medication errors and resulting malpractice claims. The success of the CQI process depends on the proper selection, training, and functioning of employee teams whose role is to uncover and correct quality variances in processes that affect patient outcome. CQI differs from traditional management styles and initiatives in that it departs from authoritarian roles and the "command and control" style of management, giving teams the opportunity to implement corrective measures.

CQI requires the selection of an area for improvement, the formation of a team that knows the process, the identification of participants (or process owners) in the activity, and the selection of a method for improvement after process evaluation. In the retail pharmacy setting, such areas for improvement might include auxiliary label attachments, offers to counsel, final prescription check, and order entry verification. Using a team approach, CQI could be used if a determination is made that errors in directions for use or medications to be dispensed were the result of order entry error. The team could then recommend, based on error analysis, a method for improving order entry with the purpose of achieving correct directions for use and/or decreased medication errors. While using CQI is an effective method in addressing current dispensing issues and errors, the most effective continuous improvement occurs when it becomes a natural part of everyday work.

AUTOMATION/INFORMATION TECHNOLOGIES

An important step in reducing the number of medication errors and resulting malpractice claims will be the greater use of automation and information technologies in prescribing and dispensing medications. By using point-of-care reference information, typically accessed over the Internet or from personal digital assistants, prescribers may obtain detailed information about the particular drugs they prescribe and get help in deciding which medications to prescribe.

Tying e-prescriptions in with the medical history allows prescribers to check automatically for such problems as drug allergies, drug-drug interactions, and overly high doses. Furthermore, these devices also allow for the transmission of electronic prescriptions, eliminating many of the handwritten errors that currently plague pharmacists. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 require national standards for e-prescribing by 2009. This requirement should be the impetus necessary to virtually eliminate handwritten prescriptions.

CASE EXAMPLES

Kahn v. CVS Pharmacy, Inc.

Marla Kahn was the adoptive mother of Rose and Sara Kahn. As a result of their difficult early years before adoption, both girls, who are half-sisters, suffered from various psychiatric problems. Kahn sought treatment for the girls to address the problems. Joseph Cresci, a doctor, prescribed Clonidine for both girls. According to Cresci, he hoped that Clonidine would curb Rose's aggressive behavior and Sara's impulsivity. The drug treatment, along with other therapy, was generally successful.

In January 1999, when Rose and Sara were six and four years old respectively, Kahn called a CVS store to refill the girls' Clonidine prescriptions. On Tuesday, Jan. 12, she picked up the drug and returned to her home. While at home, Kahn realized that the new pills appeared larger than the pills that remained from the last refills and that the pills had a different shape. According to Kahn, she called CVS to confirm that she had received the correct drug. An unidentified person answered the telephone and allegedly told Kahn that "[she was] prescribed Clonidine and that's what was filled." Assured by the telephone call, Kahn gave the pills to the girls. The girls took the new pills for three or four days.

After the girls had taken the new pills, Kahn observed physical changes in the girls. They had dry, cracked lips, trouble urinating, and decreased appetites. The girls' behavior also

changed. According to Kahn, Rose and Sara had become more irritable and hyperactive.

Approximately four days after the prescription had been filled, Kahn went in the girls' room in the morning and found an unusually messy room and both girls naked.

Kahn returned to the CVS store with the pills and asked the pharmacist to confirm that the pills were, in fact, Clonidine. The pharmacist determined that the pills were not Clonidine but rather Cogentin, a drug used to treat symptoms of Parkinson's disease. CVS acknowledged that the prescription had been misfilled.

In the weeks and months following the misfill, Kahn alleged the behavior of the girls deteriorated. Both girls became more aggressive. Kahn and other witnesses testified that the girls were no longer friendly with one another and that Sara began to exhibit sexualized behavior.

Kahn filed a lawsuit against CVS, Robert Husman (the pharmacist who had filled the prescription) and unnamed defendants. Though the plaintiff made many claims, for purposes of this article, only two claims will be discussed. First, the pharmacy clearly misfilled the prescription, and after damages were shown at trial, the court awarded damages of \$25,000 for each girl.

The second issue raised in this case focused on whether punitive damages (damages meant to punish the defendant) should be awarded to Kahn.

Kahn sought punitive damages based on CVS's failure to investigate and to ensure that she had received the correct prescription. To succeed on her claim for punitive damages, Kahn had to demonstrate that CVS acted with actual malice. Actual malice is demonstrated either by "behavior characterized by hatred, ill will, or a spirit of revenge or by extremely reckless behavior revealing a conscious disregard for a great and obvious harm." Kahn argued that CVS and its employees acted with conscious disregard. To survive a summary-judgment challenge on punitive damages based on conscious disregard, Kahn had to show that

"reasonable minds could differ as to whether CVS was aware its act had a great probability of causing substantial harm," and that reasonable minds could differ as to whether "CVS consciously disregarded Rose and Sara Kahn's rights or safety."

In support of her claim for punitive damages, Kahn offered the affidavit of Albert Patterson, director of pharmacy at Children's Hospital in Boston, and the deposition of Jennifer Rudell, a pharmacy supervisor for CVS. In his affidavit, Patterson stated that "Mr. Husman had to know that the children could suffer from not only the Clonidine withdrawal but also the ingestion of an unknown medication that could be extremely dangerous to them." In his affidavit, Patterson also listed the results that could follow from a withdrawal of Clonidine, including hyperactive, agitated behavior and irrepressible sexualized behavior.

In her deposition, Rudell stated that if a pharmacy employee received a call from a customer who thought she had received the wrong medication, the employee should have immediately given the phone to the pharmacist. According to Ruddell, a reasonable pharmacist should have asked for a description of the pills and should have compared the description with the prescribed pills. If a discrepancy occurred, Ruddell stated, the pharmacist should have asked the customer to bring the pills in for further investigation.

CVS disputed whether Kahn called the pharmacy to report her misgivings about the pills that she had received, but that was a factual issue best resolved by a jury. Viewing the evidence in the light most favorable to Kahn, the court concluded that reasonable minds could come to different conclusions about whether CVS was aware that its actions had a great probability of causing substantial harm to Rose and Sara, and about whether CVS consciously disregarded the girls' safety. As such, this issue was allowed to proceed at trial.

McKee v. Wal-Mart Stores

The second case illustrates the importance of patient counseling. A mother took her child to see her pediatrician on Nov. 10, 2003, due to sinus, allergy, and related complaints. Initially, the pediatrician told the mother that he would give her daughter an antibiotic called Omnicef. He counseled her on the proper administration of Omnicef and gave her an instruction sheet concerning this drug. However, apparently when he realized that he did not have

samples, he wrote a prescription for another antibiotic called Septra DS. He did not advise her of the change.

She took the prescription to the Wal-Mart store in Zachary, Louisiana, where the pharmacist filled the prescription as written. Wal-Mart stipulated that it did have a duty to counsel regarding the prescription and that it breached the duty by failing to properly counsel. Furthermore, had the Wal-Mart pharmacist counseled, the pharmacist would have called the pediatrician to see what he intended to prescribe, yet they did dispense generic Septra DS to the child, and the child did suffer certain damages.

Wal-Mart allegedly breached the duty of its pharmacist to counsel the child's mother regarding a prescription it dispensed for her daughter. Specifically, this case focused on whether the patient's harm was foreseeable on the part of the pharmacist.

No evidence in the record filed in connection with the motion for summary judgment suggested that Wal-Mart acted in a dangerous or improper manner when dispensing Septra DS to the mother's child. At worst, her medical expert states that such a prescription was "not a prudent choice." Other evidence asserted that the prescription for generic Septra DS was appropriate, though perhaps not the first choice for treatment. And no evidence suggested that the side effects suffered from the prescription were common or expected. Instead, the only evidence presented in this regard was that the child's reaction was extremely rare, especially since she had taken the medication before.

While complications are foreseeable from taking any medication, the court did not find it to be reasonably foreseeable that the rare harm suffered in this case would result from the failure to counsel a patient, which resulted in the dispensation of an apparently appropriate antibiotic. The court found that it could not associate Wal-Mart's failure to counsel the child's mother with the development of a rare side effect from an allegedly incorrect, nevertheless appropriate, antibiotic. By reviewing federal and state counseling requirements, the duty imposed on Wal-Mart did not require that a patient be counseled regarding rare or remotely possible side effects.

The stated purpose of a pharmacist's duty to counsel is "to improve therapeutic outcomes by maximizing proper use of prescription medications and devices." The child's mother only argued that had she received counseling, she would have been alerted, and the

pharmacist would have called the doctor, who would have realized his mistake and corrected the prescription to prescribe Omnicef. While the court recognized that a jury could believe this scenario, the court did not hold that the purposes underlying the regulated duty for pharmacy counseling encompassed this factual scenario in which the child's mother would have been alerted to a possible error.

A fact important to note is that though this adverse effect was deemed "rare" and not foreseeable on the part of the pharmacist, the pharmacist still did not fulfill his duty to his patient. Pharmacists must make the "offer to discuss" to all patients matters they deem significant in their professional judgment. This is one of the requirements of the Omnibus Budget and Reconciliation Act of 1990 (OBRA '90), a law the courts will often examine in determining a pharmacist's duty.

Deed v. Walgreen Company, et al

The last case focuses on the issue of whether a pharmacist may be found liable for continuing to fill prescriptions for a patient who ultimately dies as a result of continued use of controlled substances.

Pauline Deed died on Jan. 4, 2002, of "acute carisoprodol and oxycodone toxicity," according to the state medical examiner. These facts are undisputed. Further undisputed facts include that in the year preceding her death, Deed regularly took carisoprodol and oxycodone for pain relief, muscle tension, anxiety, depression, and nausea, and that prescriptions for those medications were filled at the East Hartford drug store of the named defendant, the Walgreen Co. (Walgreen's).

During the year prior to her death, Deed submitted to Walgreen's approximately 149 prescriptions, all of which were filled according to the directions of the physicians prescribing the medications. Her primary care physician wrote the overwhelming majority of those prescriptions.

This lawsuit was an action for damages for Deed's wrongful death brought by the plaintiff,

Philip L. Deed, administrator of her estate. The allegations of negligence on Walgreen's part claimed that "Walgreen's knew or should have known that the combination of medications being supplied to Deed would cause her harm and could have and should have taken measures to remedy or correct it, but that the defendant negligently and carelessly failed to do so," and/or "Walgreen's continued to fill prescriptions for medications it knew or should have known would cause harm and/or death to Deed."

In examining this case, the court held that the "learned intermediary doctrine" applied in determining the liability of pharmacies for dispensing drugs prescribed by physicians. That doctrine had originally been applied to shield drug manufacturers from liability for not warning consumers of the negative effects of their drugs as long as they had given adequate warnings to prescribing physicians of the dangers associated with their products. The physician became the learned intermediary between the drug manufacturer and his patient. "The learned intermediary doctrine stands for the proposition that, as a matter of law, the prescribing physician of a prescription drug is the person best able to take or recommend precautions against the harm associated with the drug." The court concluded that "there was no logical reason why the learned intermediary doctrine should not be extended to pharmacies and pharmacists," subject to certain exceptions delineated in case law from other states which had previously considered the issue.

The one exception to the doctrine which the plaintiff claims applies here arises "when a pharmacy or pharmacist has specific knowledge of potential harm to specific persons in particular cases." When that situation exists, the pharmacy has a duty to warn and may be liable for the consequences of its failure to do so. In finding for Walgreen's, the court stated:

"[C]ourts holding that pharmacists owe their customers a duty beyond accurately filling prescriptions do so based on the presence of

additional factors, such as known contraindications, that would alert a reasonably prudent pharmacist to a potential problem." For example, in another case, a doctor prescribed psychotropic drugs to a patient the pharmacist knew to be an alcoholic. The pharmacist also knew the drugs were contraindicated with the use of alcohol, yet continued to dispense them to the patient for six years without warning her of the danger. The patient died of pancreatitis associated with a severe degree of cirrhosis. The court in that case reversed the summary judgment granted in favor of the pharmacy because it knew or should have known that the prescribed drugs were contraindicated with alcohol. In the absence of such special circumstances, courts generally hold that "a pharmacist owes no duty to warn his customer of the potential dangers of a prescribed medication."

Even where a patient is being overmedicated or overdoses on a medication, a pharmacy has no duty to notify the patient that he is being overmedicated because the duty to warn falls on the prescribing physician. The court noted the patient has the duty to notify the prescribing physician of other drugs that the patient is taking. In another case, the plaintiff's wife died of an overdose of prescription drugs. He sued the dispensing pharmacy, alleging negligence in its dispensing of drugs in quantities beyond those normally prescribed. The court found in favor of the pharmacy, noting that placing such a duty on pharmacists would require them to learn a patient's condition and to monitor their drug usage—functions the court noted were more appropriately undertaken by physicians.

The administrator in the present case argues that Walgreen's had a duty to Deed to warn her and/or to contact her physician based solely on the number and frequency of the prescriptions she submitted. He cited no authority for such a duty, and the court could find none. The cases in which courts have found a duty to warn on the part of a pharmacy are based on some knowledge on the pharmacist's part superior to that of the customer; in other words, that the prescribed drug is contraindicated for the customer or conflicts with other drugs the customer is taking. Here, Deed knew all the drugs she was taking, from whom she had obtained them, how frequently and for what purpose; so, the pharmacy had no knowledge superior to hers and no duty to warn. Further, the duty to inform her physician of the drugs she was taking was Deed's. "To impose a duty to warn on the pharmacist

would be to place the pharmacist in the middle of the doctor-patient relationship.”

Such a duty would compel the pharmacist to “second guess every prescription a doctor orders in an attempt to escape liability.” The material fact here is whether Walgreen’s had any specific knowledge of potential harm to Deed that might arise from the prescriptions she was taking. No genuine issue exists: Walgreen’s did not have any such knowledge and therefore, had no duty to warn her and no liability for the tragic consequences of her ingesting those drugs.

As mentioned earlier, the court found for Walgreen’s. Though the pharmacy prevailed in this particular lawsuit, the court made some disturbing comments. Specifically, the courts stated that pharmacists should not be placed in the middle of the doctor-patient relationship. As a valued and essential member of the health-care triad relationship, pharmacists play an important role in ensuring patients’ health and well being. Though the courts implied that the pharmacist’s role would involve “second guessing every prescription,” pharmacists should question an inappropriate prescription and drug usage. This not only protects pharmacists legally, but more importantly, this is the right thing to do.

Furthermore, with the advent of controlled substance prescription drug databases, pharmacists have a greater ability to potentially track and determine controlled substance use or abuse. With more states enacting such tracking devices, pharmacists who fail to utilize this technology may find themselves liable in a court of law. Therefore, the imperative is clear—pharmacists must use every resource available in the hope of preventing patient harm.

CONCLUSION

Perfection is not an attribute of human nature. Medication misadventures will happen. Even with the brightest professional operating the most sophisticated technology, errors will inevitably result which may cause patient harm. Pharmacists should recognize that opportunities do exist to prevent errors and to take actions to minimize the risk of harm to a patient. In the event patient harm does result, multiple opportunities are available to minimize the risk of loss to the individual pharmacist and the employing organization.

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Editor’s Note: To obtain the complete list of references used in the article, contact Chris Linville at NCPA (703-838-2680), or at chris.linville@ncpanet.org.

CONTINUING EDUCATION QUIZ

Select the correct answer.

1. Preventable medication errors harm approximately how many people each year?

- a. 500,000
- b. 1.5 million
- c. 2.5 million
- d. 4 million
- e. 4.5 million

2. Under the common law theory of *res ipsa loquitur*, an injured patient:

- a. Has the burden of proof to establish that the pharmacist failed to exercise reasonable care of a professional nature
- b. Must file such an action in federal court
- c. Must show that the patient's injury could not have occurred without the pharmacist's negligence
- d. Will frequently establish negligence in this manner

3. In establishing a negligence-based case the patient must establish all of the following elements EXCEPT:

- a. That the pharmacist was licensed in the jurisdiction in which they practiced
- b. That the pharmacist had a duty to protect the patient
- c. That the pharmacist breached their duty to protect the patient
- d. That the patient was injured by the pharmacist's actions
- e. That a causal relationship existed between the breach of duty and the patient's injury

4. A breach of the duty of care a pharmacist owes to a patient would include which of the following?

- a. Dispensing an incorrect drug
- b. Substituting an incorrect ingredient into a compound
- c. Incorrectly labeling physician instructions
- d. Dispensing an incorrect dosage of a drug
- e. All of the above

5. It has been reported that _____ percent of all malpractice claims result from the right prescription being placed in the wrong patient's bag.

- a. 2 percent
- b. 4 percent
- c. 8 percent
- d. 11 percent
- e. 13 percent

6. If a patient suffers injury from a pharmacist's negligent action, the patient may be able to recover which of the following?

- a. Cost of medical bills associated with injury
- b. Loss of income
- c. Damages for pain and suffering
- d. A and B only
- e. A, B, and C

7. Which of the following will likely to result in a greater damage award to the patient if pharmacist negligence is determined?

- a. Cost of medical bills associated with injury
- b. Loss of income
- c. Damages for pain and suffering
- d. A and B only
- e. A, B, and C

8. Under the legal element of causation in negligence case, a pharmacist may:

- a. Be found to cause some, but not all, of a patient's injuries
- b. Be found to be responsible for some, but not all, of a patient's damages
- c. Be held liable if a connection is made between the patient's injuries and the pharmacist's improper filling of a prescription.
- d. A and B only
- e. A, B, and C

9. A *per se* violation might be considered if the pharmacist failed to perform which of the following acts?

- a. Apologizing to a patient for a medication error
- b. Patient counseling
- c. Accurately complying with antitrust provisions
- d. Allowing a state board of pharmacy inspector to enter the pharmacy
- e. Accurately charging a patient for a medication

10. Which of following individuals at a trial typically determine if a pharmacist has breached professional practice standards?

- a. Jurors
- b. Judge
- c. Other pharmacists
- d. Experts
- e. Professors

11. Pharmacists are typically held to which of the following practice standards?

- a. City
- b. Regional
- c. State
- d. National
- e. International

12. The first step in error prevention is to:

- a. Address sound-alike drug names.
- b. Eliminate abbreviations.
- c. Utilize electronic transmission devices for prescriptions.
- d. Encourage patients to take a more active role in their own medical care.
- e. Eliminate distractions in the pharmacy practice setting.

13. Which of the following practices may help minimize or prevent potential medication problems?

- a. Pharmacists should encourage patients to ask questions, but pharmacists should never ask the patient questions.
- b. Pharmacists should open vials to allow patients to make connections between information presented and the drug.
- c. Pharmacists should provide written information that emphasizes the major counseling points.
- d. A and B only
- e. B and C only

14. Which of the following are likely to result in medication error prone situations?

- a. Abbreviations
- b. Symbols
- c. Dose designations
- d. A and B
- e. A, B, and C

15. With the legal theory of contributory negligence, the patient would:

- a. Be completely barred from damage recovery if the patient's own negligence, even slight, contributed to his injuries
- b. Be partially barred from damage recovery if the patient's own negligence contributed to his injuries
- c. Be able to collect full damages for injuries even if the patient's own negligence contributed to his injuries
- d. Have his recovery reduced by a percentage of his own fault associated with his injury
- e. Have his recovery reduced up to 50 percent if his contribution to his own injury was less than 50 percent

16. Statutes of limitations in pharmacy malpractice actions:

- a. Are governed by federal laws
- b. Are laws which provide for an unlimited period of time in which to bring a negligence based cause of action
- c. Typically prescribe the period of time with which a legal action must be brought
- d. Generally limit the size of the damage award allowed in such actions
- e. Prohibit claims if the pharmacist acted within the scope of practice

17. Apology legislation:

- a. Typically protects partial apologies and expressions of remorse from being used in court
- b. Typically protects full apologies and expressions of remorse from being used in court
- c. Typically protects apologies made within seven days of the event from being used in court
- d. Has been adopted in all states
- e. B and C

- 18.** When an error occurs, the patient needs to hear which of the following comments?
- An explanation of what happened
 - Assurances that changes have been made to prevent the error from happening again
 - An apology from whoever is responsible
 - A and B
 - A, B, and C

- 19.** An apology serves which of the following functions?
- To heal hurt feelings
 - To provide an avenue for resolution of patient-pharmacist conflict
 - To replace the need for patient compensation
 - A and B
 - A, B, and C

- 20.** An occurrence insurance policy provides that for the policy to cover a claim:
- The pharmacist must be registered in the state where the claim is filed.
 - The policy must be in effect during the time the claim is filed.
 - The policy must have been in effect when the incident occurred resulting in the claim.
 - The pharmacist must have continued the policy over time until the claim is filed.
 - The pharmacist must have purchased a single-premium tail policy.

Pharmacy Malpractice: Understanding, Mitigation, and Prevention

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 Last 4 digits of SSN MM-DD of birth

 Name

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 Phone number (store or home)

 Store e-mail (if avail.) Date quiz taken

Quiz: Shade in your choice

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Quiz: Circle your choice

21. Is this program used to meet your mandatory C.E. requirements?
a. yes **b.** no
22. Type of pharmacist: **a.** owner **b.** manager **c.** employee
23. Age group: **a.** 21–30 **b.** 31–40 **c.** 41–50 **d.** 51–60 **e.** Over 60
24. Did this article achieve its stated objectives? **a.** yes **b.** no
25. How much of this program can you apply in practice?
a. all **b.** some **c.** very little **d.** none

How long did it take you to complete both the reading and the quiz? _____ minutes



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