

Pharmacist Practice and Liability

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The risk management of pharmacist malpractice includes identifying theories of liability through the examination of case law and civil litigation. Pharmacists have an independent duty to protect their patients from harm and must consult with prescribing physicians in a positive way so that mistakes and misunderstandings can be avoided or corrected. The volume of daily work that each pharmacist must perform has made it necessary for pharmacy technicians to perform many of the steps in filling a prescription. Unfortunately, this practice may increase liability for the pharmacist. This article presents an overview of pharmacy practice and liability and suggests policies and procedures that may help mitigate the potentially perilous legal consequences for pharmacists.

Keywords: pharmacist malpractice; OBRA 90; pharmacy technicians; counseling; liability; pharmacokinetics

PHARMACIST MALPRACTICE OVERVIEW

The risk management of pharmacist malpractice includes identifying theories of liability through the examination of case law and civil litigation. Pharmacists have an independent duty to protect their patients from harm and must consult with prescribing physicians in a positive way so that mistakes and misunderstandings can be avoided or corrected. The volume of daily work that each pharmacist must perform has made it necessary for pharmacy technicians to perform many of the steps in filling a prescription. Each and every prescription must still be checked and approved by a licensed pharmacist. This is mandated both by law and by professional obligation. All of these obligations are in force for all prescription drugs.

Pharmacists Mutual Insurance Claims Study 2000 has compiled statistics for claims made for the period 1989–1999 (Figure 1).

Pharmacists Mutual has identified the categories of errors and omissions that are most responsible for claims made against pharmacists for malpractice. Some of the most common errors, such as wrong drug (50%) or wrong strength (25%), have not varied much over this 10-year period, probably because errors made under a continuous and stressful workload are part of the human condition. Other sources of claims, such as breaches of patient confidentiality and issues of free speech, may simply be due to ignorance and can be corrected through continuing pharmacist education.

Wrong Drug

In the latest version of the Pharmacists Mutual study, the largest category of claims against pharmacists (50.4%) is wrong drug. This is also the most potentially dangerous error. Since 1990, this number has remained relatively consistent in each version of the study.

The causes of and reasons for these errors are varied. In one claim, the pharmacist took a prescription over the phone from a doctor's office for digoxin. The pharmacist prepared the label, counted the correct drug (digoxin) into the tray, and then poured it into the bottle. As he placed the bottle next to the completed label, the phone rang again, with a request for warfarin. The pharmacist filled the prescription for warfarin in the same manner, but somehow, the two labels were mixed up. The warfarin bottle received the digoxin label and was given to the wrong patient.

In other cases, a technician simply took the wrong bottle from the shelf and counted out the wrong drug. If a busy pharmacist does not catch the error when performing the check, or does not check the technician's work, the results can be serious. Often caused by misinterpretation of poor handwriting, this is the most dangerous type of pharmacist error. There is increased interest in electronic prescribing, which would help obviate such interpretative errors between physician and pharmacist.

Sometimes drug names look alike. For example, prescriptions for Navane can be mistaken for Norvasc, Prilosec for Prozac, Lasix for Losec. Interestingly, the Lasix/Losec error precipitated a name change by the

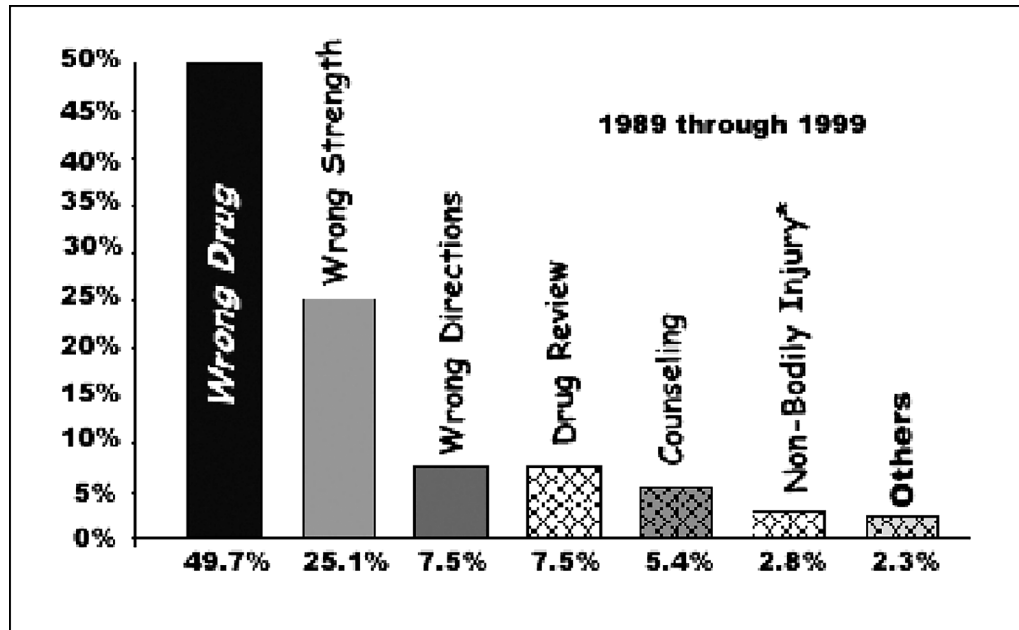


Figure 1. Pharmacists Mutual Claims Study 2000.

Losec manufacturer (it was renamed Prilosec). After that, Prilosec and Prozac began to be mistakenly dispensed in place of one another. This problem occurs so frequently that a special committee of the United States Pharmacopeia (USP) has been formed to look at the selection of new drug names. There is an evolving science in understanding and preventing this error of fine distinction.

Distractions in the pharmacy are another common and unavoidable part of every workday. Label switches can result, due to a pharmacist's multitasking, or filling multiple prescriptions for a single patient. A patient may have a prescription for Coumadin once a day and Lasix twice a day, for example. If the labels are switched, and the patient ends up taking Coumadin twice a day, he may suffer a serious hemorrhage.

Wrong Strength of the Drug

The second largest category of claims (24.4%) shown in the Pharmacists Mutual Study is wrong strength. A common example would be receiving a prescription for digoxin 0.125 mg, and filling it in error with digoxin 0.25 mg. Depending upon the drug prescribed, the results of selecting the wrong strength could be dangerous, or even fatal, in drugs with narrow margins of therapeutic safety. The other common outcome is a

lack of efficacy, such as thrombosis with a Coumadin low-dosage error, or congestive heart failure in a low-dosage digoxin error.

Particular problems in the area of wrong strength claims are those drugs available in multiple strengths, such as Coumadin and Synthroid. There are two main ways in which these errors occur. The first is simply picking up the wrong bottle when filling the prescription. The label may be correct, but a different strength drug is placed in the bottle. The second way is by entering the strength incorrectly into the computer for a new prescription. Pharmacists and technicians need to be alert to these types of errors and develop risk management techniques to prevent them from occurring.

Even old, familiar drugs are subject to this kind of error. The drugs that are filled most frequently are going to be involved in more errors, simply as a matter of incidence. For example, Haldol is used for senile dementia. It would be unusual for Haldol 5 mg to be prescribed for an ambulatory elderly patient. A more common dosage is 0.5 mg. The drugs with the greatest numbers of available dosage forms offer the greatest probability for a dosage error.

The drugs that can cause the most toxicity are also those that will result in claims. If the patient suffers some type of damage or adverse effect—even if the patient only has to present to an emergency room because

of the error—this can result in a cause of action against the pharmacist and the pharmacy.

Wrong Directions

At 7.8%, wrong directions represents a significant number of the claims reported in the Pharmacists Mutual Study. These cases involve incorrectly entering the directions into the computer. For example, in one claim, the pharmacist entered a new prescription for birth control tablets into the computer and inadvertently typed, "Take two tablets daily." For nine months, this patient refilled her birth control prescription every 15 days while following the erroneous label directions, apparently without anyone at the pharmacy noticing the discrepancy.

Often these wrong directions claims are for children's prescriptions. Technicians and pharmacists need to be particularly alert to directions when a young child is involved—especially when the child is under six years of age. The pharmacist should always know the age of the child when checking a prescription. The "under-six" rule is a good one to follow. If any patient is under six years of age, the pharmacist should take extra care when reviewing the directions and when looking for errors.

With all patients, the pharmacist should check the label directions against the "hard copy" prescription. Another good idea is for the pharmacist to follow a standard procedure of removing the prescription from the bag as he counsels each patient. The pharmacist should read the written directions to the patient and ask, "How did your doctor explain you were to take this medication?" The pharmacist can use similar words to determine whether the patient understands what the directions mean. This serves two additional purposes: it allows the pharmacist to double-check the label directions, and, by removing the prescription from the bag, it creates the appearance of a professional service rather than merely sales of a commodity in a sack.

Physicians are shielded from distraction by their receptionists and office staff members, who often pride themselves on not allowing interruptions of the busy doctor. However, these prescription errors are examples of occasions when the physician must be consulted. Pharmacists cannot read physicians' minds—even if they are used to reading their handwriting. Pharmacists must have the determination to actually call and ask for help in interpreting a confusing prescription. When the pharmacist observes what appears to be an error in the physician's prescription, diplomacy is the best tactic. The pharmacist should not just identify a problem but also offer a solution.

Drug Review

The largest category of "intellectual errors" is now represented by drug review claims. A part of the OBRA-90 (Omnibus Budget Reconciliation Act) mandate is that the pharmacist is charged with reviewing all prescriptions prior to filling them—checking for interactions, allergies, and a list of other potential problems. This area of claims has risen from 0% in 1991 to over 9% of all claims.

Although the drug review is a new area of liability for pharmacists, it was actually first described in *The Standard of Practice of the Profession of Pharmacy* (Kalman & Schlegel, 1979). The American Pharmaceutical Association (APhA), in concert with the American Association of Colleges of Pharmacy (AACCP), has defined standards of practice for the profession of pharmacy. Many or all of the requirements that were eventually legislated and mandated by the Omnibus Budget Reconciliation Act (OBRA) were already components of the standards of practice, even before this legislation. OBRA requires medication profiles, as well as review for therapeutic duplication, allergy, cross-sensitivity, drug disease, and contraindications.

It took 15 to 20 years from the development of these safety practices described in the 1970s until the passage of OBRA. As a result of this mandate, failure to provide meaningful patient drug review has resulted in claims and lawsuits that plead error of omission. If pharmacists counsel patients and talk to them about how a drug should be used, what it is intended to do for their health, and what to avoid, the pharmacist is involving the patient in making sure that his or her drug therapy is safe and effective. By the time the pharmacist then hands the drug to the patient face to face, 95% of the errors that occur in the filling process will have been detected.

Progressive pharmacy companies make it a standard business practice to actually counsel the patient on every new prescription, instead of merely offering a perfunctory option to the patient of obtaining counseling if they have any questions for the pharmacist. Rather than actually requiring counseling, OBRA requires that the pharmacist *offer* to counsel the patient. With critical-care drugs, failure to counsel leads to predictable and serious problems. Inadequate or incomplete counseling—as well as lack of documentation or proof of counseling—are omissions that can indicate that the pharmacist is providing a lower-than-standard level of care. The patient cannot be expected to understand everything in the patient package insert (PPI) without professional advice and guidance from the pharmacist.

The Supreme Court of Illinois recently reviewed a case involving Wal-Mart Pharmacy, where the patient

told all of her physicians that she was allergic to aspirin. After a medical procedure, the patient was given a prescription for Toradol, despite her known allergy. She took the prescription to the Wal-Mart Pharmacy, who (appropriately) asked her if she had any drug allergies. As always, the patient responded that she was allergic to aspirin. The Wal-Mart Pharmacy filled the Toradol prescription anyway. The patient developed anaphylaxis, recovering after emergency treatment. When the patient brought suit against Wal-Mart, the insurance carrier and Wal-Mart's counsel argued strenuously that the pharmacist had no duty to warn, because warning of cross-allergenicity was the physician's responsibility.

Precedent cases involving the same theory have accumulated, eliminating any doubt that the pharmacist has a duty to screen for cross-allergenicity. The standard of care requires that the pharmacist should have called the physician and informed him that his patient was allergic to aspirin. Because there is cross-sensitivity for Toradol in patients allergic to aspirin, giving Toradol was contraindicated. The pharmacist should have suggested an analgesic with no cross-allergenicity to aspirin. In any case, he should have refused to dispense this drug to a patient at risk (*Heidi Happel v. Wal-Mart Stores*, 2002).

Counseling

Counseling is also a growing area of claims (compared to just a few years ago). Most of these claims are for "failure to counsel," but a few involve allegations of "inadequate" or "incorrect" counseling. Patients often report that the pharmacist failed to counsel, when in reality, they did receive counseling (but there is no record of this having taken place). This is also a growing area for boards of pharmacy to administer disciplinary actions.

In one case, when dispensing trazodone, a pharmacist printed out only the short form of the PPI from the computer, instead of the long form, which included the USP DI warning that this drug can cause prolonged erections, and to call a physician if this side effect occurs. The standard of care requires that pharmacists provide complete and accurate counseling, which should include printing the long form PPI (*Cottam v. CVS Pharmacy*, 2002).

It is important that the pharmacist follow state laws. It is equally important that there be some form of quick documentation (that can be later shown as evidence) that counseling took place. One practical means of doing this is to place a mark on each new prescription, such as "O/W_____ initials of RPh_____ date____," written on the front of the

prescription. This shows that the pharmacist provided oral (O) and written (W) counseling (in the form of a patient-information leaflet). Documentation must always be after the fact, so the marks must be made only after the counseling was actually given. This type of documentation is not foolproof, but it is certainly better than not having documentation at all.

Non-Bodily Injury

"Personal injury" is an insurance term. These types of claims are also referred to as non-bodily injury claims. These claims involve liable, slander, false arrest, and/or unauthorized release of confidential records. Unauthorized release of confidential records accounts for approximately one-half of these types of claims. This is another fast-growing area of professional liability claims against pharmacists. These claims usually involve the pharmacist or technician but may involve any employee in the pharmacy or hospital.

The risk of being sued increases when there are confidentiality violations or breaches related to mental health issues, sexually transmitted diseases, use of birth control, or the release of prescription records to a relative. For example, one technician filled a prescription for an AIDS drug and recognized that the man was receiving treatment for HIV. The patient's son was acquainted with the technician's own children, and the technician told her children not to associate with their friend anymore. When the patient discovered that the pharmacy had disclosed information about his HIV treatment, he brought suit against the pharmacy.

Others

Safety cap claims either involve the pharmacist not following federal law, or the pharmacist being unable to prove it was the patient who requested "no safety cap." From Pharmacist Mutual's claims experience, the pharmacist cannot rely on a notation in the computer, nor on the testimony, "I always use safety caps, unless the patient requests otherwise." For the pharmacist's protection, the patient or caregiver should be required to sign a written request for each new prescription. It is also not wise to rely on a blanket release that is renewed only once a year.

Generic claims usually involve pharmacist mistakes. In these claims, the pharmacist believes the product is generically equivalent and bioequivalent but is mistaken. Recently, however, Pharmacist Mutual has received a couple of claims involving AB-rated drugs. In these few cases, damages have been alleged, but they have not been proven to be the result of substitutions.

HOSPITAL AND HOME-CARE PHARMACY

Specialty Compounding

Hospital therapy involving the preparation of intravenous (IV) solutions for treating acutely ill patients is an area in which it is critical to avoid mistakes. Total parenteral nutrition (TPN) involves a form of specialty compounding performed in the hospital pharmacy. Close coordination between the medical staff and the compounding pharmacist is a vital necessity here. There is a greater risk for errors with this activity, and when errors occur, they tend to result in more serious outcomes from life-threatening infections. TPN involves many ingredients. Incorrect mixing of TPN solutions exposes patients to rapidly occurring, life-threatening events. TPN patients can suffer from brain damage—or even die—as a result of a lack of control or supervision in this programming. Examples include the substitution of insulin for heparin, overdoses of sodium, excessive or no glucose, and alterations and errors in almost any ingredient. Many deaths and permanent injuries have been reported as a result of compounding errors in hospital and home-care pharmacies.

One home-care pharmacist with sloppy pharmacy techniques dispensed syringes filled with potassium chloride, instead of sodium chloride, which resulted in sudden asystole and cardiac arrest. The infant patient was resuscitated, but profound brain damage resulted from the period of hypoxia during the cardiac arrest. An investigation revealed that the technicians prepacked syringes of NaCl and KCL for use in home-care compounding and syringe dilution. The bags were mislabeled in the refrigerator storage bags; individual syringes were not labeled. The investigation further revealed that the pharmacist in charge was not licensed as a pharmacist in the United States. The home-care pharmacy settled the lawsuit with the family of the brain-damaged child, rather than going to court.

Cardioplegia

Cardioplegia solutions must be mixed extemporaneously, if the surgeon wants a particular formula. Incorrect formulations have involved excessive potassium and the absence of potassium or dextrose. All of the components are critical. A Springfield, Missouri, hospital once inaccurately compounded cardioplegia solutions, with fatal results. The hospital was sued and was subjected to a punitive-damage award (*Lester B. Cobb Memorial Hospital, Springfield, MO v. Baxter Laboratories*, 1989). In my own hospital practice, 30 years ago, we sent a sample of each cardioplegia production

solution to the hospital's stat chemistry lab to document dextrose, potassium, electrolyte, and pH results, thus assuring that the specially compounded solution was, indeed, accurate. If the patient did not respond as expected, it was not considered a compounding error by the pharmacist.

Pediatrics

Pediatric patients are at greater risk (Koren, 2002). A child in Boston was given an enalaprilate compounded in the hospital (because a commercial solution of the intended concentration was not available, as is often the case with pediatric drugs). The drug was not diluted. A 125x overdose caused prolonged hypotension and resulted in serious brain damage to the child, who was awarded a multi-million-dollar judgment.

Another child in a Wisconsin hospital received a ten-fold overdose of digoxin, due to a dosage miscalculation by a hospital pharmacist. The nurses did not detect the error. The child died. The hospital was sued and settled the case. The State Pharmacy Board of Wisconsin learned of the lawsuit and settlement and charged the pharmacist and the hospital pharmacy director with failure to report the error (a little-known regulation in Wisconsin—one that exists in only a few states).

Pharmacokinetics—Aminoglycoside Nephrotoxicity and Ototoxicity

Aminoglycosides, such as gentamicin, have a well-known ability to cause damage to the kidneys, as well as to both the auditory and vestibular portions of the inner ear. This toxicity is both dosage- and time-dependent, requiring careful monitoring of serum peak and trough concentrations to attempt to provide antibiotic coverage without having a concentration level likely to cause nephrotoxicity and ototoxicity. One patient developed vestibulopathy after 30 days of treatment with an aminoglycoside. The pharmacist responsible for monitoring the therapy testified that, despite having a policy and procedure describing ototoxicity monitoring, pharmacists do not usually perform this monitoring.

Pharmacists should realize that while their pharmacies may not order or perform the tests for renal or audiometric function, they are still responsible for recommending that the testing be done. They are also responsible for checking the results of patients' testing, in order to safeguard them from avoidable harm. Part of the pharmacist's duty to counsel the patient is to see that his drug therapy is being correctly given, and monitored, if necessary. This is especially true with pharmacokinetic dosing for aminoglycosides,

where “gentamicin dosing by pharmacy” is a commonly seen order. There are so many patients who have suffered vestibular damage from gentamicin that they have created their own Web site (<http://www.wobblers.com>).

Normally, the vestibular system allows the brain to “cancel out” the head motion from the visual images we see. Without it, all motion is seen, and this causes our visual world to appear as though it were a video taken by an amateur. All of this causes a person to appear to be intoxicated when they walk (hence, the nickname “wobblers”).

Anticoagulation

Advanced practice anticoagulation clinics employ transplant pharmacists who are becoming more involved in treatment. This setting necessitates a higher standard of care for the pharmacist. Protocol should be developed in concert with responsible physician clinicians, and pharmacists should strive to observe protocol.

Managed Care

In another insurance-related case, an instance of patient abandonment occurred in New Jersey. A psychiatric patient getting mail-order pills from a Florida pharmacy called and placed a phone order. When the promised prescriptions did not arrive, the patient called the pharmacy back to inquire about the status of his pills. He was told, “They are in the mail.” In reality, the pharmacy had placed the prescription on hold because the patient’s insurance company was delinquent in paying the pharmacy for its mail-order prescriptions. The patient never received his drugs. After being without his required medication, his mental state deteriorated. He was admitted to a psychiatric hospital several times and eventually committed suicide.

In court, the patient’s psychiatrist testified that the suicide was the result of decompensation caused by the withdrawal of effective psychotropic medication. An investigation of the case revealed that the patient was abandoned because he had fallen into some type of “insurance-hold loop.” A more professional and compassionate approach would have been to call the patient and explain that he would have to do something else to obtain his medication for a short period of time, because of lack of insurance approval.

CONCLUSION

This author is frequently asked by pharmacists and risk managers, “How can we avoid malpractice?” The response has always been to practice at a high level. When you do your job well, drugs will be used more effica-

ciously and safely, and patients will suffer fewer drug injuries. Do not try to do more work than can be safely done in a specified period of time. Make sure you have adequate resources. Also, talk to your patients. It is a widely accepted fact that 95% of pharmacists’ errors can be detected during patient counseling. Counseling is the standard of practice, and it is good business. Stay within your practice area. Supervise your support staff. Utilize quality assurance and control techniques, where appropriate. Monitor the pharmacy literature. Read and circulate the Institute for Medication Safety Practices’ (www.ismp.org) newsletter. While pharmacy errors (and, thus, pharmacy malpractice) will never be completely eliminated, we must continue our efforts to minimize our mistakes and thereby protect the lives of our patients.

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