

Chapter 38

Pharmacist Malpractice and Liability

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A handful of high-profile medication error cases came under the media spotlight in November 2005, and television stations in Northern California (where the incidents were uncovered) reported the issue as though it was a horrifying new revelation. However, as every health care worker (and attorney) knows, drug mishaps are nothing new. In fact, studies dating back several years¹ show that about 2% of hospital patients experience preventable adverse drug events, although the majority of the events are not fatal. Medication error has been cited as the cause of death for one out of every 131 outpatient deaths and one in 854 inpatient deaths. One study estimated that 6.7% of hospitalizations resulted in an adverse drug reaction, and 0.32% of cases were fatal. This extrapolates to about 2,216,000 cases annually in hospitalized patients and 106,000 deaths.² Of course, it doesn't take a lawyer to figure out that this adds up to a whopping number of potential lawsuits against medical personnel.

Although originally these lawsuits were almost always aimed at physicians and nurses, pharmacists are now increasingly becoming the target of malpractice litigation. This phenomenon, predictably, has resulted in the development of strategies to help reduce the risks of medication errors, as well as to manage pharmacist liability.

THE SCIENCE OF RISK MANAGEMENT

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.

Pharmacists Mutual has identified the most common categories of errors and omissions that are responsible for claims made against pharmacists for malpractice (Fig. 38-1). They are, in order of frequency: wrong drug; wrong strength of drug; wrong directions; lack of drug review (which can result in allergies or contraindicated combinations of

drugs being administered); failure to properly counsel patients on medication usage; non-bodily injury; and other (miscellaneous).

MOST COMMON ERROR: WRONG DRUG

Since 1990, the number of "wrong drugs" administered has remained relatively consistent, although the reasons for these errors appear varied. In one case, the pharmacist took a prescription over the phone from a doctor's office for digoxin. The pharmacist prepared the label, counted the correct drug 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.

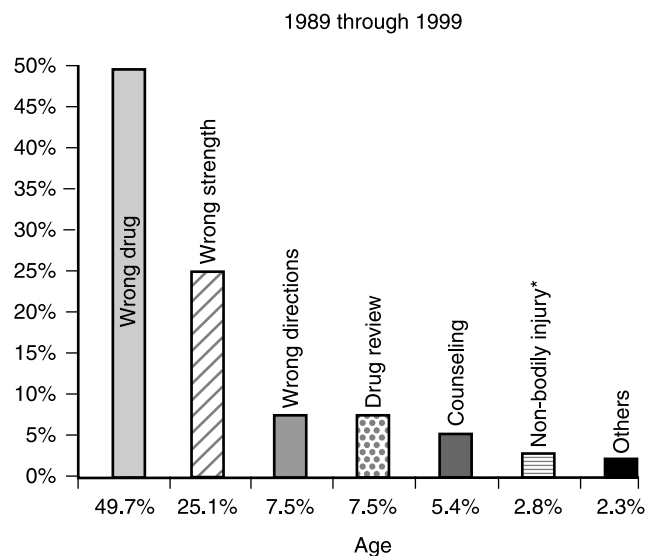


Figure 38-1 Pharmacists Mutual claims study, 2000.

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In another case, 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 he or she performs his check, or does not check the technician's work, the results can be serious.

Distractions in the pharmacy are another common and unavoidable part of every workday. Label switches can result because of a pharmacist's "multitasking," or filling multiple prescriptions for a single patient. A patient may have a prescription for Coumadin (warfarin) 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 from the Coumadin and congestive heart failure from undertreatment of the Lasix (furosemide).

THE "LOOK ALIKE" DRUG NAME PROBLEM

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 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.

Physicians' handwriting is another cause of pharmacist error. Often the subject of jokes, the typical physician's scrawl presents 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.

WRONG DRUG STRENGTH: ANOTHER COMMON ERROR

The second largest category of claims (25.1%) shown in the Pharmacists Mutual study (see Fig. 38-1) 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. In fact, misplacement of a decimal point is a very common way these errors occur. Another error is picking up the wrong bottle when filling the prescription. Perhaps the drug is correct, but the dosage is wrong. Depending upon the drug prescribed, the results of selecting the wrong strength can be dangerous, even fatal. Another common outcome is a lack of efficacy. For example, if too low a dose of an anticoagulant (such as Coumadin) is administered, it could fail to prevent a fatal clot.

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. These drugs also have the lowest "therapeutic index," that is, the relationship between a therapeutic level and toxic level is small. 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 7.5% of all claims, "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 case a pharmacist entered a new prescription for birth-control tablets into the computer and inadvertently typed, "Take two tablets daily." For 9 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. The most dangerous "wrong directions" claims are for children's prescriptions (and especially prescriptions for children under the age of 6 years).

In order to avoid labeling the prescription with the wrong directions, pharmacists should always check the label directions against the "hard copy" prescription. Another good practice 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. The pharmacist should ask the patient to repeat the directions on the prescription. 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 the sale of a "commodity" in a sack.

LACK OF DRUG REVIEW

OBRA-90 (Omnibus Budget Reconciliation Act) required pharmacists to review all prescriptions prior to filling them—checking for interactions, allergies, and a list of other potential problems. Especially because pharmacy technicians are increasingly being used to reduce the pharmacist's workload, this area of claims—previously almost unheard of—now represents over 7% of all claims.

Drug review was first described in the Standards of Practice of the Profession of Pharmacy.³ The American Pharmaceutical Association (APHA), in concert with the American Association of Colleges of Pharmacy (AACP), has defined standards of practice for the profession of pharmacy. Many or all of the requirements that were eventually legislated and mandated

by the 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. Failure to provide meaningful patient drug review has resulted in claims and lawsuits that plead error of omission.

The Supreme Court of Illinois recently reviewed a case involving Wal-Mart Pharmacy, in which 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, a drug contraindicated for patients allergic to aspirin. 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 (ketoralac) prescription anyway. The patient developed a life-threatening anaphylactic shock after taking the drug; fortunately, she recovered after emergency treatment. The patient later sued the Wal-Mart Pharmacy.

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 or she should have refused to dispense this drug to a patient at risk.⁴

COUNSELING: A POWERFUL WEAPON AGAINST LIABILITY

Progressive pharmacy companies make it a standard business practice to actually counsel each 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 without professional advice and guidance from the pharmacist.

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 action.

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 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.⁵

To avoid future litigation, pharmacists should employ some form of quick documentation (which 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). It should be noted, however, that simply providing a patient leaflet (patient information sheet) does not replace requisite counseling dictated by the prescription. Documentation is always verified after the fact, so the record must be made only after the counseling was actually provided. 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 libel, 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 any more. When the patient discovered that the pharmacy had disclosed information about his HIV treatment, he brought suit against the pharmacy.

OTHER (MISCELLANEOUS) ERRORS

At the end of the list of medication errors reported by Pharmacists Mutual is a category for “other.” This category may include several types of miscellaneous errors responsible for a significant number of claims.

One relatively new area of claims involves utilizing proper safety caps on prescription bottles. 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

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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 ordered without a safety cap. A once-a-year blanket release is inadequate.

Another area of miscellaneous claims involves the use of generic drugs. In these claims, the pharmacist usually believes that a generic product is equivalent to the brand-name drug, but is mistaken. Inadequate generic substitution may result in therapeutic inefficacy, adverse reactions, or allergies. A recent case in Illinois arose out of a pharmacist illegally substituting Dilantin (phenytoin) with a generic form of phenytoin. The patient, a 32-year-old quadriplegic who was in good seizure control, experienced a grand mal seizure. When the patient was hospitalized, the blood levels showed very low levels of phenytoin. An immediate investigation revealed that the pharmacist illegally substituted generic phenytoin, without any authorization from the prescriber. Once the case was in litigation, the pharmacist admitted that he violated the Illinois Pharmacy Practice Act; the case was eventually settled.

Hospital and home-care pharmacy therapy involving the preparation of intravenous (IV) solutions for treating acutely ill patients is another area where critical mistakes occur. These solutions are usually mixed in the pharmacy (called "compounding"). 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. 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 was reported to have dispensed syringes filled with 10% potassium chloride, instead of sodium chloride, which resulted in an infant patient's sudden cardiac arrest. Profound brain damage was the result. An investigation revealed that technicians had mislabeled the refrigerator storage bags. The case was eventually settled out of court.

In other case, a Springfield, Missouri, hospital inaccurately compounded a cardioplegia solution, with fatal results. The hospital was sued, and was subjected to a punitive damages award.⁶

When it comes to compounding, pediatric patients are at the greatest risk. In one case, a child in Boston was given a 125× overdose of a drug, causing prolonged low blood pressure and serious brain damage. The family was awarded a multimillion-dollar judgment. Another child in a Wisconsin hospital received a 10-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).

Some classes of drugs seem to lend themselves to medication errors and adverse events. For example, the 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 (eighth cranial nerve toxicity). This toxicity is both dosage- and time-dependent, requiring careful monitoring of serum peak and trough drug concentrations. Lack of monitoring can cause catastrophic kidney and ear damage to patients, and liability for the pharmacist and physician. The vestibular damage can result in terrible balance problems for affected patients. In fact, there are so many patients who have suffered vestibular damage from gentamicin that they have created their own website (<http://www.wobblers.com>).

Pharmacists must realize that they are still responsible for recommending to prescribers and other caregivers that the proper testing be undertaken, monitored, and responded to detect this type of toxicity. Pharmacists are also responsible for checking the results of these patients' tests.

MAIL-ORDER PHARMACIES

The emergence of the mail-order pharmacy has created its own unique category of liability. In one case, a psychiatric patient in New Jersey called in a phone order to his Florida mail-order pharmacy. 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." The proper conduct and 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

A frequent question posed to the authors is, "How can we avoid malpractice?" The best response has always been "to practice at a high level." When pharmacists do their jobs well, drugs will be used more efficaciously and safely and patients will suffer fewer drug injuries. Working more slowly and hiring in more staff can avoid a situation where the pharmacist has to take on more work than can be safely done in a specified period of time. Another way to manage risk is to make counseling their standard practice, supervise

support staff, and to employ quality- assurance techniques, wherever possible. Pharmacists always have to stay up-to-date with the pharmacy literature and read and circulate the Institute for Medication Safety Practices' (www.ismp.org) newsletter.

It is important to speak up—to communicate with physicians on a regular basis. 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, it is negligence to avoid calling the physician to diplomatically address the problem and offer an alternative.

Although pharmacy errors (and, thus, pharmacy malpractice) will never be completely eliminated, the entire profession must continue efforts to minimize our mistakes and protect the lives of patients.

Endnotes

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