PHARMACISTS AND THE PEOPLE WHO SUE THEM:
LIABILITY AND DEFENSE ISSUES IN THE REPRESENTATION
OF PHARMACISTS

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Pharmacists are often presented with opportunities to avoid unfortunate prescription-related outcomes for their customers. With a convergence of increased public expectations, federal and state regulation, and technological advancement, pharmacists are also increasingly finding themselves as codefendants in medical malpractice cases for allegedly failing to exercise independent judgment about the propriety of medications prescribed for particular customers.1

The opportunities for negative outcomes in connection with pharmacy matters abound. One FDA estimate suggests that thirty to fifty percent of patients fail to comply with their prescription drug instructions.2 Considering that physicians write more than 1.5 billion prescriptions per year,3 it should come as no surprise that, by one account, prescription drug misuse accounts for as many as 125,000 deaths per year.

In terms of litigation against pharmacists, about seventy-five to eighty percent of the claims are due to mechanical errors—wrong drug in right bottle, right drug in wrong bottle, and right drug but wrong strength. The remaining cases arise out of so-called intellectual errors that give rise to questions about whether, in light of a lack of agreement on liability standards, a full-blown standard of professional liability should apply. This paper concerns the standards governing cases in which intellectual errors are charged.

There is no question that claims against pharmacists are on the rise. One of the many reasons for the increase is that the landscape of available medications and how they are dispensed has changed during the past fifty years. The old-

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1 Virginia illustrates the disparate treatment accorded pharmacists under some state laws. Although pharmacists are protected by the broad scope of the Virginia Medical Malpractice Act as if they were professionals, they do not have a legal relationship similar to that of a doctor and patient. Rather, the patient who brings a prescription to the pharmacy is merely a customer. Nevertheless, the Virginia Medical Malpractice Act requires expert testimony on standard of care, suggesting that liability should be addressed under a more generalized standard of care, rather than either the more traditional no-duty analysis or a duty-to-warn standard.


time neighborhood pharmacist is almost gone, the PDR is thicker than a booster seat, the federal government and many states have stepped in with complex and overlapping statutes and regulations regarding pharmacy practice, and of course, there is the Internet. We cannot forget that existing computerized databases in so-called national pharmacy chains provide the pharmacist the ability to synthesize more information about the customer than ever before.

Pharmacists are also being called out from behind the counter. HMOs use them on committees to help determine the covered drug formularies, and sometimes they are even asked to set dosages of medications to be dispensed in the hospital through alternate routes of administration, such as a patient-controlled analgesia ("PCA"). In this context, various questions arise, such as: Can the pharmacist be held independently liable for failing to question a doctor’s judgment, either to the patient or to the physician by whom he is called upon to consult? If the pharmacist is aware of a risk posed by a valid prescription, does he have to act upon that information? Should the pharmacist be concerned about the addictive nature of the medication at issue and its long term use? Can a pharmacist refuse to fill a prescription based on ethical or religious beliefs? And if the answer to some or all of the above questions is yes, what is the standard by which the pharmacist should be held liable in the event of a bad outcome?

There are currently conflicting views throughout the United States regarding how to deal with alleged intellectual errors on the part of pharmacists in the discharge of their duties. Each is outlined below.

I. THE TRADITIONAL "NO DUTY" VIEW (AND ITS CHALLENGES)

For many years, pharmacists have been viewed as mere pill counters who ought not, despite extensive training, exercise independent professional judgment. As long as the prescription was followed, pharmacists fulfilled their duty to the patient-customer by properly following the physician’s orders, that is, filling the prescription correctly. No matter that the amount of the drug seemed excessive, or the customer was taking other contraindicated medications, or the customer was known to the pharmacist to have a condition or allergy that would make taking the drug dangerous or even deadly. This so-called “no duty” defense or “no duty to warn” view still prevails in many jurisdictions.

Two related ideas underlie the rationale for the traditional model: (1) pharmacists should not come between the patient and the physician, thereby affecting the physician-patient relationship, and (2) products liability law embodied in the learned intermediary doctrine best governs the tort liability analysis. Concerns about interference with patients and physicians are obvious. As applied to pharmacists, however, the thrust of the learned intermediary doctrine is that because the drug manufacturers can provide warnings and recommendations to physi-

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...cians, and the patient is closer to the physician than to the pharmacist, the pharmacist has no duty to warn about the drugs dispensed. If there is a mistake concerning the drug prescribed, the physician should be held responsible.

In those states that have adopted and maintain this view, the pharmacist has virtual immunity from all negligence claims, save for those that involve a misfiled prescription. The problem with the learned intermediary doctrine as applied to pharmacist malpractice cases is the uncomfortable fact that about sixty-eight percent of physicians decide against full disclosure of medication hazards and side effects to their patients.

A. A PHARMACIST CALL FOR EXPANDED LIABILITY?

Ironically, it is pharmacists themselves who have urged a departure from this traditional view, thereby inadvertently inviting greater legal liability. For example, the American Pharmaceutical Association ("APhA") has stated publicly not only that "the mission of pharmacy is to serve society as the profession responsible for the appropriate use of medications, devices, and services to achieve optimal therapeutic outcomes" but also that, remarkably, the profession "accepts the attendant liabilities associated with medication use." This statement can be fairly interpreted to mean that the APhA advocates the elimination of the traditional no-duty rule.

The National Association of Boards of Pharmacy ("NABP") has also advocated scrapping the no-duty rule. This view makes sense given the extent of the pharmacist's training and education, which emphasizes professional standards. It also makes little sense to be trained to such high standards and nevertheless be told in judicial opinions that your health care role is much less important. (Has any other provider in the health care chain done so much to open the door to potential lawsuits on a collective basis?)

As a result of changing attitudes toward pharmacy practice (both inside and outside the profession), there are various situations in which pharmacists are being sued for errors arising from their professional services, apart from the obvious one of misfiling or mislabeling prescriptions that are otherwise appropriately prescribed. Pharmacists have been sued for failing to warn of the addictive properties of Quaaludes, failing to recognize overprescribed medications, and failing to determine if the patient-customer was an addict. Ordinarily, such claims that once would have failed under a no-duty analysis are being allowed to go forward in the courts.

5 The misfiled prescription can range anywhere from the wrong drug in the right bottle to the wrong dosage of the correct drug in the correct bottle.


In any event, the traditional model has been criticized in the last fifteen or so years, and it appears to be giving way to either a modified duty-to-warn standard or a full-fledged professional-liability standard. One reason for this sea change is the movement of the federal government into the arena.

B. FEDERAL AND STATE LAW CHALLENGES TO TRADITIONAL MODEL

1. OBRA

On the federal level, pharmacists were recognized by the Omnibus Budget Reconciliation Act of 1990 (hereinafter “OBRA 90”), adopted on the state level beginning in January 1993, as health care professionals whose expertise can be used to detect drug regimen concerns. Under the statute, each state was required, for example, to institute a plan to provide for review of a patient’s drug regimen by a pharmacist before the state could receive funds for Medicaid prescriptions. Such a review would include screening for drug therapy problems in a variety of contexts. These measures were to be implemented by January 1, 1993. Once OBRA reached the state level, it was not long before the question of a national standard of liability arose.

At least one state, Missouri, judicially recognized the prospective drug use review as defined by OBRA 1990 as the standard of pharmacy practice. In Horner v. Spalito, the patient had been prescribed two controlled substances, one of which was given in a high dosage. The patient later died from what the autopsy revealed were the “adverse effects of multiple medications,” and the pharmacist was sued for failing to protect the patient from an unreasonable risk of harm.

Reversing summary judgment in favor of the pharmacist, the Missouri Court of Appeals observed:

[while] the physician is responsible for assessing what medication is appropriate for a patient’s condition, . . . the pharmacist may be in the best position to determine how the medications should be taken to maximize therapeutic benefit to the patient, to communicate that information to the customer or his physician, and to answer any of the customer’s questions regarding consumption of the medication.

The Horner court was, perhaps unwittingly, turning the learned intermediary doctrine on its head. It reasoned that the pharmacist, not the physician, may be in the best position to determine whether the drugs being prescribed would be of benefit or, by extension, of harm. The Horner decision thus dealt a blow to the only other remaining argument against allowing greater intervention by pharmacists—the concern about interprofessional conflicts:

10 42 U.S.C. § 1396.
11 1 S.W.3d 519 (Mo. Ct. App. 1999).
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We disagree that a pharmacist's consulting with a physician about an unusual prescription would result in antagonism exceeding the potential public benefit. Pharmacists are trained to recognize proper doses and contra-indications of prescriptions, and physicians and patients should welcome their insights to help make the dangers of drug therapy safer.

While Horner stopped short of an expanded liability definition, the opinion is a cautionary tale of needing to be mindful of what you wish for.

2. OBRA Applied—Virginia

Under Virginia law, a licensed pharmacist has certain responsibilities that are outlined by statute in Code section 54.1-3319:

A pharmacist shall conduct a prospective drug review before each new prescription is dispensed or delivered to a patient or a person acting on behalf of the patient. Such a review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contra-indication, drug-drug interactions, including serious interactions with nonprescription or over-the-counter drugs, incorrect drug dosages or duration of drug treatment, drug-allergy interactions, and clinical abuse or misuse . . . .

This statute, passed as a result of the OBRA-90 legislation, sets forth a clear standard of liability for pharmacists under limited circumstances. Failure to conduct such a mandatory review could give rise to liability in certain situations. The only question would be how and under what circumstances a review was conducted, and that would seem to require standard of care testimony.

3. Safe Harbor—The “Orange Book”

Drug bioequivalence and generic substitution is the area where state and federal law converge for the pharmacist: state laws allow pharmacists to make the decision regarding quality generic substitution medications. In defending generic and bioequivalence-type claims, counsel needs to be aware of a publication called Approved Drug Products with Therapeutic Equivalence Evaluations (the so-called “Orange Book”).

The Orange Book contains new drug application information (“NDA”) and the abbreviated new drug application (“ANDA”), which is submitted to obtain approval of generics. Some drugs get approved through a process called a 505(b)(2), which essentially allows for approval of a drug if there is evidence of safety in studies conducted by the sponsor. The 505(b)(2) drugs are listed in the Orange Book, but will not be listed as bioequivalent with the initial patented

12 The Orange Book was published in 1979 and an updated version through 2006 can be accessed at www.fda.gov/deriob/default.htm.
product. (There are no equivalents for patented new drugs because in theory they cannot be compared to any other drug.)

An exhaustive review of the coding used for generics and bioequivalents—these go from AA through BX—is not possible here, but suffice it to say that the Orange Book can be used to provide a safe harbor defense in cases involving substituted medications. At least one group of commentators has determined that no pharmacist has been found liable in a case in which the substitution was permitted by the Orange Book.\footnote{David Brushwood \textit{et al.}, \textit{Meeting Regulatory Challenges in the Changing World of Pharmacy Practice}, U.S. Pharmacist, Supplement to June 2005 Issue (June 1, 2005).}

4. The Internet

The rise of Internet pharmacies has drawn the attention of the federal government and given rise to proposed legislation. Research as of the date of this writing indicates that the proposed Ryan Haight Internet Pharmacy Consumer Protection Act of 2005, which proposed to amend chapter 5 of the Food Drug and Cosmetic Act,\footnote{21 U.S.C. § 351 \textit{et seq}.} has lapsed but is an example of what is likely to come and worth considering. It is safe to assume the passage of legislation that will prohibit the purchase of prescription drugs on the Internet when the pharmacy mails or ships it to the customer, \textit{unless}

\begin{itemize}
  \item the seller gets the customer’s name
  \item the seller is licensed
  \item the seller’s address is provided
  \item the seller has a licensed pharmacist on staff
  \item and if they provide a so-called “consultation,” the person providing the consultation has to be authorized to provide the consult.
\end{itemize}

Nor can the on-line pharmacy sell or dispense medication without a so-called qualified medical relationship (“QMR”). This way, the legislation effectively prohibits an exclusively Internet relationship. That means the prospective customer will need to have a valid prescription or a qualified or appropriate medical relationship, suggesting that the contact person at the pharmacy cannot issue the prescription (although valid) without a QMR. The proposed legislation provides for exceptions, such as for telemedicine and group practices that have at least 100 physicians.

II. Duty to Warn (Only under Certain Circumstances)

In those jurisdictions where a duty to warn on the part of the pharmacist is recognized, it is limited to four special circumstances.
A. PRESCRIPTION HARMFUL ON ITS FACE

This category seems fairly obvious, although under the traditional analysis, the pharmacist in this type of case would still have the protection of the no-duty rule. One example of how liability has been found in this category appears in Riff v. Morgan Pharmacy.15 In this case the prescription was for a suppository to be administered for a headache every four hours. No warning was given that no more than two suppositories should be used per headache and no more than five in a single week. Unaware of the danger posed by use permitted by the prescription, the patient suffered nerve damage and liability was found against the pharmacist for failure to warn the customer.

B. WAS THERE SPECIAL KNOWLEDGE?

What, if anything, did the pharmacist know about the customer that could have prevented an injurious outcome?

The court in Hand v. Krakowski16 found negligent a pharmacist who correctly filled a prescription for a heavy-duty psychotropic drug but gave it to a known alcoholic. The drug and alcohol were contraindicated, and the pharmacist not only filled the prescription once, but continued to fill it for several years. While it is rare for pharmacists to have such knowledge, especially in the age of the large chain pharmacy setting, it is conceivable that the increasing volume of patient information available within the database could give rise to liability if not properly analyzed.

C. DID YOU ADVERTISE?

In Baker v. Arbor Drugs, Inc.,17 a pharmacy advertised to the public that it had computers—the Arbortech Plus system—able to detect dangerous drug combinations. The Michigan Court of Appeals held that a pharmacy could be held liable to a plaintiff whose antidepressant (Parnate) and nasal decongestion medication (Tavist-D) caused a stroke. Following the stroke, the patient pursued claims against both the physician and the pharmacist. The allegations against the physician were eventually settled out of court, but the case did not end there.

After his stroke, the customer’s depression deepened and then he committed suicide, leaving a note that the stroke had been “too much for him” to endure. The decedent’s estate continued to pursue claims against the pharmacy, all of which were dismissed based on the learned intermediary doctrine. On appeal, the plaintiff’s estate argued that it should be allowed to pursue claims of negligence, violations of the Michigan Consumer Protection Act, and fraud based on

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the pharmacy having advertised that its computer system prevented the dispensing of drugs that were incompatible or harmful. The appellate court agreed.

D. THE DANGER OF VOLUNTEERING

There are some occasions in which the pharmacist voluntarily will go beyond the call of what is required by law. The pharmacist, for example, may offer the customer a list of side effects to taking the medication but omit the one side effect from which the customer suffers after taking the drug. In Cottam v. CVS Pharmacy,18 the pharmacy volunteered information that appeared to be complete, but was in fact materially lacking. The court ruled that, having volunteered, the pharmacy had a duty to provide a more comprehensive list.

III. FULL PROFESSIONAL LIABILITY

A professional liability standard for pharmacists would look much like the standard used in malpractice claims against other professionals: architects, engineers, attorneys, and physicians. In a negligence action, the pharmacist would be held to a standard of care within the profession to be determined by competing expert testimony and balanced at trial by the jury. This model has the advantage of encouraging the profession as a whole to develop, on its own, national standards of training and conduct, in much the same way other health care specialists have done. On the other hand, imposition of such a standard would, in the short term, inject uncertainty into pharmacists’ daily activities, as well as pharmacist malpractice claims, as national (or statewide) standards of practice rush to catch up with the outer limits of expert opinion.

IV. SPECIAL PROBLEMS IN DEFENDING PHARMACISTS

Like any case with a health care professional defendant, the pharmacist case comes with unique challenges. The first challenge is that in developing a causation defense (often the only defense available) little or no help will come from the drug manufacturer. The defense will need to know what actually happens when someone takes a drug that is not intended for them, or takes a very high dose of a drug intended for them. Even if the defense attorney can work his way through the chain to make contact with in-house counsel, drug companies are not interested—and their lack of interest is understandable—in assisting defense counsel.

A related problem is how to prove the causation case. The individuals most knowledgeable about how particular medications behave are academic pharmacists or toxicologists, yet many states, like Virginia, require a witness to have a medical degree in order to testify that drug $x$ did not cause reaction $y$ in a specific patient, despite what the plaintiff’s expert says. What defense counsel can do is get a pharmacologist or toxicologist on board to prepare a report that is

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then fed to the physician expert. How well that strategy plays in front of a jury is problematic, however.

The main reason counsel needs the pharmacologist or toxicologist in the first place is that there is likely to be limited support in the literature for the defense position. Drug companies and academic pharmacists simply do not perform overdose testing of human drugs on individuals who, for example, do not need the drug in the first place. Generally, counsel is left with what can be gleaned from the PDR, which is to say, not much.

Finally, counsel has to be thinking about jurors' impressions of pharmacists, which is often better than physicians as far as errors go. Jurors likely know physicians and hospital employees can make mistakes; but everyone goes to pharmacists, and few jurors know anyone who has had a problem. Given this view of the world, a jury could be inclined to hit a pharmacist harder on damages, especially if the pharmacist is employed by a national chain, something not encountered in typical medical malpractice litigation. The relationship between the negligent health care provider and the national corporation codefendant may even warrant its own consideration as a separate problem, especially when the local pharmacist defendant is likeable and, for instance, a very large national retailer is the codefendant.

A. HEALTH PRIVACY LIABILITY

Given the opportunity for the potential disclosure of sensitive medical information, especially in the setting where the pharmacist may not know the customer personally, it is surprising that there are not more claims against pharmacies for breach of confidentiality under HIPAA and under state statutes that confer a private right of action. As an example, Doe v. American Medical Pharmacies, Inc.,19 involved allegations that a pharmacy employee disclosed a customer's HIV positive status in the waiting area. The slander, invasion of privacy, and intentional infliction of emotional distress claims resulted in a $100,000 verdict.

B. PHARMACY TECHNICIANS

Every state requires the pharmacy technician to have some degree of supervision. The requirements vary from requiring a pharmacist to be on duty on the premises to requiring only access, not physical presence. Often the pharmacy technician is barred from accepting verbal prescriptions.

Some states even go so far as to mandate the ratio of technicians to pharmacists. In the institutional setting, the ratios range from 1:2 to 1:3. In the community setting they vary from 1:1 to 1:2. You also need to be aware that in some jurisdictions the regulations and statutes may be silent on the subject.

Sometimes, even liability of the pharmacist for the errors of the pharmacy technician is regulated. Ordinarily, the doctrine of respondeat superior would

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apply, but such statutes can provide for joint responsibility for the pharmacist and pharmacy technician in the event direct supervision is mandated.

V. Conclusion

Through changes in pharmacy practice and advances in medical records technology, the pharmacist's role is becoming more important in the health care continuum. The pharmacist is demanding greater respect, and that demand is leading toward increased liability. Although many jurisdictions still retain the traditional no-duty model, the law is moving, at a minimum, toward a modified no-duty-to-warn, and may be heading toward a full-fledged professional-liability standard.