Pharmacist Advice: Where Should the Line Be Drawn and Who Should Draw It?

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The changing role of pharmacists in recent years is now well-documented. Pharmacists’ role has clearly shifted from that of merely dispensing prescriptions to that of advising and counseling in relation to drugs. This expanded role means that “…it is no longer enough to get the right medication to the right patient in the right amount with the right directions on the label.”1 Many pharmacies in Australia are now specifically designated as “pharmacist advice” pharmacies and are “patient oriented” rather than “product oriented.”2 With this broader role, one might expect an expanded duty of care and potential for liability,3 but tortious actions against pharmacists in Australia are still relatively infrequent. This may be attributed to the fact that insurance companies in Australia have a strong policy of settling out of court. This situation makes it difficult to define the scope of a pharmacist’s duty in Australia, although some disciplinary cases refer to it obliquely.

This paper considers some recent negligence cases in the United States and disciplinary cases in Australia in order to elucidate the scope of the pharmacist’s duty regarding the provision of negligent advice about prescribed medications. It is beyond the scope of this paper to also consider disciplinary cases in the United States. The negligence cases in the United States indicate that the duty is still quite confined, and it is argued that this limited duty is to some extent inconsistent with the expanded role in patient care which pharmacists have recently assumed. It is also argued that professional bodies whose functions include “the protection of the public” could play a greater role in elucidating the responsibilities and duties of pharmacists.

Disciplinary Decisions in Australia

Although there have been very few negligence actions in Australia against pharmacists, these professionals are regularly the object of complaints and disciplinary proceedings.4 In recent years, such complaints have alleged the inappropriate supply of drugs, careless or non-existent recording and labeling of medications, failure to operate pharmacies in a professional manner, fraudulent conduct, dispensing errors and sexual misconduct.5

Conspicuous by their absence are complaints specifically about negligent advice, although inadequate advice in relation to medications was a factor in some of the cases involving dispensing errors. In one case, a pharmacist had misread a dose of morphine and dispensed a

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morphine mixture ten times greater than that prescribed, contributing to the death of a patient who was terminally ill. The pharmacist had simply noted the high dose to the nurse who collected it but had not warned of its dangers. He was a newly registered pharmacist on his first day alone in the pharmacy and was reprimanded for the incident. In another case, a pharmacist failed to dispense medication in accordance with a prescription and caused a seriously ill cancer patient to be without her proper medication for sixty days. She died a short time later. The pharmacist had told the patient to take the wrongly dispensed medication daily and had failed to advise the patient about possible side effects.

However, the failure to advise about the side effects was not a particular complaint and was an issue that emerged in evidence when the matter was raised by peer reviewers. The decision noted that two recent publications of the Pharmacy Board of New South Wales (which is responsible for the registration and regulation of pharmacists) had drawn the attention of local pharmacists to the importance of patient counseling as part of every pharmacist’s quality assurance and harm minimization protocol. The decision also pointed out that there is a professional responsibility by the pharmacist to keep abreast of pharmacy knowledge.

These cases indicate that disciplinary proceedings can provide an ideal forum for elucidating the duty of the pharmacist to advise about medication after a prescription is dispensed. Under the Pharmacy Act of 1964 of New South Wales (Section 19A), “professional misconduct” as defined for pharmacists includes, “any conduct that demonstrates a lack of adequate: (i) knowledge, (ii) experience, (iii) skill, (iv) judgment, or (v) care, by the pharmacist in the practice of pharmacy…”

Not only do dispensing errors fall within the scope of this definition; so does the giving of negligent advice and the duty to warn of side effects. If a complaint of professional misconduct is proved against a pharmacist, a range of sanctions, including de-registration, may follow. However, it remains to be seen whether complaints of negligent advice will be made against pharmacists in New South Wales and whether professional bodies will take the opportunity to set appropriate standards in this respect.

**Negligence Cases in the United States**

The learned intermediary defence appears to be regularly used by pharmacists in the United States. Although the defence is consistent with Australian law, which recognizes the importance of the doctor–patient relationship and the provision of warnings about medical treatment, the dearth of case law against pharmacists generally means that to date the defence has not been used by pharmacists in Australia. It nevertheless helps to demarcate the respective duties of physicians and pharmacists.

In *Kasin v. Osco Drug, Inc.* (2000), the plaintiffs sued both a doctor and a pharmacist for negligence. The action against the doctor was dismissed with prejudice. The facts as recorded in the judgment were as follows. The plaintiffs were Clarence Kasin and his brother Paul. Clarence sought treatment from Dr. Gross for a swollen right ankle. He had not seen Dr. Gross before and had been in good health for nearly twenty-five years, except for a bout of flu. Dr. Gross prescribed a drug called Daypro, a nonsteroidal anti-inflammatory drug available only on prescription. The plaintiff had the prescription filled at Osco Pharmacy and was provided with an information sheet about the
drug which included the following information:

COMMON USES OF THE DRUG:
For arthritic conditions, pain, inflammation, fever.

HOW SHOULD I TAKE IT?
Take with food or antacid to reduce stomach upset. Avoid alcohol or aspirin. Follow doctor’s instructions. Report other drugs you take/diseases you have.

ARE THERE ANY SIDE EFFECTS?
Very unlikely, but report: Eye/ear problems, change in urine color, bloody stools, difficulty breathing, mental changes.

No discussion occurred between the plaintiff and the pharmacist about the risks or side effects associated with Daypro. The plaintiff admitted relying upon his doctor rather than on the pharmacist to advise him of the risks. He took the drug for ten days and for the first nine days experienced no side effects and felt normal. On approximately the tenth day, however, he noticed that he lacked energy and his stools were black. He collapsed later that day. He was diagnosed with three ulcers and kidney failure, necessitating a kidney transplant from his brother Paul.

He alleged that the pharmacist, in dispensing the prescription drug Daypro, had negligently advised him of the side effects of the drug when he failed to advise him “of symptoms to be aware of and possible injury to kidneys and possible renal failure.” At first instance, the pharmacist filed a motion for summary judgment pursuant to the “learned intermediary doctrine.” This doctrine provides that manufacturers of prescription drugs have a duty to warn prescribing physicians of a drug’s known dangerous propensities and that physicians, in turn, have a duty to convey the warning to their patients.\(^\text{10}\) His motion was successful, but the plaintiffs appealed on the basis that, because Osco had voluntarily undertaken to provide an information or warning sheet with a prescription drug, it removed the pharmacist from the protection of the learned intermediary doctrine. Osco, however, maintained that on the basis of the decision in *Frye v. Medicare-Glaser Corp.*\(^\text{18}\) he was protected by the doctrine.

In *Frye*, the court made the point that consumers should look primarily to their prescribing physician for warnings about drugs; it was the physician’s duty to convey those warnings. It determined that the duty of care under the voluntary undertaking theory of liability was limited to the extent of the undertaking. Therefore, the duty that the *Frye* court imposed upon pharmacists was that when they warned of possible side effects, the warning should be accurate. The appeal court in *Kasin v. Osco* found *Frye* determinative. The plaintiffs did not allege the warnings provided by Osco were inaccurate but rather that Osco had failed to warn of some other side effects. The court held, “By voluntarily undertaking to list some of the drug’s side effects, Osco did not assume a duty to list all possible side effects. Concluding otherwise would ignore the public policy considerations pointed out in *Frye* and would deter pharmacists from providing any information at all.”\(^\text{11}\)

It seems that the court in this case was having a bet each way. It acknowledged that patients rely upon pharmacists for advice but limited the duty of pharmacists to the extent of their undertaking and followed the ruling in *Frye* that patients should rely upon their physicians for drug advice. However, as one commentator notes, this does seem inconsistent
with current pharmacy practice\textsuperscript{12} and the expanded role of pharmacists in providing advice to patients.

In the case of \textit{Cottam v. CVS Pharmacist},\textsuperscript{19} a Massachusetts court was asked to decide whether a pharmacist had a duty to warn a patient of an antidepressant’s potential side effects, particularly when this particular pharmacist had a policy of providing extensive written information with each new prescription.\textsuperscript{13} The plaintiff had been admitted to a hospital for treatment of depression and prescribed the antidepressant trazadone. He had his prescription filled at the defendant’s pharmacy after he was discharged from the hospital. The pharmacy had a computer system which enabled it to print out information about the risks and side effects of prescription drugs in either a short version or a longer, more detailed version. It also had a policy of providing the more extensive version with each prescription, but the plaintiff was given only the short warning form. Both forms focussed mainly on the risk of drowsiness, and the pharmacist counseled the patient about this effect.

The patient took the first dose of medication that night and awoke the next morning with an erection that persisted throughout the day. He took another dose the following evening and saw his physician the next day for a scheduled appointment. He was immediately referred to a urologist and had emergency surgery. Because he had waited thirty hours before seeking medical attention, the surgery left him permanently impotent. He sued his psychiatrist, physician, and pharmacist. His case was settled with the psychiatrist and physician but went to trial against the pharmacist. The pharmacist was found fifty-one percent negligent and the plaintiff forty-nine percent negligent.

The appeal court affirmed the decision at first instance, holding that while a pharmacy generally had no duty to warn its customers, it had voluntarily assumed a duty to provide the information. The longer version of the patient’s information leaflet included a warning to notify a physician if painful erections developed. As the form was not given to the patient, he may reasonably have believed that all of the side effects were included in the short form. The pharmacy failed to meet its own voluntary standards in dispensing prescriptions.

**Discussion**

One writer asks whether there is a legal balance that allows pharmacists to give partial warnings without overwhelming the patient with encyclical wisdom.\textsuperscript{14} \textit{Cottam} indicated the possibility of giving long or short versions of information about various drugs. The short version would constitute a partial warning. However, the voluntary nature of the type of warning given means that it will inevitably lead to inconsistent pharmacy practice. For this reason it is arguable that professional bodies should determine the extent of the duty to warn. The learned intermediary defence, while offering legal protection to pharmacists, may not be in the best interests of the patients to whom they give advice.\textsuperscript{15} In the above case of \textit{Cottam v. CVS Pharmacist}, although the pharmacist was held to be fifty-one percent negligent, the victory may have seemed a hollow one for the patient, given the pharmacy’s breach of its own policy regarding the provision of advice and the fact that the patient was counseled mainly about drowsiness.

One Australian writer distinguishes between risk assessment and risk management, arguing that risk assessment is within the physician’s domain as it involves weighing the risks and benefits of proposed drug therapy and as
specific patient-related medical knowledge is required. She argues that risk management, however, “… is the domain of the pharmacist as it occurs after prescribing and involves determining how the drug can best be used. General drug-related pharmaceutical knowledge is required to convey this information which may prompt the patient to use a drug in a way which will maximize its benefits and reduce its risks. Risk management information can be given by the pharmacist to all patients who receive a particular drug.”

Conclusion

The learned intermediary defense employed by pharmacists accused of negligent advice in the United States has successfully enabled them to keep their role in the provision of advice quite confined. The courts have held, however, that a pharmacist can voluntarily assume a duty not otherwise imposed upon him or her. This is an unsatisfactory state of affairs for patients and may lead to inconsistent pharmacy practice, with different pharmacists assuming different voluntary duties to warn about medications. It is arguable that the profession, rather than the courts, should determine the standard of advice that should be given to a patient. In both the United States and Australia, there is clearly scope within the regulatory system to determine professional standards in this respect. In Australia, however, case law in both negligence and disciplinary proceedings regarding negligent advice by pharmacists is still in its infancy.

References

3. Crawford Note 2 at 295
4. Kiel, H. Pharmacist misconduct: The pitfalls of practice Journal of Law and Medicine Vol 12 February 2005 Number 3 at 351 In a twelve-year period in the state of New South Wales there were 78 complaints involving a diverse range of offences
5. Ibid.
6. Dean v Green Pharmacy Board of New South Wales 9 December 1992 www.austlii.edu.au
11. Ibid. at 4.
15. Ibid.
17. Ibid.
19. Cottam v. CVS Pharmacist, SJC No. 00-P-1287.