PHARMACY PRACTICE DEVELOPMENTS: THE POTENTIAL IMPACT ON PHARMACISTS’ LEGAL LIABILITY

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The practice of pharmacy has changed over recent years with a greater emphasis on the patient and the provision of patient care services. This expanded role of pharmacists as medication managers has resulted in changes to their professional responsibility and potential legal liability. Recent international case law demonstrates an increased legal liability of pharmacists in certain instances. However, pharmacists’ liability in this new context in Australia is yet to be clarified.

INTRODUCTION

Australia has been at the forefront of an international trend towards the incorporation of cognitive services in community pharmacy practice. Patient care services in community pharmacy practice have expanded. Pharmacists are increasingly required to advise patients regarding medication therapy and evaluate the appropriateness of prescribed medication. This expansion of the pharmacist’s role necessitates accountability for and a sharing of responsibility with medical practitioners for patients’ medication-related needs. It also requires that pharmacists in everyday practice have an up-to-date knowledge of a wide range of medicines and be able to communicate this knowledge to consumers. With the ongoing development and registration of new and complex medicines by the pharmaceutical industry, a pharmacist’s knowledge base must continually expand and continuous education is a priority. Pharmacy regulatory authorities throughout Australia are currently developing measures specifying pharmacists’ annual re-registration requirements.

The increasing tendency in Australia and overseas towards down-scheduling of prescription medicines to become available as Pharmacist Only Medicines also requires additional

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3 Best JR, Day R et al. “To prescribe or not to prescribe: issues surrounding our approach to new drugs” (2001) 19 NPS News
6 Pharmacist Only medicines are also referred to as Schedule 3 medicines. These medicines have been defined by the National Drugs and Poisons Scheduling Committee as “substances of which the safe use requires professional
pharmacist responsibility. Pharmacists not only have a responsibility to ensure the appropriateness of a Pharmacist Only Medicine for a specific patient but also need to carry out detailed counseling and record keeping when supplying these medicines.\textsuperscript{7} This requires supportive time-management initiatives. Further, increased support from Government towards generic prescribing places increased responsibility on pharmacists who must assess the suitability of a generic product for a specific patient and provide counseling to minimise confusion over brand changes.\textsuperscript{8}

These additional responsibilities are further complicated by the increased expectations of consumers towards health professionals and a trend to litigate.\textsuperscript{9} In addition, advances in technology, including computer systems to maintain patient profiles and automatically warn of drug interactions, expand the capabilities but also the responsibilities of pharmacists. However, there is limited research on pharmacists’ potential legal liability within the context of the expanded role and new technologies in Australia. It is therefore crucial to evaluate the potential liability and inform the profession of the possible legal and disciplinary consequences. Awareness of such outcomes will assist the profession to develop much needed risk management procedures.

This article will explore pharmacists’ potential legal liability within their expanded role in community pharmacy. It will examine the current professional and the legislative structures and the relevant international pharmacy practice case law. It will also analyse the developments of Australian civil litigation as a model for predicting pharmacists’ legal liability outcomes. Queensland Legislation will be used to demonstrate specific application to pharmacists.

**PROFESSIONAL STANDARDS AND GUIDELINES**

The Australian pharmacy professional organisations\textsuperscript{10} have assumed a significant role in the development of contemporary practice standards and guidelines for pharmacists. The standards and guidelines aim to promote consistency and uniformity in service delivery, implement continuous quality improvement and reduce the risk of misadventure. Two sets of standards are specifically applicable to community pharmacy practice, namely the:

1. Professional Practice Standards, and
2. Standards for the Provision of *Pharmacist Only* and *Pharmacy Medicines* in community pharmacy practices (S2/S3 Standards).

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\textsuperscript{7} In Queensland this requirement is specified in s277 the *Health (Drugs and Poisons) Regulation 1996* (Qld). Similar legislative provisions exist in the other States and Territories


\textsuperscript{10} The pharmacy professional organisations specifically involved with the development of professional practice standards are the Pharmaceutical Society of Australia, the Pharmacy Guild of Australia and the Society of Hospital Pharmacists of Australia
Recent research by Benrimoj on the supply of Pharmacy Medicines\textsuperscript{11} and Pharmacist Only Medicines\textsuperscript{12} noted the extent to which community pharmacists incorporated the nationally recognised S2/S3 Standards.\textsuperscript{13} However, evidence about how, and by what means, pharmacists utilise the Professional Practice Standards is lacking.

The Professional Practice Standards and the S2/S3 Standards have been endorsed by the Pharmacists Board of Queensland in terms of section 374 of the \textit{Health Practitioners (Professional Standards) Act 1999} (Qld).\textsuperscript{14} In accordance with section 376 of the Act, the Board uses the Standards as admissible evidence in disciplinary proceedings. To identify and manage risk, pharmacists should incorporate these standards into everyday practice. However, the standards do not distinguish between services or actions which are absolutely essential. That is, the “must-do” actions aimed to provide safe pharmaceutical services are not distinguished from those “nice-to-do” or desirable actions aimed to provide a good quality service. Pharmacists therefore need to use their experience and personal judgement in determining which functions are required to provide the minimum service level to provide safe patient care.

**THE LEGAL CONTEXT**

In the legal context, instances of unintentional or inadvertent dispensing errors in pharmacy practice are relatively straight-forward. Dispensing the wrong product or incorrectly labelling a product can be used as evidence in cases of liability or unsatisfactory professional conduct. Although it is often a complex process to determine who was at fault, once a mistake has been identified and a pharmacist found to have been negligent or guilty of unsatisfactory professional conduct, the legal outcome is relatively predictable.

Conversely, with the expanded areas of pharmacy practice such as the giving of advice regarding potential side effects of medication, there is a greater scope for error. The activity is less task oriented and often requires professional judgment specific to the individual patient’s needs.\textsuperscript{15} These higher cognitive functions pose a different challenge in determining a pharmacist’s liability. For example: cases involving a failure to identify clinically significant medication interactions or medication-disease interactions, or failure to detect an overdose, have a substantial discretionary element. The pharmacist’s potential responsibility in these instances is open to varied interpretations of the standard of care and the identification of risks. However, Australian litigation involving claims of negligence regarding pharmacists’ expertise in the more recently expanded areas of practice have yet to emerge and pharmacists’ legal liability towards patient care services is not yet well-defined.

\textsuperscript{11} Pharmacy Medicines are also referred to as Schedule 2 medicines. These medicines have been defined by the National Drugs and Poisons Scheduling Committee as “substances, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person” in Department of Health and Ageing, \textit{Standard for the Uniform Scheduling of Drugs and Poisons (2005)}

\textsuperscript{12} Department of Health and Ageing, n 4

\textsuperscript{13} Benrimoj S, \textit{A cost-benefit analysis of Pharmacist Only (S3) and Pharmacy Medicines (S2) and risk-based evaluation of the standards} (University of Sydney) at \texttt{http://beta.guild.org.au/research/project\_display.asp?id=246} viewed 10 May 2006

\textsuperscript{14} \textit{Health Practitioners (Professional Standards) Act 1999} (Qld)


\textsuperscript{16} Sweet BV, Tatro DS and Whitsett TL, \textit{Pharmacy Law Digest} (Milwaukee, Douglas-McKay, 2004) p 254
International case law

The law deals with precedent, and as pharmacy moves into unprecedented areas, it is not possible to make broad statements about the pharmacist’s legal duty that would be applicable in all cases. However, one approach to help predict Australian pharmacists’ duty of care regarding patient care services and assist the profession in developing precautionary practices is to explore recent international case law.

Over recent years in the United States of America (USA) pharmacists had been found liable for a range of pharmacy practice services involving the negligent dispensing of prescription items. The courts recognised that pharmacists had a duty to verify, or refuse to fill, a prescription that contained a patent or obvious error. The traditional approach taken by the USA courts was to decline to impose liability on pharmacists for anything other than mechanical dispensing errors. The courts followed the Learned Intermediary Doctrine, in which the prescribing physician was the “learned intermediary” between the drug manufacturer and the patient. Under the Doctrine, only physicians had the duty to warn patients of medication adverse effects as only physicians could relate the characteristics of the medicine to the “physical idiosyncrasies of the patient”, as cited in McKee v American Home Products (1989). Courts therefore viewed it as only the prescriber’s responsibility to discuss medication issues with patients and indicated that interference by pharmacists could potentially confuse patients. Therefore, the traditional approach was that a pharmacist had no duty to warn the patient or notify the prescriber in the case of over dosages or adverse reactions - an approach which had been criticised in a number of legal commentaries.

More recent USA case law, however, suggests that the approach by the courts towards pharmacists’ legal liability is being eroded by changes in legislation and the expanding role of pharmacists in health care. Courts are now considering the altered professional context in which pharmacists practise and are allowing new and unprecedented theories of liability claims. Court decisions have, over recent decades, verified that the pharmacist has drug expertise as well as the personal knowledge of a particular patient. For example:

18 Sweet et al, n 11 at p 256
19 McKee v American Home Products 782 P.2d 1045 (Wash. 1989)
24 Asbury RP, n 14 at 938
25 Sweet et al, n 11 at 253
In the case of *Riff v Morgan* (1986)\(^{26}\) it was held that a pharmacist had a duty to warn a patient about the maximum dosage of a prescription medicine. In this case 65% fault was awarded to a pharmacy for not warning a patient about the maximum dosage for the dangerous and potentially toxic migraine medicine, Cafergot® suppositories. The pharmacy dispensed the medication with the prescriber’s directions on the label, namely to use one per rectum every four hours. The pharmacy did not include maximum dose information on the label and as a result of overuse, the plaintiff’s foot suffered permanent damage. The court specifically reviewed the pharmacist’s training, internship requirements, and comprehensive licensure examination and stated:

“a pharmacist is a professional. In the performance of his professional duties, he will be held to the standard of care, skill and intelligence, which ordinarily characterises the profession. In judging the degree of skill, consideration will be made of the advanced state of the profession at the time of the injury”.

The findings of the Supreme Court of Illinois in *Happel v Wal-Mart Stores Inc.* (2002)\(^{27}\) supports the changed approach taken by the USA courts. In this case the pharmacist’s duty to warn a patient about a contraindication was considered and the court found that the pharmacist had a legal duty to warn the doctor or the patient about a contraindication. The patient was prescribed and dispensed Toradol®, with active ingredient the non-steroid anti-inflammatory drug (NSAID) ketorolac. Despite the fact that the patient previously reported her allergy to other NSAIDs and it was entered into the pharmacy’s computer system, the medication was dispensed and labelled without a warning statement. The patient subsequently suffered an anaphylactic shock and sustained serious, ongoing disabilities. The court, in reaching its decision, took the view that the pharmacist’s duty to warn did not require the pharmacist to either make a medical judgement or to intrude in the doctor-patient relationship and found that the pharmacist was guilty of negligence.

In the case of *Cottam v CVS Pharmacy* (2002)\(^{28}\) the court found the pharmacy 51% negligent for not warning a patient of priapism as a potential side-effect of the antidepressant trazodone and the patient was left permanently impotent as a result of using trazodone. The court found that the pharmacy voluntarily assumed a duty to provide information, advice and warnings to a patient as it was the pharmacy’s normal practice to issue a “long form” list of side-effects when a drug was dispensed for the first time. The court found that by giving out a list of information as part of normal practice the pharmacy voluntarily assumed a duty to warn, and in doing so had to perform that duty with due care. Where the information provided could be reasonably understood by the patient as a complete list of side effects, it is appropriate to impose the duty to warn about all potential side effects.

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\(^{27}\) *Happel v Wal-Mart Stores* 766 N.E.2d 1118 (Ill. 2002)

• The Illinois Appellate Court in *Frye v Medicare Glaser Corporation* (1992)\(^{29}\) similarly ruled that a plaintiff may maintain an action against a pharmacist who voluntarily assumes a duty to warn of a drug’s adverse reactions, but does so in an incomplete manner.

The above cases represent examples from a range of USA cases in which courts have found pharmacists to be liable for their failure to warn the patient or notify the prescriber in the case of over-dosages or adverse reactions. This changed approach has been criticised,\(^{30}\) arguing that judicial recognition of pharmacists’ increased liability could displace the physician’s role and thereby compromise patient care. It has also been stated that such liability may have a negative impact on the efficiency and efficacy of pharmacist care by encouraging pharmacists to act contrary to the public interest through a “don’t ask, don’t tell” policy.\(^{31}\) This theory presumes that if pharmacists refuse to ask customers about their medical history (don’t ask), they would not be liable for failing to warn (don’t tell) because they do not have the requisite knowledge upon which to form a clinical opinion and advise the customer (to tell). However, this theory is not consistent with the changed role and competency standards of Australian pharmacists.\(^{32}\)

**Australian civil litigation developments**

Pharmacist negligence cases in Australia are rare and pharmacists have remained largely invisible in the literature on health law.\(^{33}\) Pharmacists’ civil liability in Australia is therefore not well defined. In predicting pharmacists’ potential civil liability, two issues need to be considered, namely:

1. The changed and expanded role of pharmacists as an advisor through the provision of patient information. Pharmacists need to counsel patients to make them aware of and understand how to take prescribed and over-the-counter medication.\(^{34}\) Pharmacists also need to inform patients of potential relevant side effects as a result of taking the medication; and

2. The factors that will be taken into consideration by a court in making a determination of civil liability. These factors are influenced by the new Civil Liability Acts (CLAs)\(^ {35}\) in the various Australian States and Territories. The impact of these CLAs

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\(^{29}\) *Frye v Medicare-Glaser Corporation* 579 N.E.2d 1255 (Ill. App. 1991)


\(^{33}\) Kiel H “pharmacist misconduct: The pitfalls of practice” (2005) 12 JLM 348

\(^{34}\) Includes Pharmacist Only Medicines, Pharmacy Medicines and unscheduled medicines.


\(^{36}\) Civil Liability Act 2003 (Qld), Personal Injuries Proceedings Act 2002 (Qld)

\(^{37}\) Civil liability Act 2002 (NSW), Civil Liability Amendment (Personal Responsibility) Act 2002 (NSW)

\(^{38}\) Civil Law (Wrongs) Act 2003 (ACT), Civil Law (Wrongs) Amendment Act 2003 (ACT)


\(^{40}\) Volunteers Protection Act 2001 (SA), Recreational Services (Limitation of Liability) Act 2002 (SA), Wrongs (Liability and Damages for Personal Injury) Amendment Act 2002 (SA)
on the practice of pharmacy has yet to be determined, as is the case with other health professionals.\textsuperscript{44}

In Queensland the \textit{Civil Liability Act 2003} is applicable to health professionals in cases of alleged professional negligence. Section 21 covers the "Proactive and reactive duty of a doctor to warn of risk". However, this section only covers doctors, and it is therefore not clear which standard would be applicable to health professionals other than doctors. Section 22 describes the "Standard of care applicable to professionals", and subsection 22(1) specifies that

\begin{quote}
A professional does not breach a duty arising from the provision of a professional service, if it is established that the professional acted in a way that (at the time the service was provided) was widely accepted by peer professional opinion by a significant number of respected practitioners in the field as competent professional practice.
\end{quote}

However, subsection 22(5) specifies that section 22 does not apply to liability in connection with the giving (or the failure to give) a warning, advice or other information. The \textit{Act} is therefore unclear regarding:

1. The duty of a pharmacist to warn of risk as section 22 only covers doctors; and
2. The standard of care that applies to the giving of advice or the failure to give advice as section 22(5) specifically excludes this responsibility.

In terms of the Act, it is therefore not clear which standard will be applied to the duty of the pharmacist to warn patients of medication risks.

With regard to Australian civil case law, the rejection of the \textit{Bolam} principle\textsuperscript{45} in cases of negligence due to failure to warn, following the decision in \textit{Rogers v Whitaker 1992},\textsuperscript{46} is of particular importance to pharmacists. In the \textit{Rogers v Whitaker} case, the court rejected the reliance on expert witnesses if the allegations involved the provision of information and advice. The Australian position was subsequently based on the principle that the court may reject the opinion of expert witnesses about the information provided to patients about treatment risks if the court was of the opinion that the individual patient would have been likely to attach significance to it.

However, the introduction of the CLAs has now reintroduced peer professional opinion and practice as the benchmark to be considered by the court, similar to the \textit{Bolam} principle. This change in the Australian approach emphasises the significance of professional standards and guidelines and the responsibility on health professionals to follow best practice.

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\textsuperscript{42} \textit{Duties Act 2001 (Tas)}, \textit{Civil Liability Act 2002 (Tas)}
\textsuperscript{43} \textit{Personal Injuries (Liabilities and Damages) Act 2003 (NT)}, \textit{Personal Injuries (Civil Claims) Act 2003 (NT)}
\textsuperscript{44} Madden B, "Changes to the definition of negligence" (2003) 12(1) Australian Health Law Bulletin 6
\textsuperscript{45} \textit{Bolam v Frien Hospital Management Committee} [1957] 2 All ER 118
\textsuperscript{46} \textit{Rogers v Whitaker} (1992) 175 CLR 479
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Professional misconduct

Regulation of the pharmacy profession is the principle means of ensuring public trust and confidence in the services provided by pharmacists. State and Territory legislation provides for the regulation of the profession throughout Australia by Pharmacy/Pharmacist Boards in each jurisdiction, which act as registering authorities for the protection of the public and the maintenance of professional standards. The main objective of the State and Territory legislation is to ensure the quality use of medicines in the community by requiring that the supply of medicines is undertaken by appropriately qualified professionals. The structures within which the Boards operate differ between the States and Territories and although there are similarities between the respective Acts and regulatory authorities, there are inconsistencies that impact on the day-to-day practice of pharmacy.

Complaints received by the Pharmacists Board of Queensland are dealt with under the provisions of the Health Practitioners (Professional Standards) Act 1999 (Qld) and the definition of “unsatisfactory professional conduct” includes:

(a) professional conduct that is of a lesser standard than that which might reasonably be expected of the registrant by the public or the registrant’s professional peers;

The endorsed standards and guidelines are hence used by the Board as a benchmark for the appropriate standard of practice in investigations of alleged professional misconduct cases. However, it is not clear to what extent pharmacists apply the standards to improve risk management procedures. This is of particular importance as the practice standards are used in disciplinary proceedings.

CONCLUSION

The practice of pharmacy has changed over recent years with a greater emphasis on the patient and the provision of patient care services. This expanded role of pharmacists as medication managers has resulted in changes to their professional responsibility and potential legal liability.

The ability to identify and improve patient safety measures is dependent on the management and recording of medication incidents by community pharmacists. To assist pharmacists to develop these critical risk management procedures, professional practice standards have been developed by the professional organisations and endorsed by the regulatory bodies. However, it is not known how well community pharmacists utilise these standards to develop their risk management procedures.

Recent international case law demonstrates an increased legal liability of pharmacists in certain instances. Yet, the liability of Australian pharmacists with the expansion of pharmacy practice and patient care and the impact of civil liability developments and new civil liability legislation is yet to be clarified. It is therefore imperative to specifically clarify Australian pharmacists’ potential legal liability in the provision of medication management services.

47 Health Practitioners (Professional Standards) Act 1999 (Qld)