A Duty to Care: Pharmacists’ Negligence: Implications for Pharmacists and Lessons Arising

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Abstract

The role of pharmacists has changed dramatically over the last few decades, and increasingly pharmacists are providing pharmaceutical healthcare to patients. As the direct relationship between pharmacists and patients develops, the increased possibility arises of professional negligence in their everyday practice. The High Court of Australia has stated that in determining negligence, it will not defer to current professional standards but will impose such duty of care as demanded by the law. Pharmacists should be aware of the current legal environment in their professional practice and they should exercise the appropriate standard of care to provide optimal pharmaceutical care to the public to thereby avoid possible litigation.

Introduction

With the rapid advances in health care development, the role of the pharmacist has changed dramatically. The nature of pharmacy practice has changed from a chemist store - whose primary function was to dispense prescriptions and to make up preparations - to a modern pharmacy that incorporates pharmaceutical healthcare into direct patient care. A recent study in the United States found that many patients do not take their medications correctly as prescribed by their doctors. The pharmacist is often the first health care professional that the patient consults and the pharmacist may also be the last health care professional the patient sees before obtaining and consuming their medication. Therefore the pharmacist’s role is crucial in reinforcing the doctor’s advice to the patient and acting to ensure the safety and optimal use of pharmaceuticals. With these responsibilities and roles, pharmacists are also more exposed to increasing legal liability for failure to meet their responsibilities. This article aims to identify current issues surrounding pharmacist negligence and its implications to pharmacists.

What is negligence?

The tort of negligence is described by Professor Fleming as ‘conduct that falls below the standard regarded as normal or desirable in a given community’ for those who are perceived to be competent in carrying out their profession within the standards of reasonable skill and proficiency. Hence negligence for pharmacists may be due to the pharmacist dispensing the wrong drug, the wrong strength, the wrong route of administration, the wrong frequency or failure to detect the chance of a significant and possibly fatal overdose.
mix ups with drug names and mistakes in extemporaneous preparations.\textsuperscript{5}

**Duty of care**

A duty of care is an obligation by a person who has assumed control of dangerous things or holds a status that requires specific professional skills that are recognised by the public and by the law.\textsuperscript{6} A person owes a duty of care to another person when they know the other person is going to rely on them, and must therefore take reasonable care to ensure that the advice is correct. The accepted test use to determine the duty of care is the ‘neighbour test’ as set out by Lord Atkin in the leading Donoghue v Stevenson case; where ‘you are to love your neighbour and must not injure your neighbour …’, and your neighbours are those who are ‘so closely and directly affected by your act …’.\textsuperscript{7}

It is reasonably foreseeable that harm may arise if patients do not take their medications correctly. Therefore, pharmacists as the pharmaceutical healthcare professionals owe a duty of care to patients who seek their advice and acquire medications from them. A pharmacist does not discharge the duty of care merely by dispensing the prescription in exact accordance with the written prescription.\textsuperscript{8} Pharmacists also have a duty to prevent or to minimise opportunities for patients to cause harm to themselves\textsuperscript{9} and to refuse to dispense a prescription if it is likely to be subjected to misuse.\textsuperscript{10} This should also include monitoring sales of over-the-counter medications (such as laxatives) to avoid misuse by the public.

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\textsuperscript{6} J. Fleming, above n 4.

\textsuperscript{7} Donoghue v Stevenson [1932] AC 562 at 580.

\textsuperscript{8} M. Brazier (ed), Clerk & Lindsell on Torts (1995, 17th ed) 444.


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**Standard of care**

The standard of care refers to what a reasonable person would do in the same circumstances.\textsuperscript{11} For the pharmacist, this refers to what other pharmacists would do in the same situation, whether or not it conforms to the standard of practice that is acceptable. However, Fleming has raised the clear distinction between making a bad decision and a decision that turns out badly (errors of clinical judgment) in medicine - both errors may amount to negligence if they fail to measure up to the appropriate standard and skill expected.\textsuperscript{12} For many years, the so-called Bolam principle was used to determine the standard of care for professionals in UK and in Australia.\textsuperscript{13}

**The Bolam principle**

The Bolam principle was laid down in Bolam v Friern Hospital Management Committee.\textsuperscript{14} In this case, the defendant doctor was sued for negligence for not warning the plaintiff patient of the risks, for not giving any relaxant before the electro-convulsive treatment (ECT) shocks were given and for not holding the plaintiff’s body while he underwent the ECT. As a result, the plaintiff fell and broke his pelvis. The patient’s claim was unsuccessful, the court holding that the defendant doctor had conformed to the expected standard of a reasonable doctor and that it was the common practice not to hold down the body of the patient during the treatment. According to the ruling, as long as the doctor follows the practice that is accepted at the time by other doctors, the doctor’s act would not be found negligent.\textsuperscript{15} Moreover, a doctor should act according to what the doctor thinks is best for the patient. This implies that the acceptable medical practice and the doctor’s medical judgment will

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\textsuperscript{11} D. Newgreen, above n 5.

\textsuperscript{12} J. Fleming, above n 4.

\textsuperscript{13} Editor’s Note: Query whether the Bolam test (which certainly does apply to doctors and allows the court when determining the standard of care to accept what other doctors have to say about negligence on the facts of each case), also applies to pharmacists or whether the normal ‘standard of care’ applies i.e. a ‘reasonable pharmacist’.

\textsuperscript{14} [1957] 1 WLR 582; [1957] 2 All ER 118.

\textsuperscript{15} [1957] 2 All ER 118 at 122.
determine the standard of care required by doctors as well as other health professionals. This Bolam test was further supported and upheld by the English courts in cases such as Whitehouse v Jordan and Sidaway v Board of Governors of the Bethlem Royal Hospital.

Opposition to the Bolam Principle by Australian Courts

In 1983, the Supreme Court of South Australia adopted the view that the non-disclosure of the risk is a breach of the duty of care. Moreover, the court confirmed that it is for the court to determine the standard of care demanded by the law - thus preventing the medical profession defining the standard of care as a matter of medical judgment. The decision of the High Court of Australia in 1992 in Rogers v Whitaker disapproved the Bolam principle - that the standard of care in assessing negligence is a matter of medical judgment - and upheld the duty of care of a doctor. However, the court did point out that the factors by which a court will determine breach of the standard of care will vary according to whether the case involves diagnosis, treatment or the provision of information or advice. Hence, the doctor has a duty to warn the patient of the material risk in the proposed procedure when a reasonable person in the patient’s position would likely attach significance to it when warned of the risk. It is the patient’s right to obtain information to make their own decisions and health professionals owe a duty to warn the patients of the risks even if they do not ask for the information. This view is also supported by both Canadian and American authorities. However, this is subject to the therapeutic privilege where a doctor does not have to warn the patient of the risks, if based on clinical judgment, it will cause harm to the patient.

Apart from this, Australian courts have also held that doctors should disclose information regarding their skills compared with other practitioners in relation to the risks posed by the patient undergoing the procedure.

Standard of care for pharmacists

The standard of care for pharmacists and the professional standards of pharmacy practice are outlined in the Acts and the Regulations under State and Territory Laws. For example, the Pharmacy Board of Victoria has also issued Guidelines for Good Pharmaceutical Practice and there are other guidelines by professional bodies such as the Pharmaceutical Society of Australia and the Society of Hospital Pharmacists of Australia to ensure good pharmaceutical practices by pharmacists.

Damage

In medical negligence cases, it is often hard to prove that damage was caused by the negligence of the health professional. The Harvard Medical Practice Study has found that only less than two percent of injuries caused by medical negligence lead to claims.

For example, if a pharmacist negligently dispenses the wrong drug, the drug may already have broken down and excreted from the body before any test can be performed to determine the cause of the negligence. To deal with this issue, the Australian courts use the ‘but for’ test - that the plaintiff would not have suffered injury ‘but for’ the negligence. But this is not an exclusive test and the court may sometimes have to apply a test of common sense to determine the causation.
In the United Kingdom

In English law, the standard of care is in principle a matter of medical judgment, and the courts still uphold the Bolam principle. However, and in response to community attitudes, the courts have refined the Bolam test so that it is no longer enough for a doctor to produce evidence that the relevant conduct is in line with the current professional practice. The conduct will have to withstand logical analysis as well. For National Health Service (NHS) hospitals in the U.K., the NHS litigation authority has taken all of the responsibility for compensating injured patients caused by their individual healthcare professionals. But for pharmacists, the ‘Code of Ethics’ has also made it compulsory for all pharmacists to take up professional indemnity insurance to protect the customers.

In the United States of America

In general, the United States’ common law of negligence recognises different degrees of negligence, whether it is ordinary, gross or slight, unlike Australia and the U.K. where there is only a single standard of care. Moreover, the law in the United States often integrates both the common law and breach of statutory duties as one, contrary to the situation in the U.K. and in Australia where the court will determine the breach of negligence while the statutory body (the Pharmacy Board) will determine the breach of statutory duty by the pharmacist. However, the American courts also uphold patients’ rights for self-determination rather than relying on professional medical judgment.

The pharmacist negligence cases in the United States usually only involve pharmacist dispensing errors on the basis that they do not owe a duty to warn patients. United States law accepts that it is the doctor’s responsibility to warn the patient and that the pharmacist as the third party should not intervene in the existing doctor-patient relationship. But pharmacists still owe a duty to exercise due care and diligence in warning patients and contacting the prescriber if the medication will cause significant risk to the patient. A comparison between Australia and the U.K. and the USA is found in a table at the end of this paper.

Negligence cases involving pharmacists

1) Wrong drug

In Prendergast v Sam and Dee Ltd; Kozary and Miller, a patient suffered irreversible brain damage as a result of overdosing of an anti-diabetic medication due to a prescriber’s poor handwriting. The script was for an antibiotic which was misinterpreted by the pharmacist as an anti-diabetic tablet. Both the doctor and the pharmacist were found negligent. In this case, the pharmacist failed to check with the doctor the doubtful writing, the unusually high strength (25 times the normal dosage) for the misinterpreted anti-diabetic tablet, the unusual frequency of dose, the unusual quantity and the unusual combination of medications in the script to contain both diabetic and asthmatic medication.

2) Failure to detect prescriber’s wrong directions

In Dwyer v Rodrick, a pharmacist in the U.K. dispensed an overdose of an anti-migraine tablet in exact accordance with the prescription. It resulted in the patient developing gangrene and having toes amputated.

36 Ingram v Hook’s Drugs Inc 476 NE 2d 881 (Ind App, 1985).
the unusually high dose, and therefore shared 40 percent of the responsibility with the doctor.

3) Mistakes in preparation
In the U.K., a trainee pharmacist made up a peppermint water mixture with 20 times the normal dose of chloroform (as preservative) which led to cardio-respiratory arrest and the death of the baby patient. Both the trainee and the supervising pharmacist were charged with manslaughter, but the case was later dropped.41 Both the supervising pharmacist and the trainee pharmacist were also fined by Chester Crown Court for not supplying a medicine of the nature or quality demanded under the Medicines Act 1968 (UK).

4) Failure to provide adequate supervision
In the U.K., a pharmacist was reprimanded after an error in dispensing a phenobarbitone mixture containing eight times the prescribed dosage to a child, which resulted in hospitalisation of the child. The pharmacist failed to check the calculations or weighing and to use the appropriate formula to include a preservative when the extemporaneous mixture was prepared by a trainee technician.42

5) Wrong Label
In NSW, an elderly patient died after taking overdose quantities of a potent medication Methotrexate for rheumatoid arthritis.43 A coroner’s inquest found that the patient took 19 tablets over 24 days instead of 12 tablets. The specialist had wanted the patient to take the dose once a week but that the dose should be broken down to three times during one day. The general practitioner relied on the patient’s secondary information and prescribed the medication to be taken everyday. The dispensing pharmacy had attached a label onto the medication with erroneous instructions. Moreover, there was no record of the pharmacist contacting the doctor to query the dose. This case highlights the difference the pharmacist can make by providing adequate counselling to carefully explain the dosage to the patient.

6) Wrong Advice
In Victoria, a doctor sought advice from a pharmacist for the appropriate dosage of a cocaine mouthwash for a patient with pain after a tonsillectomy. The pharmacist recommended a dose at least 10 times stronger than that used for cancer patients. The doctor followed the pharmacist’s advice and prescribed the medication which was dispensed by the same pharmacist. The patient’s friend then drank it at a party. This led to her death from combined drug toxicity of alcohol and cocaine. According to the coroner, this was simply a case of the blind leading the blind. While both doctor and pharmacist argued that they did not owe a duty of care to the deceased, the matter had been referred to the Pharmacy Board of Victoria and the Australian Medical Association for possible professional misconduct.44

Implications of negligence to pharmacists
The common types of pharmacist negligence include error in compounding (making the wrong product), dispensing error (wrong drug, wrong strength, wrong quantity or wrong label), supplying medication with poor quality (contamination, using expired medications) and failure to warn patients adequately.45 A study in the UK has found that one percent of prescriptions dispensed contain errors, of which 0.18 percent are serious errors.46 Studies in the US found that the average prescription errors are about 3 to 5 percent,  

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slaughter.html
43 Refer to Inquest: Death of Winifred Green, NSW, No 427.1996, cited in P. Dwyer, above n 34, 757.
45 http://www.channel1.com/users/medlaw/legal/pharm.htm
with about one percent of these being potentially serious errors.\textsuperscript{47} Although no similar studies have been found for Australia, it is the author’s opinion that Australian pharmacists are equally vulnerable in making dispensing errors in their daily practice.

Why do pharmacists make mistakes?
According to the 1971 study by Wolfert and Stevens, 90 percent of errors made by pharmacists are due to lack of concentration (51%), similarity in drug names (16%), inexperience or lack of knowledge (10%), interpretation, by misreading medication order (8%) and wrong assumptions by pharmacists not investigating the prescriber’s order (5%).\textsuperscript{48} In an Australian survey of pharmacists’ attitudes towards dispensing errors, high prescription volumes, pharmacist fatigue, pharmacist overwork, interruptions to dispensing, and similar or confusing drug names were found to be the main contributing factors in dispensing errors.\textsuperscript{49} The shortage of pharmacists in Australia means many pharmacists are often too busy and working long hours which causes fatigue and increases the risk of making more mistakes.

Consequences
Although very few cases are brought against pharmacists for professional negligence in Australia compared to the record in the United States, this does not mean that pharmacists are unlikely to be sued for negligence. Professional negligence can lead not only to huge insurance claims and disciplinary actions from the Pharmacy Board, but gross negligence can sometimes lead to charges of manslaughter. In the UK, as many as 21 doctors were charged with manslaughter in the 1970s, 1980s and 1990s, and many doctors have been tried for manslaughter.\textsuperscript{50} This has happened in Australia, where, for example, a doctor was convicted and jailed for wrongly injecting high doses of morphine into a baby who later died.\textsuperscript{51} With quite a significant rate of dispensing errors made in their practice, pharmacists should give immediate attention to attempt to minimise their liabilities in professional negligence. Minimising legal liability would of course be second to the desire to avoid patient misadventure.

Lessons learned
To minimise healthcare negligence cases, the NHMRC (National Health and Medical Research Council) has issued a series of Clinical Practice Guidelines to assist healthcare professionals in making appropriate decisions for specific clinical circumstances.\textsuperscript{52} Moreover, the Quality Care Pharmacy Program has also issued guidelines for good dispensing for pharmacists.\textsuperscript{53} It is important to adhere to good dispensing practice every time, as pharmacists are reminded that even dispensing the same prescriptions all the time does not exempt a pharmacist from his duty of care.\textsuperscript{54}

To minimise negligence, pharmacists should familiarise themselves with all medications, and continue keeping themselves up to date with the latest advances in pharmaceutical healthcare.\textsuperscript{55} In order to ensure that pharmacists keep their knowledge up to date, the Pharmaceutical Society of Australia has introduced the CPE (Continuing Pharmacy Education) program.

\textsuperscript{47}http://www.voiceoftheinjured.com/a-mm-drugstoremistills.html
\textsuperscript{50}C. Dyer, ‘Doctors face trial for manslaughter as criminal charges against doctors continue to rise’ (2002) 325 British Medical Journal 63.
\textsuperscript{51}M. Oberhardt, The Courier Mail, (Brisbane), 16 November 2000, cited in Newgreen, above n 5.
\textsuperscript{52}P. Dwyer, above n 51.
\textsuperscript{54}Chin Keow v Government of Malaysia [1967] 1 WLR 813, 111 Sol Jo 333, PC- A doctor administered a penicillin injection to a patient allergic to penicillin who later died. The claim by the doctor that he had given similar treatment to a large number of patients each day and it was not part of his routine did not grant him immunity for having been negligent, as cited in D. Pittaway and K. Hay, 1998, 535-536.
However, disappointingly, a survey conducted in New South Wales found that only 25 percent of pharmacists were actively engaging in CPE programs with 35 percent not contacting CPE at all, as it is not compulsory at this stage. Communication between health professionals is crucial, so pharmacists should also take reasonable care to ensure that patient care information is transferred to other health care providers. In one case, a hospital doctor failed to communicate directly with the patient’s doctor about the patient’s knife wound, which was wrongly diagnosed. Therefore, the doctor did not re-examine the patient’s wound which had in fact penetrated the abdominal cavity, the patient later dying from fulminating peritonitis. The failure to pass on material information from the hospital doctor to the patient’s doctor deprived the doctor with the necessary foreknowledge that he should have had in order to deal properly with the patient’s case. Therefore, Finch argues that pharmacists have no choice but to query the prescriber whenever there is a doubt, even though this may cause a sense of unpleasantness amongst the prescribers when they have been queried.

The Law Reform Committee in Victoria recommended that professional indemnity insurance cover should be compulsory for all health care providers. Although it is not compulsory in Australia, many pharmacists have acquired professional indemnity insurance to cover themselves in an event of a dispensing error. Moreover, according to a report by the National Audit Office in the UK (May 2001), 41 per cent of claimants interviewed said that they might have been dissuaded from taking legal action had they been given a proper explanation and apology, prompt compensation and evidence that the mistake made in their case would be corrected in the future. Therefore, pharmacists and other healthcare professionals are now encouraged to apologise to the patient in the case of making an error, as this can often diffuse the situation and avoid possible litigation.

Current crisis
According to the National Audit Office’s report, the total liability cost in medical negligence in the National Health Service in the UK has increased by £500m from the previous year to £4.4bn for 2000-2001. The increasing litigation against healthcare professionals over the last decade has seen medical indemnity insurance premiums skyrocket. With the continuing problems in the medical indemnity insurance crisis, the federal and state governments have taken action to limit liability under the ‘tort law crisis’.

Conclusion
Pharmacists are facing increasing legal liability for negligence as their health care role increases. The shortage of pharmacists has put more pressure on existing pharmacists, sometimes resulting in fatigue which invariably increases dispensing errors. Pharmacists should be aware of the current legal environment in the healthcare sector. They should be vigilant and attentive to patients’ pharmaceutical needs and adhere to the guidelines for good dispensing to ensure that they provide the best possible standard of care to the public in their everyday pharmacy practice.

63 e.g., Tort Reform (2002) 76 ALJ 341; P. Latimer, Australian Business Law (2003) para 4-216 (‘Tort law crisis’).
### Comparing Australia to the UK and US

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<th><strong>Australia</strong></th>
<th><strong>United Kingdom</strong></th>
<th><strong>United States</strong></th>
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<tr>
<td>Pharmacist’s duty to warn</td>
<td>Yes</td>
<td>Yes</td>
<td>No, doctor’s duty, contrary to Omnibus Budget Reconciliation Act (OBRA) 1990¹</td>
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<tr>
<td>Degrees of Negligence</td>
<td>A single standard of care</td>
<td>A single standard of care</td>
<td>Different degrees, ordinary, gross or slight</td>
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<td>Standard of care</td>
<td>The court to determine</td>
<td>Current standard of practice will determine</td>
<td>The court to determine</td>
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<tr>
<td>Statutory duty and Common law duty</td>
<td>Two separate issues</td>
<td>Two separate issues</td>
<td>Integrate both under common law</td>
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| Relevant cases                      | **Rogers v Whitaker**  
1) The doctor has a duty to warn the patient of the material risk in the proposed treatment  
2) It is the patient’s right to obtain information to make their own decisions | **Bolam v Friern Hospital Management Committee**  
1) The doctor should follow the practice that is accepted at the time professional standards  
2) The doctor should act according to what he or she thinks is best for the patient | **McKee v American Home Products**, 782 P.2d 1045 (Wash. 1989)²  
1) Pharmacists have no duty to question a doctor’s judgment  
2) No duty to warn patients of risks and hazardous side effects, should be doctor’s duties |
| Pharmacist litigation               | Rare          | Few cases          | Many cases        |

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¹ S. Huang, above n 37.