PHARMACY PRACTICE TODAY: AN INCREASED EXPOSURE TO LEGAL LIABILITY?

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Traditional pharmacy practice has changed towards a greater emphasis on patient care. This is reflected in relevant legislation and in the education and standards adopted by the profession. The changing nature of pharmacy practice represents better use of a pharmacist's expertise in drug-related matters, to which the community has ready access. This article examines the nature and effect of such change and considers any increased exposure to legal liability associated with it. The focus is on community pharmacy practice, and not that of hospital pharmacy.

I. INTRODUCTION

The practice of pharmacy has changed markedly over the last fifty years, influenced significantly by the growth of large pharmaceutical manufacturing corporations whose research and development efforts have led to the availability of beneficial, frequently complex, medications. Until comparatively recently, many diseases could not be treated successfully or even at all. Advances in pharmaceutical research and development techniques have produced increasingly effective medications. Because of the importance of drug therapy today, there may well be an expectation in the community that there is a drug product to treat every ill. Consumers today are more demanding than ever for information about their medication. This will be discussed below, together with measures taken to meet this demand.

Pharmacy's traditional emphasis on extemporaneous formulation and manufacture of medicines has decreased in response to the manufacturing corporations' product development activities. Pharmacy practice has a more *patient* oriented function in which the traditional expert knowledge of the pharmacist is utilised in order to assist in achieving optimal levels of safety and efficacy in drug therapy. This shift in emphasis involves greater consideration by a pharmacist of the appropriateness of medication for patients and how best to assist such patients to achieve the most favourable outcome with the prescribed

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therapy. It follows that a pharmacist necessarily will have increased contact with patients. Appropriate intervention, if indicated, will avoid any untoward drug effects whether at the time of first dispensing of the prescribed medication, or at a later date. Because of this more *direct* patient care, pharmacists will potentially be exposed to an increase in legal liability. In some areas of pharmacy practice, potential legal liability is reasonably predictable. In the newer areas which are less mechanistic and more focussed on patient-management, liability may not be so clear.

The erosion in Australia of the so-called *Bolam* test[1] to determine the standard of care (for present purposes, that of a pharmacist) is relevant to current legal liability issues in pharmacy practice as they evolve, including any increased exposure to legal liability in the newer areas of pharmacy practice and the standard likely to be applied. Even if there is no general acceptance by the profession of the need for a more direct patient-oriented practice, a court may well find this to be an element of proper practice. As observed by the High Court of Australia, the standard of care is not determined solely or even primarily by reference to the practice followed or support by a responsible body of opinion in the relevant profession or trade.[2] A pharmacist's legal liability may arise from contract or statutory provisions including liability for sale of medications 'over the counter'.[3] In this article it is not possible to cover all areas of potential liability. Accordingly, attention will be restricted to a pharmacist's tortious liability in negligence.

Australian litigation involving claims in negligence against pharmacists has, to date, been rare. The pharmacists' professional indemnity insurer, however, is known to be responsive and effective. Because pharmacy continues its evolution, it seems useful to 'set the scene' to reflect upon any increased exposure to liability and how it might occur. This is especially relevant, given the increasing emphasis on *patient* care and the need for pharmacists to ensure optimal safety and efficacy of drug therapy, including 'patient counselling' or the provision of information, sometimes described (particularly in the United States) as the 'duty to warn'. Pharmacists must be aware of, and appreciate, the potential for legal liability and implement appropriate risk management techniques, particularly in the area of expanding responsibility.

II. SOME HISTORY

The profession of pharmacy is of considerable antiquity, evidenced by records dated back to Assyrio-Babylonian and Egyptian times.[4] The ancient Egyptians received from their gods, prayers to accompany medical care and the ingestion of

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1 *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582; [1957] 2 All ER 118.

2 *Rogers v Whitaker* (1992) 175 CLR 479 at 487.

3 'OTC' is used to generically describe items available from a pharmacy without the need for a medical practitioner's prescription

4 P Boussel, H Bonnemain and FJ Bové, *History of Pharmacy and the Pharmaceutical Industry*, Asklepios Press (1982) p 17

prescribed drugs. One doctor practising in the reign of Ramses I, founder of the 19th dynasty (1314 BC), formulated the following precept: "Incantations are excellent for cures and cures are excellent for incantations"![5] The history of drugs and the role of the apothecary (now pharmacist) is considerable. It, like the profession's history in Australia, deserves further consideration. The profession's evolution is characterised by constant efforts to maintain it as distinct from other health care professions.[6] The apothecary of colonial and frontier America usually functioned as both pharmacist and physician. As medications became more complex, it took greater expertise to prepare them, and the necessary expertise became more difficult to acquire. Druggists emerged in the United States and became members of local associations which promoted exchange of knowledge and the growth of professionalism.[7]

In the early twentieth century a more scientific approach to medicine developed. Pharmacists became more involved in the formulation of new ways to administer medicines to patients. Their expertise related primarily to the product and its formulation, while the physician looked to the patient and the effect of the drug. Following World War II, many new drugs were developed as the responsibility for manufacturing drug products became increasingly that of the pharmaceutical manufacturing corporation.[8]

The history of the pharmaceutical industry demonstrates how many of today's major multi-national corporations grew from a pharmacist's practice.[9] Extensive and costly research and development programmes of pharmaceutical manufacturing corporations were directed to the discovery and production of safe and efficacious drugs for the treatment of a wider range of disease conditions. These efforts brought about a range of increasingly effective medications. These included antibiotics and novel psychotropic drugs to treat psychiatric conditions. Accordingly, the demand for pharmacists' extemporaneous compounding of medicines declined.

From the late 1950s, it became increasingly clear that the pharmacist's role had shifted in emphasis, from *product* to *patient*. This resulted from the increasing complexity of new medications and their potential adverse reactions and interactions with other drugs and also with certain foods. This trend continued, leading to increased emphasis on patient-oriented practice and less on product orientation.[10] This is not to suggest that a patient's welfare was not an important consideration in earlier practice. Pharmacy, like other health care professions, has always regarded as paramount the health and welfare of patients receiving both prescribed and non-prescribed medication from a pharmacy.

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5 *Ibid* p 19.

6 G Haines, *The Grains and Theepenn'orth - Pharmacy in New South Wales*, 1788-1976, Lowden Publishing Co (1976); G Haines, *Pharmacy in Australia - The National Experience*, The Australian Pharmaceutical Publishing Co Ltd (1988), G Haines, *A History of Pharmacy in Victoria*, The Australian Pharmaceutical Publishing Co Ltd (1994).

7 DB Brushwood, *Medical Malpractice Pharmacy Law*, Shepard's/McGraw-Hill, 1986, p 3

8 *Ibid* p 7

9 Note 4 *supra*

10 Note 7 *supra*, p 4

It is the author's personal experience that the traditional product-orientation of earlier years did not exclude consideration of the patient receiving the medication. This is important and should not be overlooked when considering the changes that have lead to current professional practice. The increasing complexity of pharmaceutical products provides greater potential for adverse effects in their administration and potentially serious interactions between them. Pharmacy has responsibly undertaken to convey information to patients about medications, and to ensure such instructions are understood, to avoid the possibility of the occurrence of any adverse effects. As changes have occurred, pharmacy education has incorporated new pharmaceutical (and related) scientific disciplines: the aim - to equip pharmacists with skills necessary to meet the challenges of modern drug therapy. Arguably, pharmacy's failure to respond effectively to these continuing changes could render the profession, in effect, redundant.

Quite apart from the potentially adverse effects of drugs upon patients, it is necessary to consider economic impact of those effects, especially where, as in Australia, there is Federal Government subsidy of many pharmaceuticals. One study is reported to have assessed the direct cost of morbidity and mortality associated with prescribed medications in the United States at US$76b.[11] If indirect costs, such as those related to lost productivity and social factors, were taken into account, the figure would potentially be much higher.[12]

By becoming more directly involved in patient care, pharmacists are not intruding upon the primary functions of medical practitioners. Both professions are part of the Community's Health Care Team. Pharmacists are uniquely placed as readily accessible experts to supplement patients' drug therapy, to ensure optimal safety and efficacy. Assisted by computerised programs,[13] pharmacists are concerned to detect any potentially serious drug interactions in modern drug therapy. Maximum safety, efficacy and patient compliance are the essential objectives of proper professional practice. It is not only medications prescribed by medical practitioners that have potentially adverse effects and interactions, but those available without prescription at a pharmacy, some of which are required by law, to be *personally* handed to a purchaser.

The above discussion indicates that the changing nature of pharmacy practice raises questions of increased exposure to legal liability for breach of a pharmacist's duty of care to those obtaining medication, prescribed or otherwise.

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11 R Davies, "Drug-related Morbidity Costs Grossly Underestimated" (1997) 78 *The Australian Journal of Pharmacy* 998.

12 *Ibid.*

13 P Dwyer and T Kot, "Computerised Drug Interaction Programs. Servants or Masters of Pharmacists?" (1993) 12(4) *Australian Pharmacist* 214 at 214-9

III. PHARMACEUTICALS GENERALLY, SOME RELEVANT BACKGROUND

A. The Elixir Sulfanilamide Disaster, 1937

Apart from the growth of pharmaceutical manufacturers and their effect on the practice of pharmacy, it is useful to consider in this context, some major events leading to the greater regulation of pharmaceuticals. In the United States, the Elixer Sulfanilimade Disaster in 1937 has been described as one of the most consequential mass poisonings of the twentieth century.[14] Sulfanilamide, the first antimicrobial of its type, was produced using a poisonous diluent. One hundred and five patients died from its therapeutic use. In later evidence, a US Food & Drug Administration ("FDA") agent described the manufacturing company's new drug development strategy as one which "throw[s] drugs together, and if they don't explode they are placed on sale".[15] Failure to test the toxicity of individual ingredients or the finished product was the critical feature of this tragedy. Under then existing drug regulations, premarketing toxicity testing was not required. In response, the US Congress passed the 1938 Federal *Food, Drug and Cosmetic Act* requiring proof of safety before release of a new drug.[16]

B. Thalidomide

When introduced into the market in the late 1950s, Thalidomide was hailed as a superior tranquilliser due to its non-toxicity, lack of side effects and that it was safe for use by pregnant women. None of these claims were true but were apparently accepted by those who prescribed the drug.[17] Women who took the drug during the first trimester of pregnancy gave birth to babies with a wide, but distinctive, range of deformities. This tragedy resulted in more stringent controls in the screening of new drugs.

C. Australian Legislation

In Australia, the *Therapeutic Goods Act* 1989 (Cth) provides for the marketing approval of new drugs. The system overseeing clinical trials of drugs requires ethical approval by Institutional Ethics Committees ("IECs") in accordance with guidelines issued by the National Health and Medical Research Council ("NHMRC").[18]

Part VA of the *Trade Practices Act* 1974 (Cth) (hereafter "The Act") introduced into Australia a strict product liability regime based on the 1985 European Community Product Liability Directive. It provides a regime of strict

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14 PM Wax, "Elixers, Dilutents, and the Passage of the 1938 Federal Food, Drug and Cosmetic Act" (1995) 122(6) *Annals of Internal Medicine* 456

15 *Ibid*

16 *Ibid.*

17 A Deutsch, "Suffer the Children: The Story of Thalidomide", *The Sunday Times*, 1979, pp 1-2.

18 P Dwyer, "The Legal Note" (1997) 16(4) *Australian Pharmacist* 215 at 215-16, A Abadee, "Institutional Ethics Committees (Part 1): Are Their Ethical and Legal Responsibilities Always in Unison?" (1997) 16(4) *Australian Pharmacist* 217 at 217-21

liability whereby a person who is injured or suffers property damage as a result of a defective product, has a right to compensation against the manufacturer without the need to prove that the manufacturer was negligent.

It is generally accepted that no drug can be declared absolutely safe and all drugs could potentially be described as inherently unsafe. As a Scottish Professor of Pharmacology, Sir John Gaddum, once observed, each administration of every drug should be considered an experiment.[19] Accordingly, it is no surprise to find specific reference to pharmaceuticals in the *Explanatory Memorandum* ("the Memorandum") which accompanied the introduction into Parliament of the *Trade Practices Amendment Bill 1992* (Cth).

The Act provides that goods are defective if they do not provide the level of safety which persons generally are entitled to expect. This is an objective standard based upon what the public at large, rather than any particular individual, is entitled to expect.[20] As drugs have the features described above, then almost by definition, they could fall within the statutory definition. Fortunately, Parliament, through s 75AC(2), requires that in determining the extent of the safety of goods, regard must be given to a range of matters including those specified in the subsection. The Memorandum includes the following:

> Safety expectations may also depend on matters such as the nature of the product and community knowledge of that product. For example, there are a number of known, negative side effects associated with certain pharmaceuticals and vaccines. It is also generally accepted and known that these side effects cannot be avoided. Such products are known to confer substantial benefits which flow to the wider community at large. The small statistical chance of injury associated with them does not of itself mean that they are 'defective'.[21]

Importantly, also, in the context of this article, the Memorandum refers to the roles of pharmacists and prescribers as matters which might need to be taken into account as "relevant circumstances" for the purpose of s 75AC(2) of the Act:

> The role which intermediaries may play in the supply of goods may also need to be taken into account. For example, prescription pharmaceuticals are supplied to the consumer by a qualified pharmacist and only on the prescription of a qualified medical practitioner. Due to the complex nature and effects of these products, complete instructions and warnings may not be provided to the consumer by the manufacturer. However, detailed product information is provided to doctors and pharmacists by the manufacturer so these learned intermediaries are sufficiently informed to be able to decide whether or not it is appropriate to dispense pharmaceuticals to particular consumers. This factor will be relevant in determining whether a pharmaceutical is defective, particularly where a claim of a defect in information provided is made.[22]

When directing attention to defences available to a manufacturer under the Act, the Memorandum again refers to "intermediaries":

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19 (Author anon) Abstract of Paper *Patient Information - a Physician's Perspective* Meeting *DIA*, Montreal, May 9-10, 1994.

20 *Trade Practices Act* 1974 (Cth), s 75AC(1).

21 *Explanatory Memorandum* Trade Practices Amendment Bill 1992 (Cth) at [21]

22 *Ibid* at [24] Emphasis added.

> The role of intermediaries may be relevant in relation to this defence. As noted above in relation to matters relevant to determining whether goods are defective, due to the complex nature of pharmaceuticals, detailed product information is provided to the qualified intermediaries rather than directly to the consumer. The information is provided with the expectation that it will be used to properly inform the consumer about the product as the doctor or pharmacist sees fit. A product cannot be considered to be defective if it acts in an injurious or damaging manner due to the failure of the intermediary to properly inform the consumer, provided that the proper information is provided by the manufacturer to the intermediary.[23]

The Memorandum's specific reference to "learned intermediaries"[24] is relevant to the United States "learned intermediary doctrine". In effect, this requires the manufacturer of a pharmaceutical product to provide relevant information including warnings, adverse effects and the like, to physicians who then carry out their duty independent of the manufacturer, in assessing whether the drug is appropriate for the individual patient. Provided that the information supplied is adequate, a manufacturer may avoid liability. There are exceptions to the doctrine which are not presently relevant. The above-described aspects of pharmaceuticals regulation reflects the role expected of pharmacists in the Australian drug distribution system including their supply of pharmaceutical benefits pursuant to the *National Health Act* 1953 (Cth).

The cost of drug-induced morbidity and mortality in the community needs to be reduced. The potential for adverse drug-related events is well illustrated by the "Quality in Australian Health Care Study".[25] Although this Study was focused on hospitals, it is relevant to similar practice issues in the non-hospital area. The patient-management role of pharmacists should contribute to reduction of this cost, in terms of enhanced patient-outcome and financial savings in drug therapy.

E. Australia's Pharmaceutical Benefit Scheme ("PBS")

Spending on the Australian PBS is growing at a rate of approximately 10-15 per cent annually. In effect, this means that each year, approximately $300 million more is spent on drugs than in the previous year.[26] Any discussion of health economics includes cost-benefit analyses of prescribed medication. In New Zealand, the speed and scale of health reforms have been described as unprecedented in health management.[27] According to Maling, academic detailing (by pharmacists calling upon medical practitioners and providing particulars of drug products) can reduce pharmaceutical expenditure, but its effectiveness in New Zealand, with economic efficiency so explicit a goal, remains to be defined. Nonetheless, budget-holding contracts have provided for

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23 *Ibid* at [50]. Emphasis added.

24 *Ibid* at [23].

25 RM Wilson, WB Runciman, RW Gibbard, BJ Harrison, L Newby and JD Hamilton, "The Quality in Australian Health Care Study" (1995) 163(9) *Medical Journal of Australia* 458-71.

26 D Henry, "Prescribing Costs. Whose Responsibility?" (1997) 20(2) *Australian Prescriber* 26.

27 TJB Maling, "Front Line Pharmaceutical Management in the New Zealand Health Reforms" (1997) 20(2) *Australian Prescriber* 30 at 30-1.

the employment of practice pharmacists to co-ordinate formulary development and prescribing audits.[28]

F. The Australian Medicines Handbook

The importance of drug information (and the role of pharmacists therein) is reflected in a project to develop a national formulary for Australia: The Australian Medicines Handbook ("AMH") is a non-profit, collaborative venture between the Royal Australian College of General Practitioners, the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists, and the Pharmaceutical Society of Australia.[29]

The AMH has several aims. These include:

- to enhance the quality use of medicines in Australia;
- to be an inexpensive, up-to-date, readily accessible source of independently produced, comparative drug information for health professionals; and
- to be a foundation drug information text for teaching therapeutics to medical, pharmacy and other students.

The AMH is expected to be published in late 1997 or early 1998, in both printed and electronic versions. It will provide concise and practical drug information relevant to the daily needs of medical practitioners, pharmacists and others and will include pharmacology, indications, contra-indications, and potentially adverse drug interactions. Also to be included are cautionary and advisory labelling together with information concerning patient education.[30]

IV. PHARMACISTS: EDUCATION, REGISTRATION AND REGULATION

A pharmacist's undergraduate education is extensive, covering all relevant aspects of pharmaceutical science and practice. At the Pharmacy School at the University of Sydney, the undergraduate program is to be increased from three to four years. Within the School there is a Chair of Pharmacy Practice reflecting an increased emphasis on patient care. Likewise, the author's lectures to the School's undergraduates, on the law relevant to pharmacy practice, reflect the expanding ambit of pharmacy practice. The extent of undergraduate education reflects the evolving role of pharmacists as drug experts in the community- 'learned intermediaries' to adopt the American description discussed above.

The Pharmaceutical Society of Australia ("PSA") conducts post graduate, continuing education programs throughout Australia, which reflect the changing role of pharmacists and the shift towards greater patient care. These programs are voluntary but may become mandatory. In 1995 the Department of Education

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28 *Ibid*

29 GMH Misan, "The Australian Medicines Handbook" (1997) 20(1) *Australian Prescriber* 2 at 2-3

30 *Ibid* Cautionary and advisory labels are appended by pharmacists to some medications directing attention to special warnings This is intended to achieve optimal levels of patient compliance, safety and efficacy.

at the University of New England, held a national conference on continuing professional education which included a presentation urging an even greater need for continuing education programs for pharmacists. One paper addressed the changing role of pharmacy practice by reference to that of earlier days and asserted:

> A pharmacist now has extensive training in pharmacology and therapeutics and has a duty of care to the patient to see that the drug is appropriate for the patient, will be taken or used correctly, will not interact with any other drug, food or lifestyle of the patient and [must] be prepared to discuss those matters with the patient or the prescriber, even if either one is reluctant to listen. To fail to do all this is a grave dereliction of professional responsibility.[31]

The Pharmacy Board of New South Wales ("the Board"), the relevant registering and disciplinary body, recommends that all pharmacists should undertake at least 20 hours of continuing professional education each year of which at least ten hours should be in contact activity, unless impractical because of geographic or other factors. In communicating its concern to the profession, the Board referred to a survey conducted in New South Wales which revealed that only about 25 per cent of pharmacists participated in twenty hours or more of continuing professional education ("CPE") and "an astonishing 35 per cent did not contact CPE at all".[32]

In the Board's words:

> Our patients deserve better than this. It cannot be denied that it is absolutely essential to keep up to date. Neither can it be denied that the public has the right to be attended to by a pharmacist [who] is up to date. It is completely up to each pharmacist to decide the manner in which it should be done. CPE is not compulsory at the present time (except for a few pharmacists who have been ordered to participate as a result of a disciplinary hearing) but unless the level of voluntary participation rises significantly, the Board can see the time drawing near when it will be required to seek to make it mandatory for the protection of the public.[33]

It is clear that undergraduate and post-graduate pharmacy education is directed to the protection of the public by ensuring that patients (and also those receiving non-prescribed medication) receive, with pharmacist contribution, optimally safe and efficacious drug therapy.

V. PHARMACIST AND PHARMACY REGULATION

In the Australian States and Territories, pharmacists cannot practice without registration pursuant to local legislation. In New South Wales this is achieved through the *Pharmacy Act* (NSW) 1964, as amended. This Act, inter alia, constitutes the Pharmacy Board of New South Wales ("the Board") and includes provisions for the registration of pharmacists, complaints, disciplinary proceedings, pharmacy ownership and related matters.

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31 Pharmacy Board of New South Wales, "A Case for Mandatory Continuing Professional Education" (July 1996) 5 *Bulletin*, p 11.

32 *Ibid*

33 *Ibid* Emphasis added

Six of the Pharmacy Board's nine members are pharmacists, five of whom are elected by pharmacists.[34] The Board's principal functions include the promotion and maintenance of the highest standards of professional conduct and ethics in the pharmacy profession, pharmacy education and pharmaceutical research.[35] Pharmacists are subject to disciplinary provisions and a finding of professional misconduct (as with other registered health professionals) can lead to loss of registration and hence, livelihood. Professional misconduct has a broad definition including any conduct demonstrating lack of adequate knowledge, experience, skill, judgment or care by a pharmacist in the practice of pharmacy and "any other improper or unethical conduct".[36] In an appropriate case, a coroner may refer a matter to the Board following an inquest into a drug-related death and which includes a pharmacist's involvement. This may result in a finding of professional misconduct.

The Board publishes regular bulletins to pharmacists directing their attention to current concerns. Given the increasingly important role of pharmacists providing patient care, it is appropriate to note the Board's attitude to *counselling* as a professional responsibility. In 1994 the Board advised pharmacists in response to requests for clarification of pharmacists' professional responsibilities concerning the provision of counselling:

When a prescription is dispensed ... a pharmacist should be satisfied that the patient understands how to use the medication correctly. Usually, this will entail the pharmacist's counselling the patient, or the patient's agent, and/or providing written information.[37]

VI. PHARMACY OWNERSHIP IN AUSTRALIA

In Australia, unlike the United States of America and the United Kingdom, only registered pharmacists may own pharmacies. Section 25(1) of the *Pharmacy Act* (NSW) 1964 provides:

> A person (not being a pharmacist), a corporation or a body of persons unincorporated shall not carry on, as owner or otherwise, the business of a pharmacist in a pharmacy or otherwise have a pecuniary interest, direct or indirect, in the business of a pharmacist carried on in a pharmacy.

Section 3(1) of the Act includes a definition of "business of a pharmacist" as meaning:

> The business of a chemist, pharmaceutical chemist, pharmaceutist, pharmacist, druggist, homoeopathic chemist, dispensing chemist or dispensing druggist.

"Pharmacy" is also defined in s 3(1) to mean:

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34 *Pharmacy Act* 1964 (NSW), s 6.

35 *Ibid* s 5.

36 *Ibid* s 19A.

37 Pharmacy Board of New South Wales, "Counselling as a Professional Responsibility" (August 1994) 4 *Bulletin*, p 7.

> Any premises in or on which a person carries on the business of a pharmacist and includes such portion (if any) of those premises in or on which the person sells or offers for sale goods of any kind, but does not include any such premises located in a hospital.

A pharmacist must be in attendance at all times.[38]

In 1964, the then New South Wales *Pharmacy Act* was amended to include, inter alia, the requirement that only pharmacists could have a direct or indirect pecuniary interest in a pharmacy. The New South Wales Parliament clearly saw this as a necessary restriction and it is one that has continued to the present day. From time to time there are suggestions from outside the profession, seeking to end or modify these restrictive ownership principles. It would appear inconsistent with the evolving role of pharmacists towards more direct patient care to change the law as to ownership. To change the law would place at risk pharmacy's contribution to the community's health and welfare. If permitted to own pharmacies, those not qualified nor amenable to professional disciplinary sanctions may not appreciate, or allow, proper professional practice standards to operate. Like all health profession registration Acts, the *Pharmacy Act* is intended to protect the public. The pharmacist's role, indeed the profession's very *raison d'etre*, is to serve as the community's custodian of, and expert in, drugs and drug therapy. Any change in the law weakening these ownership provisions may well place the public at risk.

VII. DRUG REGULATION AND CONTROL - AN ESSENTIAL ELEMENT IN AUSTRALIA'S DRUG DISTRIBUTION SYSTEM

Australia's drug distribution system is based upon the need to restrict potentially dangerous drugs and other substances. Although these are matters of local jurisdiction, there are now varying levels of adherence by State and Territories to a national standard developed through a Committee of the NHMRC; more recently by a Standing Committee of the Australian Health Minister's Advisory Council ("AHMAC").[39]

The perceived necessity for a uniform standard resulted in what is known as the *Standard for the Uniform Scheduling of Drugs and Poisons in Australia* ("the SUSDP"), which provides a series of schedules from 2 to 9 in increasing order of restriction. For present purposes, the schedules of special interest are Schedules 2 and 3. Schedule 2 includes those drugs available only from a pharmacy. Schedule 3 includes those to be supplied personally by the pharmacist, and which cannot be advertised except as a generic drug group.

As noted by one expert:

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38 Note 34 *supra*, s 27.

39 RFW Moulds, "Drugs and Poisons Scheduling" (1997) 20(1) *Australian Prescriber* 12 at 12-13.

> Toxicity is the keystone of scheduling. Medicines are inherently toxic which will cause harm in some circumstances. Drugs should only be used when the likely benefits to be gained outweigh the possible toxic effects.
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> This premise would not of itself require a system of scheduling, except for the corollary that members of the public often do not know enough about diseases to judge whether or not to take a particular drug. They are also not sufficiently aware of the different patterns of toxicity exhibited by different medicines to make this judgment.[40]

The Commonwealth Industry Assistance Commission recently inquired into the pharmaceutical industry and proposed initially, institutional reform of scheduling, but then recommended research into the role of counselling by pharmacists.[41] The Proprietary Medicines Association of Australia ("PMAA") saw advantages in such advertising to advance fully consumers' rights by "full and free interchange of information", noting that "as things stand people have very little information about the range of OTC products ... [ie. those available *over the counter* without prescription] ... which is available".[42] However, as the author has observed, in the education of the public about potent therapeutic substances, these laudable aspirations of industry, must remain ancillary to the functions of health professionals recognised and required by the State to control supply of such substances.[43]

As Moulds observed:

> Strong forces are now at work in Australia to reduce restrictions imposed by the scheduling system on consumer access to medicines. The forces include ideological arguments regarding individual autonomy and responsibility for health, governments attempting to shift payment from the public purse to individuals, and hopes by the pharmaceutical industry that lower schedules and, in particular, the access to direct advertising to the public, which lower schedules allow, will increase sales (and profits).
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> These forces should not be allowed to increase in morbidity. Health professionals and those involved in drug scheduling are responsible for getting the balance right.[44]

In recent years, there has been an increasing 'switch' or transfer of medications from prescription-only status to availability without prescription from a pharmacist.[45] The NSW Pharmacy Board recently reminded pharmacists of their professional obligations in accordance with the statutory description of Schedule 3 medications:

> [a]bout which personal advice may be required by the user in respect of their dosage, frequency of administration and general toxicity.[46]

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40 *Ibid.*

41 *Ibid*

42 P Dwyer, "The Legal Note: A Change in the Law?" (1996) 15(1) *Australian Pharmacist* 10 at 10-11.

43 *Ibid*

44 Note 39 *supra*, p 13.

45 Cf M Novitch, "Trends Driving the Over-The-Counter Drug Market" (1994) 28 *Drug Information Journal* 445 at 445-8

46 Pharmacy Board of New South Wales, "Non-Prescriptive Supply of Schedule 3 Products" (1996) 5 *Bulletin*, p 10. [Emphasis added]. See also Pharmacy Guild of Australia "Pharmaceuticals and the Schedules" (April 1997) *Guild Bulletin*, p 1.

In accordance with the statutory provisions, before supplying a Schedule 3 product, pharmacists should assess any request by asking themselves the following questions:

- is the product appropriate for the purpose for which it is intended?
- does the person know how to use the product, with particular reference to dosage and administration?
- is the person aware of potential hazards in using the medication, including possible drug interactions?

Following this assessment, the pharmacist must then decide whether to supply the medication. The Board has emphasised that, should supply be indicated, the pharmacist must ensure that the person is fully informed on all aspects of the medication. If necessary, the pharmacist, by appropriate counselling, must "fill the gap in the person's knowledge or, alternatively, refuse the request. It may be necessary for the pharmacist to refer the person to a medical practitioner".[47] The pharmacist's role in complying with these statutory and professional obligations regarding Schedule 3 medications is not without criticism. This was exhibited in a recent consumer survey which indicated concern relating to the use of asthma medication inhalers ("puffers").[48] Consequent upon this survey, the organisation who conducted it advised consumers to request advice from a pharmacist rather than merely request medication from a non-pharmacist assistant. It stressed the importance of using the same pharmacy to obtain all medications as this enabled the pharmacist to remain aware of a consumer's medical conditions and ensure improved continuity of care.[49]

It is submitted that the above legislative, professional and consumer indicia, recognise, encourage and indeed, demand, pharmacy's evolving role.

VIII. PATIENT OR CONSUMER INFORMATION ABOUT DRUGS

A. Australia

Dr David A. Kessler, Commissioner of the US FDA, concluded that: "face-to-face counselling, conveying both oral and written information is the most effective form of patient education."[50] In 1991 Professor Peter Baume reported on the future of drug evaluation processes in Australia and made many recommendations, all adopted by the then Federal Government, including the recommendation that consumers be as well informed as possible about their medications.[51] Baume has described his recommendation as prescriptive of

47 Pharmacy Board of New South Wales, *ibid.*

48 "Pharmacies on Trial" (April 1997) *CHOICE*, pp 6-10; see discussion in A Cresswell, "Pharmacy negligence fuels ß - agonist debate" (18 April 1997) *Australian Doctor* pp 1-2

49 *Ibid*

50 DA Kessler, "A Challenge for American Pharmacists" (1992) 32(1) *American Pharmacy* 33

51 P Baume, A Question of Balance. Report of the Future of Drug Evaluation in Australia (1991) AGPS, (1991) p 63

outcomes concerning patient information but not about the mechanisms by which this could be achieved.

Regulations were enacted pursuant to the *Therapeutic Goods Act* (Cth) 1989 to give effect to Baume's recommendation.[52] These require manufacturers of pharmaceuticals approved for registration (and thereby given marketing approval) on or after 1 January 1993, to supply written information meeting the requirements of Schedule 12 of the Regulations. This patient information became known, initially, as *Consumer Product Information* ("CPI"); more recently as *Consumer Medication Information* ("CMI").

In its original form, regulation 9A applied only to *prescribed* medications. It was later extended to include written information about those medications listed in Schedule 3 of the SUSDP, ie. those available from a pharmacist without prescription. It applies to those products approved for registration on or after 4 July 1995. The type of information required for these products is to be found in Schedule 13 of the Regulations.[53]

Following introduction of regulation 9A in its original form, various working parties were formed to consider its implementation. The CPI Legislation and Implementation Guidelines Working Party, of which the author was a member, developed Draft Guidelines which were endorsed by the Australian Pharmaceutical Advisory Council and were published by the Commonwealth Department of Human Services and Health in 1995.[54] Pharmacists have an important, arguably critical, responsibility to give effect to the legislative intention of the patient information regulations.

As the Commonwealth Government lacks constitutional competence to regulate the practices of pharmacy and medicine, it would seem unable to compel doctors or pharmacists to provide the information to consumers. Arguably, the Federal Government might use the *pharmaceutical benefits* provisions of the Australian Constitution (s 51 xxiiiA) to require this as part of a pharmacist's agreement to provide pharmaceutical benefits pursuant to the *National Health Act* 1953 (Cth).[55]

The Commonwealth's CPI Guidelines were developed for health professionals who were considered best placed to provide CPI as part of their provision of information and counselling regarding medicines. The Guidelines were not intended to be specific to any particular health profession but take into account that the act of *providing* a medicine may be linked to *prescribing, dispensing* or *administering* it. The Guidelines emphasise CPI as an important additional aid to *existing* arrangements and resources for counselling about medicines. They confirm the critical role of the pharmacist in achieving the legislative intention of regulation 9A and the recommendation contained in the Baume report.

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52 Statutory Rules 1992 No 430, *Therapeutic Goods Regulations* (Cth), Part 2A - Patient Information, and Regulation 9A.

53 *Ibid*, Regulation 9A(1A).

54 *General Guidelines for Health Professionals on Consumer Product Information*, AGPS, May 1995.

55 See *infra* discussion of a mechanism adopted by the US government the *Omnibus Budget Reconciliation Act* (1990) "OBRA-'90", 42 USC § 1396 r-8(g).

The Code of Ethics of the Pharmaceutical Society of Australia ("PSA") demands that the health of a patient or client be the pharmacist's primary consideration. It also includes, consistent with the above demand, the need for a pharmacist to supply professional advice and counselling.[56] CMI (or CPI) may be delivered in the manufacturer's primary pack (of medication) or "in another manner that will enable the information to be given to a person to whom the goods are administered or otherwise dispensed".[57]

It is the author's view, that the provision of information about medication, prescribed or otherwise, has always been part of a pharmacist's professional responsibility to ensure safe and efficacious use of medications. This is hardly surprising in light of a pharmacist's training, knowledge, skill and community access. It is an essential feature of the developing concept known as Pharmaceutical Care (discussed below). This responsibility is not only an ethical one but is an integral part of a pharmacist's obligation to take reasonable care to avoid foreseeable risk of injury.[58]

B. United Kingdom

Regulations have been published which implement European Community ("EC") decisions on the labelling of medicines and the content of packaged leaflets. These regulations only affect medicines for which product licences were granted or renewed on or after 1 January 1994. The legislation implemented part of the EC Directive [92/27/EEC] which aims to improve and harmonise the provision of information regarding medicines for human use. As a result, the then existing United Kingdom labelling and leaflet regulations were strengthened by the addition of the new requirements.[59]

In effect, this system provides the United Kingdom equivalent of the Australian CMI with a significant difference: the UK system is based upon Patient Information Leaflets (sometimes described as "PILs") being provided within the primary pack. In Australia, electronic distribution (at the point of dispensing by a pharmacist) is underway. Apart from economic advantages to manufacturers, electronic distribution provides a greater opportunity to keep leaflet information current, as amendments can be incorporated with less difficulty.

Quite apart from these leaflets concerning prescribed medication, it is the intention of the UK's professional and registration authority that every person purchasing medicine from a pharmacy should be provided with product information and offered professional advice in relation to it.[60] Mullan and Brushwood recently emphasised, in a comparative study, the significance of patient information leaflets in considering a pharmacist's expanded practice

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56 Pharmaceutical Society of Australia, *Code of Ethics for Pharmacists*, April 1997.

57 *Therapeutic Goods Regulation* 1992 (Cth), Regulation 9A(2).

58 P Dwyer, "The Legal Note: Patient Information (CPI) and Pharmacist Responsibility" (1995) 14(11) *Australian Pharmacist* 659 at 659-60.

59 Current Affairs, "New Medicines Labelling and Leaflet Regulations" (1993) 252 *The Pharmaceutical Journal* 108.

60 "Introductory Protocol Points" (1994) 253 *The Pharmaceutical Journal* 805

responsibility, and its relevance to a potential increase in legal liability should a pharmacist exercise this responsibility in a careless fashion.[61]

C. USA

In the US, provision of prescription drug product information to patients has been considered in regulatory agendas encompassing two decades. In 1981 this history was described as providing a "case study of the waxing and waning of Washington's regulatory fever"[62] and almost fifteen years later, the above observation, according to one commentator is still appropriate. In early 1981, President Reagan issued an Executive Order requiring a regulatory impact analysis of the potential costs and benefits of existing and future regulations and to consider less expensive alternative approaches. As a result, the FDA Commissioner revoked the final rule establishing patient package insert requirements, citing concerns including cost-effectiveness, disagreement about the design of a program by doctors and pharmacists responsible for its implementation, and lack of necessity given private sector patient education initiatives.[63]

In late 1995 the FDA proposed regulations that would set performance standards for the quality and distribution of prescription drug information for patients. The proposed comprehensive Medication Guide Rule would:

> [r]equire manufacturers to provide pharmacists and other authorised dispensers with the means to distribute FDA-approved Medication Guides for their products to help ensure that patients receive adequate information about their prescription drugs.[64]

These proposals have caused considerable controversy in the United States. The influence of special interest groups and the anti-regulatory atmosphere in Washington could effect a change in the proposed regulation or frustrate its implementation towards a final rule. The FDA's proposed regulatory initiative to provide useful prescription drug information to patients, may, once again, be thwarted.[65]

Given pharmacist's increased exposure to legal liability, consistent with their apparently changing role, it is not surprising that patient information and education about drugs is a subject FDA Commissioner Kessler has placed high on the FDA's agenda. According to surveys, at least 30 per cent and possibly as many as 55 per cent of patients do not take their medicine as prescribed.[66] In Australia, the Adverse Drug Reactions Advisory Committee ("ADRAC") makes available to doctors, pharmacists, and other health practitioners, a form titled *Report of Suspected Adverse Drug Reaction including Birth Defects*. This is a

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61 K Mullan and D Brushwood, "The Civil Liability of Manufacturers, Doctors and Pharmacists" (1997) 258 *The Pharmaceutical Journal* 309 at 309-13

62 JL Weiner, "Constraints on Regulating Content and Distribution of Prescription Drug Information" (1996) 24(2) *The Journal of Law, Medicine & Ethics* 158.

63 *Ibid.*

64 *Ibid* at 159, citing *60 Federal Regulations* at 44,198.

65 *Ibid* at 161

66 CR Scheman "Patient Information and Education about Drugs. The FDA Perspective" (1993) 27 *Drug Information Journal* 1133.

self addressed form, postage paid, directed to the Secretary of ADRAC upon completion. There is also the ADRAC *Bulletin* which is distributed without charge to relevant health professionals, highlighting recent adverse drug reactions.

The evidence as to the consequences of a patient's non-compliance with instructions is not so clear, but most people in the health care community acknowledge that this phenomenon is a widespread and serious problem. Surveys in the US have also suggested that improved patient information is the most effective counter-measure. The FDA Commissioner has made a special point of urging pharmacists to provide consumers with oral counselling as well as to provide computer-generated printouts detailing how to take the drug, along with information concerning possible side effects.[67] As observed by one author, with the right information, a drug is a therapeutic tool of enormous value to patients.[68] Without such fundamental information, a drug is reduced to a useless and potentially dangerous chemical.

Apart from the information flow directed to patients to improve better drug therapy, there is another area where plans are being made in the US to improve the flow of drug information: the area of adverse events reporting. This is presently believed to be an under-utilised method for bringing highly important safety data from patients back to practitioners, and thence to the regulatory authority.[69]

The introduction of methods by which written information can reach patients receiving prescribed medication and those receiving medication without a prescription, is universally accepted in Australia, certain European countries, and in the United States. The pharmacist's role in the effective dissemination and explanation of such information is obvious. Failure to observe necessary professional care with respect to this information responsibility may well expose a pharmacist to legal liability for any associated injury.

IX. THE CONCEPT OF PHARMACEUTICAL CARE

Pharmacy, like other health care professions, is facing substantial change and pharmacists are being challenged to alter their approach to practice. This phenomenon appears to have reached world-wide dimensions. In the US in 1989, Hepler and Strand defined the concept of *pharmaceutical care* as the responsible provision of drug therapy for the purpose of achieving definite outcomes which improve a patient's quality of life. It involves the process through which a pharmacist co-operates with a patient and other health professionals in designing, implementing and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient. This process involves the identification of potential and actual drug-related problems, resolving such

67 *Ibid.*
68 *Ibid* at 1134.
69 *Ibid* at 1136.

problems, and preventing potential drug-related concerns.[70] The PSA has accepted the concept, describing it as "essentially similar" to the Federal Government's policy on Quality Use of Medicines published in 1992 by the Commonwealth Department of Health and Human Services, to optimise medicinal drug use to improve health outcomes.[71] The PSA recognises that if Australian pharmacists are to make the best possible contribution to the government's policy, the Pharmaceutical Care concept should be quickly adopted by pharmacists as a standard practice.[72]

The concept has also been considered in the United Kingdom and other parts of Europe.[73] However, a view was expressed at an international pharmacy congress that the main barrier to implementing the concept was the problem of convincing other people - pharmacists, health professions generally, managers and patients - of the benefits of this approach to practice.[74] A recent government proposal to remunerate pharmacists for reviewing the medication of veterans in their homes prompted the Royal Australian College of General Practitioners to set up a 'new watchdog working party' to look at the role of pharmacists and how they impact on general medical practitioners.[75] Research into implementation of the concept continues.[76] Taken to its logical conclusion, it would seem that full implementation of the concept would require pharmacists' access to particulars of a patient's condition for which a particular drug was ordered by the prescriber, together with other relevant clinical data. Accepting the potential benefit to patients and the increasing costs to government of a subsidised pharmaceutical benefits scheme, this may not be an insurmountable barrier, provided confidentiality is assured. Development of the concept is further confirmation of the change in pharmacy practice, relevant to any consideration of a pharmacist's legal liability today.

Recent US Legislation

Relevant to the concept of pharmaceutical care is US Federal legislation introduced in 1990 titled the *Omnibus Budget Reconciliation Act* ("OBRA '90"). The effect of the Act is to require States, in partnership with the Federal Government in the provision of Medicaid, to meet certain conditions.[77] If they are to obtain Federal matching funds for their Medicaid costs, States must establish Drug Use Review ("DUR") programs. States are required to enact

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70 CD Hepler and LM Strand, "Opportunities and Responsibilities in Pharmaceutical Care" (1990) 47 *American Journal of Hospital Pharmacy* 533 at 533-43.

71 Pharmaceutical Society of Australia, *Pharmaceutical Care Project Strategic Plan* (1995) p 1.

72 *Ibid*

73 "Pharmaceutical Care - Time to 'Stop Walking Around the Issue'" (1993) 251 *The Pharmaceutical Journal* at 28, "Pharmaceutical Care and its Promotion" (1992) 250 *The Pharmaceutical Journal* 802

74 "Getting Started in Pharmaceutical Care" (1993) 251 *The Pharmaceutical Journal* 427.

75 A Cresswell, "Back Off GP Turf. Pharmacists Told" (18 July 1997) *Australian Doctor* pp 1-2

76 MA Tomechko, LM Strand, PC Morley, and RJ Cipolle, "Q & A from the Pharmaceutical Care Project in Minnesota" (1995) 35(4) *American Pharmacy* 30 at 30-9.

77 Medicaid is part of the US *Social Security Act* of 1935, which provides Federal grants of money to approved State Medical Assistance Programs for the aged, the disabled and for families with income and assets insufficient to meet health-care costs

legislative requirements for pharmacists to counsel Medicaid beneficiaries receiving prescription medications paid for by the Medicaid program. If a State elects not to introduce such legislation, it would not receive Federal funds; a simple formula.

The goal of the legislation is to ensure that medications are necessary, appropriate, and unlikely to result in adverse health outcomes. The DUR programs aim to educate pharmacists and prescribers to review and evaluate Medicaid prescriptions to avoid duplicated therapy, the interaction between different drugs, and drug-disease interactions; to ensure appropriate use of generic alternatives; and to avoid incorrect use or duration of therapy, allergic reactions or clinical misuse.

Pursuant to the legislation, US Federal funds will be withheld from a State, unless as part of its prospective DUR programs it enacts standards for counselling of patients receiving Medicaid prescription medications. This must include a requirement for a pharmacist to offer to discuss with each patient such matters the pharmacist deems significant. These matters include those elements found in the Australian CPI (or CMI) information pursuant to Regulation 9A of the *Therapeutic Goods Regulations* (Cth), discussed above. The US legislation also includes a requirement for the pharmacist to make reasonable efforts to obtain, record, and maintain certain information including personal particulars of the patient, medications and individual history where significant. This includes disease states, known allergies and drug reactions and current medications, together with pharmacists' comments relevant to the patient's drug therapy. It appears that most states have enacted local legislation to give effect to the requirements of OBRA '90.[78]

X. RELEVANT LEGAL PRINCIPLES

There are well-established principles, relevant to a pharmacist's legal liability for negligence. Their application to traditional pharmacy practice is reasonably clear, for example, errors in formulation, compounding and labelling of dispensed medications, together with failure to detect excessive dosage and serious interactions. However, application of these principles to the evolving role of pharmacists may be less predictable. A pharmacist faces potentially increased exposure to liability commensurate with the profession's changing role. Much, as always, depends upon the circumstances of any particular case. The evolving changes in pharmacy practice contemplate greater patient contact for reasons discussed above. These contacts are necessary in order to ensure that patients are suitably informed (or reminded) of the need to watch for adverse effects, to avoid other drugs (including alcohol) and sometimes certain foods, which might interact with prescribed medication. Likewise, in an appropriate case, pharmacists will need to warn patients of the need for care if driving a

78 See discussion of OBRA '90 in P Dwyer, "The Legal Note" (1996) 15(9) *Australian Pharmacist* 517 at 517-8

motor vehicle or operating machinery, whilst taking certain medication. These opportunities for patient contact are not intended to 'second guess' a prescriber's drug therapy but to reinforce his or her advice to the patient.

Often, the pharmacist is a patient's final contact with a knowledgeable health professional before commencing a course of medication. This is an opportunity which should not be neglected by a pharmacist. It is an occasion in which to also discuss any printed form of patient information and to ensure it is understood.[79] The pharmacist can therefore be considered to conduct an interventionist role.

To date, there have been no locally decided cases which have considered the content of a pharmacist's duty of care in these evolving practice areas. In the United States, judicial opinion is divided on a pharmacist's duty to warn a patient about prescribed medication. This issue is discussed below.

When considering a pharmacist's duty of care, including any evolving change in pharmacy practice, the words of Lord Atkin encapsulate the "neighbour principle":

> The rule that you are to love your neighbour becomes in law, you must not injure your neighbour; and the lawyer's question, 'who is my neighbour?', receives a restricted reply. You must take reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbour. Who, then, in law is my neighbour? The answer seems to be - persons who are so closely and directly affected by my act that I ought reasonably to have them in contemplation as being so affected when I am directing my mind to the acts or omissions which are called in question".[80]

A pharmacist's intervention in appropriate circumstances falls squarely within the principles enunciated by Lord Atkin. Clearly, it is reasonably foreseeable to a pharmacist that a patient's failure properly to take prescribed (and any other) medication has the potential for harm which, by his or her intervention, when indicated, will, or might, avoid an unfavourable outcome for the patient. When indicated, pharmacists (as experts in their field) must intervene to provide the best opportunity for patients to achieve safety and efficacy with their drug therapy. Quite apart from cases where intervention is obvious to a pharmacist, patient contact should become routine.

XI. THE DUTY OF CARE

The law imposes on a pharmacist a duty to exercise reasonable care and skill in the practice of his or her profession. Adopting the words of the High Court of Australia, when applied to a medical practitioner, that duty is a "single, comprehensive duty covering all the ways in which [a pharmacist] is called upon to exercise ... skill and judgement" and will extend to the provision of information in an appropriate case.[81] In any given case it is necessary to give

79 For an example of a case involving the supply of wrong medication see P Dwyer, "The Legal Note" (1996) 15(10) *Australian Pharmacist* 591 at 591-2.

80 *Donoghue v Stevenson* [1932] AC 562 at 580.

81 *Rogers v Whitaker*, note 2 *supra*

content to the duty of care.[82] The developing areas of more direct patient care add to the ways in which a pharmacist is called upon to exercise the skills and judgement for which he or she is trained. Accordingly, these newer areas add to the content of the pharmacist's duty of care.

In relation to foreseeability:

> A risk of injury which is remote in the sense that it is extremely unlikely to occur may nevertheless constitute a foreseeable risk. A risk which is not far-fetched or fanciful is real and therefore foreseeable. But ... the existence of a foreseeable risk of injury does not of itself dispose of the question of breach of duty. The magnitude of the risk and its degree of probability remain to be considered with other relevant factors.[83]

To decide whether there has been a breach of the duty of care, Mason J said:

> The tribunal of fact must first ask itself whether a reasonable man in the defendant's position would have foreseen that his conduct involved a risk of injury to the plaintiff or to a class of persons including the plaintiff. [If] affirmative, it is then for the tribunal of fact to determine what a reasonable man would do by way of response to the risk. The perception of a reasonable man's response calls for a consideration of the magnitude of the risk and the degree of the probability of its occurrence, along with the expense, difficulty and inconvenience of taking alleviating action and any other conflicting responsibilities which [a] defendant may have. It is only when these matters are balanced out that the tribunal of fact can confidently assert what is the standard of response to be ascribed to the reasonable man placed in the defendant's position".[84]

A pharmacist's failure to ensure that a patient is aware of, and understands, how properly to take prescribed medication (indeed, all medication) may well result in harm to the patient. Every pharmacist should appreciate this risk. Accordingly, using the words of Mason J, such risk would be foreseeable to a pharmacist. Clearly, the probability of a risk materialising may be remote in many cases. It is not suggested that each and every dispensed medication needs the same level of attention by a pharmacist. However, pharmacists well know that there are some categories of drugs which require special care because of their unique properties and, if not taken correctly, can result in serious harm which may not be remote. In other words, when a prescription calls for such drugs, a pharmacist is placed on immediate notice of the need to ensure that a patient understands the need to comply with appropriate directions. Some examples are discussed below. In such cases, it is difficult to envisage any factors of expense, difficulty or inconvenience (using the words of Mason J above) to avoid responding to the potential harm which might flow from inappropriate use of certain medications.

In Australia, the standard of care to be observed by a pharmacist as a person with some special skill or competence, is that of the ordinary skilled pharmacist exercising and professing to have that special skill. But that standard is not determined solely or even primarily by reference to a responsible body of opinion in the profession.[85] The so-termed '*Bolam* principle', is, in effect, that a

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82 *Ibid*

83 *Wyong Shire Council v Shirt* (1980) 146 CLR 40 at 48, per Mason J.

84 *Ibid* at 47-8

85 *Rogers v Whitaker*, note 2 *supra* at 487

pharmacist is not negligent if he or she acts in accordance with a practice accepted at the relevant time as proper by a responsible body of pharmacists.[86] In Australia there has been a "progressive retreat" from the *Bolam* principle.[87] This is not to say that evidence of professional practice will not assist a court determining whether a pharmacist has been negligent. Often such evidence will be useful and may sometimes be decisive of that question, but ultimately it is for a court to adjudicate on what is the appropriate standard of care.[88]

As part of its consideration of the standard of care demanded by the law, a court is likely to have regard to the nature and extent of a pharmacist's education, together with evidence of the profession's endorsement of changes in pharmacy practice embracing more direct patient care. It is important, when considering a pharmacist's conduct called into question, to bear in mind the necessary emphasis on the word "reasonable". As former Chief Justice of the High Court of Australia, Sir Garfield Barwick, has stated:

> The respondent's duty [is] to take reasonable care ... it is easy to overlook the all important emphasis upon the word 'reasonable' in the statement of the duty [of care] ... Perfection or the use of increased knowledge or experience embraced in hindsight after the event should form no part of the components of what is reasonable in all the circumstances. That matter must be judged in prospect and not in retrospect.[89]

Negligence in pharmacy practice may be more readily concluded in some circumstances. Instances of unintentional or inadvertent error, such as giving a patient the wrong drug, wrongly manufacturing or compounding a prescribed medication, incorrect labelling of medication, or failing to detect the interaction between different drugs, may all lead a court to conclude that a pharmacist has been negligent. In other areas it may be more difficult, for example regarding a failure to warn. The question then to be decided is whether in all the circumstances a pharmacist's duty of care included an obligation to give relevant warnings.

The primary obligation for warning a patient about medication lies with the prescribing medical practitioner.[90] This assists a patient to make an appropriately informed decision whether or not to take the medication. Should the pharmacist be entitled to rely on an assumption that this information has been provided to the patient by the prescriber? The answer to this question should be framed in the negative. This is in no way intended to be a criticism of prescribers. Often a pharmacist will be able to reinforce or remind a patient regarding information given by a prescriber.

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86 The principle is derived from McNair J in his directions to the jury in *Bolam v Friern Hospital Management Committee*, note 1 *supra*.

87 *Woods & Ors v Lowns & Anor* (unreported, NSW Supreme Court, 9 February 1995, Badgery Parker J) at 26

88 *E v Australian Red Cross* (1991) 27 FCR 310 at 358-60.

89 *Maloney v Commissioner for Railways (NSW)* (1978) 52 ALJR 292 at 292 (emphasis added)

90 Cf *Rogers v Whitaker* note 2 *supra;* see also discussion in Law Reform Commission of Victoria, the Australian Law Reform Commission and the New South Wales Law Reform Commission Report, *Informed Decisions About Medical Procedures*, 1989.

Much will depend upon the circumstances of the individual case, but generally, a pharmacist should exercise due care to ensure, especially on the first occasion prescribed medication is provided, that the patient is aware of relevant information. This process includes the giving of CMI (or CPI) together with an appropriate explanation. Inevitably patients will have varying levels of comprehension, especially where the information may be complex or the dosage regimen unusual.[91] What pharmacists must always remember is the probability that he or she is the final health care professional contact a patient may have before commencing to take prescribed medication.

Although the primary obligation to provide relevant information may be that of the prescriber, that medical practitioner may be unaware that the patient is currently taking medication prescribed by another practitioner; or, whether the patient is currently taking any OTC product/s. Accordingly, potential interaction may not be known to the practitioner. Patients may not volunteer relevant information and perhaps not disclose it even when asked by a prescriber, or for that matter, by a pharmacist. The issue might be dealt with more effectively by a particular pharmacist to whom the patient presents all prescriptions for dispensing and from whom any medication is obtained. In this case, any potential adverse effects or interactions should be identifiable by reference to the patient records maintained by the pharmacist. On the other hand, the patient may well attend a variety of pharmacies, making it impossible *without enquiry*, for the pharmacist to know of other current medications.

The phenomenon known as "doctor shopping" is not, apparently, uncommon and presents problems associated with excessive drug use (and abuse), especially those medications known to be habit-forming or to cause dependence. This practice recently attracted the attention of a New South Wales Coroner, enquiring into a young man's death which was believed to be associated with dextropopoxyphene, a drug with morphine-like effects which can cause dependence. As evidence in the inquest demonstrated, the use of this drug can often lead to abuse even though it was originally prescribed for a legitimate purpose. The Coroner observed that it was possible "to feed a prescription drug addiction by simply going from one medical practitioner to another". He emphasised the pharmacist's obligation to act upon indicators that a patient is "doctor shopping" for the same medication.[92]

The Australian Pharmaceutical Advisory Council ("APAC") is the major body advising the Australian Government on pharmaceutical policy issues. It recently considered privacy issues relating to the use of medication data and published a discussion paper to advise government.[93] APAC has an ongoing commitment to promote quality use of medicines by consideration of ways of better achieving this objective. Patients may attend several medical practitioners, each of whom,

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91 See the example discussed in P Dwyer, "The Legal Note" (1997) 16(7) *Australian Pharmacist* 395 at 414, which involved the drug Methotrexate.

92 Discussed in P Dwyer, "Pharmacists and Adverse Drug Reactions (ADRs): The Legal Note" (1995) 14(10) *Australian Pharmacist* 604 at 604-5

93 Australian Pharmaceutical Advisory Council, Draft Position Paper, *Addressing Privacy Issues Relating to Use of Medication Data*, 1997

unbeknown to the other, may prescribe different medications. These patients may obtain their prescribed medicines from various pharmacies. They may also obtain OTC medications from more than one pharmacy. Some or all of these medications may be taken concurrently. This may pose a risk of serious harm from interactions between drugs or adversely affect optimal efficacy in drug therapy. Each of the various medical practitioners and pharmacists involved in prescribing and supplying medications respectively, may be unaware of the entirety of medication taken by the patient. "Doctor shopping" was also considered by APAC in this context.

Although APAC regarded community pharmacy in Australia as highly computerised, it observed that the pharmacist may not have a complete record of a consumer's medications as the patient may be utilising the services of more than one pharmacy and there is currently no data sharing or networking system as between pharmacies.[94] It also noted that pharmacy records are not linked to clinical records, including diagnosis and indications.[95] APAC further observed that a pharmacy record may not provide a comprehensive record of an individual's medication use, especially in respect of prescription medication obtained elsewhere and OTC medication.[96] APAC regards pharmacy records as potentially useful for public interest purposes and although some networks have been established between pharmacies, it was not clear to APAC whether these included adequate privacy provisions.[97]

Provided sensitivity about privacy aspects can be dealt with, APAC sees merit in the use of *medication smart cards*. Such cards can contain accurate, up-to-date health information which can be encrypted to provide access to information on a selective basis.[98] APAC noted the potential benefits for quantities of medicines from the use of such medication cards which would allow consumers to carry an accurate record of their prescription medication in a highly portable and convenient form.[99] APAC believes that such cards, if introduced, should be held by consumers.[100] This should assist in overcoming many concerns about privacy of recorded data.

Provided that the relevant privacy concerns can be overcome, APAC's proposals concerning a consumer medication card have the potential to contribute to reduction of drug-induced morbidity and mortality in Australia as well as making medication more efficacious. The Boots Company pharmacies in the United Kingdom have commenced the use of a medication card system, whereby participants are issued with a card which includes relevant medical and medication data. The card is held by the consumer to be produced when obtaining medication at any of the Company's pharmacies throughout the United

94 *Ibid* p 14.
95 *Ibid*
96 *Ibid.*
97 *Ibid*
98 *Ibid* p 28.
99 *Ibid.*
100 *Ibid* p 29

Kingdom. In this way, both prescribed and OTC medications can be checked for any interactions or other adverse effects.

XII. PHARMACIST LIABILITY: SOME DECIDED CASES

A pharmacist's liability for drug-induced injury may potentially arise from the dispensing of a prescription written by a medical practitioner. It may also arise where injury occurs consequent upon use of a manufacturer's OTC product (ie. without prescription) or indeed, one manufactured and provided by a pharmacist when requested or recommended.

Where an OTC is required to be *personally* provided to a client a pharmacist may fail to appropriately deal with the transaction. For example, where the manufacturer's product is requested of, or recommended by, the pharmacist, he/she may not alert or warn the purchaser of a potential drug interaction; or fail to warn of a contra-indication to its use. The pharmacist will need to raise relevant issues with the purchaser before supplying this medication. If not, and if injury occurs, liability is likely to attach to the pharmacist if the injury is causally connected to the failure. [101]

A pharmacist's obligation to exercise reasonable care in dispensing prescribed medication commences when a prescription is presented at the pharmacy. When the dispensed medication is handed to a patient and any relevant information (including CMI) given, the initial dispensing function is complete. However, continuing obligations may include subsequent refills of the medication authorised by the prescriber. The pharmacist's continuing obligations also extend to the dispensing of other prescribed medication which may have a complication (for example an interaction which may occur if taken with the drug/s dispensed on the earlier occasion).

When presented initially, a prescription may raise questions able to be answered during discussion between the patient (or perhaps a carer) and the pharmacist. Likewise, when dispensed medication is given to the patient, there is further opportunity to impart relevant information such as CMI, together with other information necessary to ensure optimal safety and efficacy of the dispensed medication. The following discussion outlines circumstances where liability might be incurred.

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101 For present purposes, it is not necessary to discuss further, the pharmacist's liability in respect of OTC medication. See discussion in P Dwyer "The Legal Note: Pharmacists and Adverse Drug Reactions (ADRs)" (1996) 15(11) *Australian Pharmacist* 647 at 647-8. This considers OTC products and a pharmacist's duty of care including Schedule 2 items of the SUSDP (ie available only from a pharmacy) in the context of a death caused by abuse and excessive ingestion of a Schedule 2 cough linctus.

XIII. WRONG DRUG

A. New South Wales

Contrary to the prescriber's request for Spirit Ear Drops which contain alcohol, a pharmacist mistakenly used a corrosive chemical - liquefied phenol (also known as carbolic acid), when preparing them. Not surprisingly, the patient suffered injury to her ears and sued the pharmacist. Liability was admitted and the court, in assessing damages, said:

> The defendant ... [ie. the pharmacist] held a privileged and responsible position in the community ... where the lack of reasonable care may well cause death or disability ... It is appalling to think that a pharmacist is permitted to locate mixtures in close proximity which might be mistakenly dispensed with results such as has occurred in this instance.[102]

With respect, the Court's description of the failure of the pharmacist to more correctly position the bottles, arguably overlooks the protocol which a pharmacist should observe in preparing the ear drops: a pharmacist should, by looking at the liquefied phenol as it is measured, be on immediate notice of its physical properties quite distinct from alcohol. Nevertheless, the Court's observations have important risk management implications.

A separate local case, not apparently litigated, became the subject of professional misconduct proceedings (which ultimately did not proceed to an inquiry).[103] A prescriber ordered Sodium Bicarbonate tablets by writing on the prescription its chemical symbols - NaHCO3. Mistakenly, the pharmacist dispensed Lithium Carbonate (a potent anti-depressant) the chemical symbols for which are Li_2CO_3. The patient required hospitalisation.

Prescribing medications using chemical symbols is a dangerous practice which should not be followed. Another example, in a hospital pharmacy setting, concerned a prescriber ordering ear drops for a patient using the chemical symbols NaOH, or Sodium Hydroxide, commonly known as Caustic Soda which, like the liquefied phenol example above, can cause serious damage to the ears. Fortunately, the error was detected at the pharmacy, the prescriber was advised, and the prescription amended. Clearly, the pharmacist's failure in the liquefied phenol example caused harm which was reasonably foreseeable and which could have been avoided by the exercise of reasonable care. The same applies to the Lithium Carbonate example. In the final example above, the pharmacist's exercise of reasonable care avoided the risk of significant injury to the patient.

B. USA

Due to a pharmacist's error, a 78 year old patient received a heart medication instead of the diuretic product prescribed by her doctor. As a consequence, she required admission to hospital and died two weeks later. The matter came before the Nevada Pharmacy Board in 1995 which found that the pharmacist had negligently dispensed the heart medication. T*he pharmacy* was placed on two

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102 *Karaolani v Kazacos* (unreported, NSW Supreme Court, Common Law Division, 15 April 1983).

103 Cf discussion above concerning s 19A of the *Pharmacy Act* 1964 (NSW).

years probation and fined two weeks of net profit, likely to be, in total, between US$21,000 and US$35,000.

Evidence before the Board suggested that the pharmacy gave its employed pharmacists too large a workload which resulted in a higher number of prescription errors than other pharmacies in the State of Nevada. The Board recommended that the pharmacy be required to document prescription errors over the following two years. Additionally, it was recommended that the pharmacy be remodelled to better facilitate the confidential counselling of patients. The Board also recommended that a half-page reprimand be placed in the Las Vegas newspapers. The pharmacy was required to develop a quality assurance program and to undertake a study to demonstrate how it would counsel all patients about their prescribed medications. The same pharmacy later became a defendant when it again failed to dispense the correctly prescribed medication. The plaintiff's allegations included the pharmacy's failure to provide adequate personnel to dispense prescriptions.[104]

XIV. COMMENT

In recent years there has been much discussion regarding dispensing errors, their causes and how to avoid them. Frequently encountered as causes of dispensing errors are different drug products whose names, presentation, pack or colour are similar.[105] According to one US study, the largest percentage of claims resulting from mechanical errors were based on the allegation that the pharmacist had dispensed a drug other than the one prescribed. The second largest percentage of claims were for dispensing the wrong strength of the prescribed medication. Together these claims accounted for almost 80 per cent of the claims studied.[106] A pharmacist's counselling of patients may also be a mechanism whereby the pharmacist is alerted to a possible mechanical error, such as those discussed above.[107]

XV. MISTAKE IN PREPARATION

Although not resulting in civil litigation, the following case was the subject of a coronial inquest and later professional misconduct proceedings before the New South Wales Pharmacy Board.[108] A pharmacist was presented with a prescription for an aqueous mixture requiring 10mg of Morphine Hydrochloride

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104 A patient suffered seizures which caused loss of consciousness and required hospitalisation. He also suffered mental and behavioural disorders and was being assessed for brain damage. The case is discussed in P Dwyer, "Profits Before Patient Safety?" (1997) 16(1) *Australian Pharmacist* 17.

105 P Dwyer, "Are Dispensing Mistakes Avoidable?" (1995) 14(8) *Australian Pharmacist* 496 at 515

106 KR Baker, D Mondt, "Risk Management in Pharmacy. Preventing Liability Claims" (1994) 34 *American Pharmacy* 60 at 60-72.

107 MJ Lynn, RE Kamm, "Avoiding Liability Problems" (1995) 35(12) *American Pharmacy* 15 at 15-21

108 NSW Coroner's Court 1991· State Coroner Mr K Waller, *Death of Winifred Chambers*, Findings, 3 Feb 1992.

in 10mls. Mistakenly, the pharmacist prepared the mixture with a concentration of 100mg in 10mls. The labelled single dosage was as ordered by the prescriber: 10mls. This resulted in a ten times error in the morphine administration. The State Coroner made a complaint to the New South Wales Pharmacy Board who, after it conducted an inquiry into the matter, made a finding of professional misconduct against the pharmacist.

In this example (as found by the Pharmacy Board at its inquiry) a dose of 100mg of morphine was sufficiently extraordinary to have put a pharmacist, exercising reasonable care, on notice of it. Although the pharmacist made a mistake in his calculation and preparation of the mixture, the (erroneous) dose should have been checked with the prescriber. This would have produced the most likely result of a corrected dose. The Coroner found that the patient died of acute narcotism associated with her illness, following her ingestion of an excessive dose of morphine, which had been dispensed in error. The pharmacist's knowledge of morphine's properties should have alerted him that a dose of 100mg posed a risk of foreseeable harm, especially when the patient was terminally ill.

The Pharmacy Board's findings included observations that under normal circumstances, for a patient who is not tolerant to narcotics, a 100mg dose would depress respiration, resulting in death. It believed that in this case the patient would have been tolerant to some extent, to morphine as a result of previous medication. Applying negligence principles to this case, it would seem uncontestable that the pharmacist was in breach of his duty of care to the patient and fell below the standard to be expected of the average, competent pharmacist in the circumstances.

It is not usually expected that a pharmacist would be found guilty of professional misconduct by making an isolated mistake. Much depends upon the circumstances. The above case is one local example and another occurred in the United Kingdom in 1985, likewise resulting in a finding of professional misconduct.[109]

XVI. PRESCRIBER'S WRONG DIRECTIONS AND PHARMACIST'S FAILURE TO DETECT

A. United Kingdom

In the English case, *Dwyer v Roderick*, a migraine preparation containing Ergotamine was prescribed for a patient.[110] The doctor ordered on the prescription, two tablets to be taken every four hours, without qualification. At the time, Ergotamine was well known to interfere with circulation if taken excessively. This in turn, could adversely affect the viability of tissue, possibly leading to gangrene. These adverse effects were well documented. Because of

109 GE Appelbe and J Wingfield, *Dale and Appelbe's Pharmacy Law and Ethics*, The Pharmaceutical Press (5th ed, 1993) pp 233-4.

110 (1983) 80 *Law Society Gazette* 3003

its potential for harm if taken excessively, Ergotamine had a usual dosage regimen restricting the amount to be taken for any single migraine attack and a maximum amount to be taken in any particular week.

Accordingly, as written, the prescriber's instructions were prima facie incorrect. The pharmacy failed to detect this, nor did any pharmacist seek to check the dosage with the prescriber. The patient ultimately suffered gangrene and required amputation of some toes. She instituted a claim in negligence against the prescriber and another medical practitioner called in to consult with the plaintiff when first experiencing symptoms of Ergotamine overdosage, which were not identified. The pharmacy was also joined as a defendant.

At first instance, the Court noted the proximity of the pharmacist to the patient at the time of labelling the medication and rejected a submission (using a cricket analogy) that the pharmacist was merely a "long stop" to cover the doctor.[111] The prescribing doctor and the pharmacy admitted liability and the other medical practitioner was also found to have been negligent. Damages were apportioned at 45 per cent (prescriber), 40 per cent (pharmacy) and 15 per cent (the second practitioner called in). On appeal the pharmacy attracted 55 per cent and the prescriber 45 per cent.

Another English case in 1988 involved a badly written prescription which called for three medications.[112] Two were for asthma and the third, an antibiotic. Instead of the antibiotic the pharmacist dispensed a drug used in the treatment of diabetes, to reduce sugar levels. Not surprisingly, the patient suffered drug-induced depletion of sugar resulting in hypoglycaemia and consequent permanent brain damage. The patient instituted an action in negligence against the prescriber and the pharmacist. The doctor was held liable because of his bad writing, in breach of his duty to write sufficiently legibly for the purpose of the pharmacist. This appears to be the first case of an injured plaintiff suing a prescriber for a badly written prescription resulting in injury.[113] The pharmacist did not escape liability. Quite apart from the need to double check a prescriber's poor handwriting, the Court found that the pharmacist should have been at least put on notice by the asthmatic preparations, that the diabetic medication may not be correct. Damages were awarded 75 per cent as against the prescriber and 25 per cent against the pharmacist.[114] As one author notes, this case is important as it appears to be the first English decision in which a professional person has been held to owe a common law duty to anyone in respect of the standard of his or her handwriting.[115]

In each of the aforementioned cases, the written prescriptions contained indicators of potential harm to each patient, reasonably foreseeable to the average, competent pharmacist exercising ordinary care. Each involved serious

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111 J Crawford "Pharmacist's Liability for Drug-Induced Injury" (1994/5) 2 *Journal of Law and Medicine* 293 at 300

112 See note 114, *infra*

113 D Brahams, "Illegible Prescriptions" (1988) *Lancet*, 1061 cited in J Crawford "Pharmaceutical Liability for drug Induced Injury" (1994/5) 2 *Journal of Law and Medicine* 293 at 300

114 *Prendergast v Sam & Dee Ltd, The Times*, 24 March 1988, p 19

115 Note 111 *supra*

and permanent injury and disability, which the exercise of reasonable care would have avoided. Given the propensity of each medication to cause the type of harm which in fact occurred, if not taken correctly, the risk thereof was reasonably foreseeable.

B. USA

Having attempted suicide, a patient was hospitalised and treated with a potent anti-depressant drug (Tranylcypramine) a member of a class of drugs known as monoamine oxidase inhibitors ("MAOIs"). The patient had been made aware of potentially serious complications should the drug be taken with certain foods or other medications. The patient and his wife were familiar with the patient information literature for the particular product. He continued to take the medication dispensed at the same pharmacy for approximately three years. Prior to the unfortunate event described below, OBRA '90 had not been implemented. The prescribed medication was successful in dealing with the patient's condition. Some three years later the patient consulted the same doctor about a cold and was prescribed two medications, one of which was contra-indicated in a patient taking an MAOI drug and if taken together, had serious consequences.

According to his records, the doctor was told that the patient was taking the MAOI. The newly prescribed medications were dispensed from the pharmacy where, eleven days earlier, his MAOI prescription had been refilled. As became evident at trial, the pharmacy's computerised drug-drug interaction program had been turned off. The interaction went undetected. Because of the interaction the patient suffered a stroke which required treatment and rehabilitation in hospital. Several months after discharge from the hospital he committed suicide, leaving a note to the effect that the aftermath of the stroke was too heavy a burden after all his earlier problems.

The widow instituted a claim against the physician and the pharmacy in negligence. The physician settled the claim before trial and the Court dismissed the widow's claim against the pharmacy, finding it was the fault of the doctor. At the trial, counsel for the widow and the pharmacy noted that earlier decisions of the Michigan Court of Appeal had held that a pharmacist had no duty to warn about prescribed medications and that pharmacists are not liable for correctly dispensing a prescription; that is, if what the doctor orders is dispensed, the pharmacist is protected.

On appeal, the Michigan Court of Appeals found the pharmacy negligent because it had "voluntarily assumed the duty of care when it implemented the [drug interaction program] and then advertised that [it] would detect harmful drug interactions".[116]

This serious interaction was well documented at the time of the incident. Wisely, the pharmacy (like those in Australia) had available to it a computerised drug/drug interaction program. Unwisely, however, it was turned off. Even without such an interaction program, the nature of the particular drug and its

116 *Baker v Arbor Drugs Inc*, Michigan Court of Appeals, 1996, discussed in "Rx Ipsa Loquitur" (1996) 23(6) *American Society for Pharmacy Law*. See also P Dwyer and T Kot, note 13, *supra*.

propensity for serious interaction, should have alerted every pharmacist to check that there was no interaction. Not only should such prescriptions be closely scrutinised for accuracy, but, as part of routine procedure, pharmacists should counsel patients receiving these medications, including explanation of any written information provided with such medications. The risk of serious harm from taking these medications as prescribed, was foreseeable and would have been avoided by the exercise of reasonable care in checking these medications.

XVII. FAILURE TO WARN

A. USA

This aspect of liability has been considered in many jurisdictions in the United States and at a variety of levels of judicial determination.[117] These decisions are of interest to Australian pharmacists, especially in light of the US OBRA '90 legislation.[118] The topic has also been considered recently as part of a comparative discussion on civil liability of manufacturers, doctors and pharmacists in the UK and USA.[119] Much in relation to the US decisions turns upon peculiar features of the many state jurisdictions, the doctrine of the *learned intermediary* and strict liability issues. However, a change has been observed in the traditional finding of no duty to warn.[120]

In 1985 a US Federal Court held that a pharmacist has no duty to warn the patient or notify the prescriber that the drug is prescribed in dangerous amounts, that the patient is being overmedicated or that the various drugs in their prescribed quantities could cause adverse reactions. To impose such a duty, the Court found, would "only serve to compel the pharmacist to second-guess every prescription a doctor orders in an attempt to avoid liability".[121] US Courts are starting to acknowledge that the pharmacist has drug expertise as well as personal knowledge of a particular patient and are now subjecting the pharmacist to potential liability.[122]

In effect, prior to introduction of the OBRA '90 legislation, courts had mainly found that pharmacists had no duty to warn patients about either the prescribed drug or the correct way to take it, regarding pharmacists as mere retailers of goods. They believed it was unfair to place a duty on the pharmacist when the physician determined what drug was appropriate for the patient. As part of this judicial reasoning, the physician was deemed more familiar with a patient's

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117 See discussion in JW Cremer and PR Pender, "Pharmacist Liability: A Duty to Warn?" (1995) 37(6) *For the Defense* 2 at 2-7.

118 Cf P Dwyer, "The Legal Note" (1996) 15(9) *Australian Pharmacist* 517 at 517-18.

119 Note 61 *supra*

120 MJ Lynn and RE Kamm "Avoiding Liability Problems" (1995) 35(12) *American Pharmacy* 15 at 15-21; cf discussion of cases therein

121 *Jones v Irvin* 602F, SUPP, 399, 402-3 (SD) iii (1985)

122 Note 120 *supra* pp 15-16

condition and hence, in a better position than the pharmacist to warn about the drug and its effects.[123]

In 1982, however, an appellate court reversed a summary judgment in favour of the pharmacist who, knowing the patient was an alcoholic, failed to warn of the potential side effects when the prescribed medication was taken with alcohol. The court returned the matter to the trial court, finding: "Such conduct ... could be found to constitute a breach of a druggist's duty of ordinary care in that it knowingly ignores the danger and consequences of ingestion".[124]

It is the author's view that a pharmacist's duty would also extend to notifying the prescriber in such circumstances. It is to be noted from *Hand v Krakowski*,[125] that the author's earlier observations of the *interventionist* nature of a pharmacist's practice is readily appreciated. The pharmacist had information which was not known to the prescriber. Accordingly, with this knowledge, there can be no dispute, whether in the United States or Australia, that the pharmacist would be in breach of their duty to the patient.

A more recent example of the recognition of the pharmacist's duty is the decision of the Indiana Supreme Court. A patient was addicted to propoxyphene (similar to the drug referred to above, the subject of a Coronial Inquest in New South Wales).[126] Neither the patient's doctor, nor his pharmacist was initially aware of that addiction. The patient received numerous prescriptions for the drug, in various brands and took them at a rate much greater than prescribed. In a single month, the patient's prescription orders were filled twelve times, confirming the patient's or his wife's attendance at the pharmacy every two or three days. His doctor decided the patient was taking the medication at an excessive rate and refused to authorise any further prescription renewals. The patient threatened to commit suicide and later sued the pharmacy.

The plaintiff's case was that the pharmacy was negligent in failing to stop dispensing his prescription orders. It was the pharmacy's defence that pharmacists did not have a duty to warn nor any duty to refuse to dispense a properly authorised legal prescription. The Indiana Supreme Court disagreed, finding that:

> A pharmacist must exercise that degree of care that an ordinary prudent pharmacist would under the same or similar circumstances. What constitutes due care in a particular case will depend upon the circumstances of that case and will usually be a question of fact ... [T]he determination of whether due care was exercised in a particular case may involve such issues as the frequency with which the pharmacist filled prescriptions for the customer, any representations made by the customer, the pharmacist's access to historical data about the customer, the manner in which the prescription was tendered to the pharmacists [sic], and the like.[127]

Prior to the above decision of the Indiana Supreme Court, an Arizona appellate court held that a pharmacy owed a patient a duty of reasonable care.

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123 *Ibid.*

124 *Hand v Krakowski* 89 App Div 2d 650; 453 NYS 2d 121 (1982) at 123

125 *Ibid.*

126 *Hooks v Super Rx v McLoughlin* (1994) WL 619 709 (Ind) Discussed in P Dwyer "The Legal Note" (1995) 14 (10) *Australian Pharmacy* 604 at 604-5

127 *Hooks v Super Rx v McLoughlin*, *ibid* at 4-5

The Court relied partly on the American Pharmaceutical Association's *Standards of Practice for the Profession of Pharmacy*.[128] This includes an obligation to warn of a drug's addictive nature and of the hazards of ingesting two or more drugs that adversely interact, as well as an obligation to notify the prescriber if the patient appears to be taking the drugs excessively inconsistent with the manufacturer's recommended dosage guideline.[129] At the time, this was the first US case to expressly acknowledge that Pharmaceutical Care may be the standard of care required of all pharmacists in the future.[130] In *Lasley*, the community standard of care imposed upon health care providers and other professionals, was held to apply to pharmacists "because they are professionals in the health care area".[131]

More recently, the Supreme Court of Tennessee affirmed that the manufacturer, doctor and pharmacist were not liable to a plaintiff on the particular facts, however it also clearly recognised that each of those defendants had a duty to provide warnings about potential drug therapy problems.[132] In this case an adult plaintiff was visiting his grandmother's home. She referred him to a place where she kept her tablets so that he could get some aspirin for his influenza. The plaintiff took the grandmother's diabetic medication believing it was aspirin. He developed a severe reaction to the drug. Upon admission to hospital he was found to be suffering from severe hypoglycaemia. He sustained permanent brain damage and became hospitalised in an extended care facility.

Apart from *Dwyer v Roderick and Ors*[133] and *Prendergast v Sam and Dee Limited*,[134] Courts in the United Kingdom have not conclusively examined the relationship between manufacturers, doctors and pharmacists, the part they play in the drug distribution process and their potential for liability should they cause injury to a patient.[135] In *Pittman*, the pharmacy argued that it owed no duty to a non-patient who had used a drug properly dispensed by it and that it had fulfilled the only duty owed to the patient by dispensing the prescription according to the doctor's order. In response, the Court emphasised that a pharmacist is a professional, owing a duty to patients to exercise a standard of care required by the pharmacy profession in the same or similar communities in which the pharmacist practices.[136] The Court noted that the increased complexities of pharmacotherapeutics and accompanying adverse drug reactions and drug interactions had led to an expanded role for pharmacists as drug therapy counsellors. The Court also observed a trend towards patient-oriented clinical pharmacy practice.

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128 SH Kalman, JF Schlegel, *Standards of Practice for the Profession of Pharmacy*, American Pharmaceutical Association, 1970

129 *Lasley v Shrake's Country Club Pharmacy* (1994) WL 109 647 (Ariz) Ct App (1994).

130 Note 117 *supra*

131 *Ibid.*

132 *Pittman v The Upjohn Company* (1994) Westlaw 663372 [Tenn 1994].

133 *Dwyer v Roderick and Ors* (1994) Westlaw 663372 [Tenn 1994]

134 *Prendergast v Sam and Dee Limited* discussed in *The Times*, 24 March 1988, p 19

135 K Mullan and D Brushwood, "The Civil Liability of Manufacturers, Doctors and Pharmacists", 258 *The Pharmaceutical* Journal 309 at 309-13

136 *Ibid* at 310.

Mullan and Brushwood note that this decision continues the trend of US courts in finding that pharmacists do have a duty to patients beyond technical accuracy in prescription processing. They advance the conclusion for the United States, that where there is an "information for patients ... section in a package insert, the doctor and pharmacist ignore it at their peril".[137]

There is evidence suggesting that in the United Kingdom, actions for failure to warn are being instituted. It is anticipated that these issues will soon be discussed and deliberated upon in courts in the United Kingdom.[138] Of course, much will turn upon the facts of any individual case, but in Australia, having regard to the erosion of the *Bolam* test and the reinforcement of the role of the court in determining in any given case the standard of care demanded by the law, the pharmacist must be prepared to accept potential liability in this area. These cases support the changed direction of pharmacy practice and justify more direct patient care.

Although it may not be necessary in every case to provide warnings about prescribed medication, it is essential to do so when particularly potent medicines are to be taken. Pharmacists are well aware of the risk of serious harm should prescribed medication be taken incorrectly. If pharmacists claim an undoubted expertise in medication matters, then this must be applied to avoid foreseeable risk of injury to those lacking such skills for whom medication is prescribed. The primary obligation to advise and warn patients about prescribed medication is that of their medical practitioners who should not abrogate this function in the expectation of pharmacist intervention. Nor should a pharmacist refrain from taking opportunities to advise patients about medication because of the prescriber's primary obligation. Both are essential for proper patient care. Each may face liability for failure to exercise this care.

XVIII. PHARMACIST INTERVENTION: A RECENT EXAMPLE

The importance of counselling by pharmacists was recently emphasised by the New South Wales Deputy State Coroner.[139] A 77 year old patient, with progressive rheumatoid arthritis, was treated with methotrexate, a potent medication and member of a class of drugs known as antineoplastics. Its effects include interference with DNA synthesis and cellular reproduction. Because of its potency and mode of action, it is taken *once weekly*. The medication had been prescribed originally by the patient's treating specialist rheumatologist, according to the once-weekly regimen. Later, the patient sought a further supply from her general medical practitioner. She advised this doctor that the dosage was one tablet to be taken three times a day, ie. without any indication of the

137 *Ibid* at 309-13. Note that this is also relevant when considering the statutory regime in Australia pursuant to Regulation 9A of the *Therapeutic Goods Regulations* (Cth), note 52 *supra*

138 *Ibid* at 313.

139 Inquest: Death of Winifred Green, NSW, No 427/1996, Findings 21 July 1997, See P Dwyer, "The Legal Note. Methotrexate - A Coronial Inquest" (1997) 16(7) *Australian Pharmacist* 395 at 414

once-weekly administration. In evidence before the Coroner, the doctor claimed to have queried this dosage with the patient but she was insistent and he ordered it without the weekly restriction.

When presented to the pharmacy (which had dispensed the earlier prescription written by the patient's rheumatologist) the erroneous instructions on the prescription were detected and the medication labelled with the correct weekly dosage. About three weeks after the prescription was dispensed, the patient was admitted to hospital and died several days later from aplastic anaemia (bone marrow failure). The Coroner found this to be the cause of death.[140]

This was the fourth death associated with methotrexate, which had come before the Coroner. The earlier deaths occurred in hospitals and were related to mistakes by hospital staff. On the evidence before him, the Coroner was unable to find a causal connection between the death and the drug as later prescribed. On the evidence, the deceased had taken nineteen tablets over the three week period, rather than the twelve tablets which should have been taken in accordance with the (corrected) instructions. Importantly, for present purposes, the Coroner found that the pharmacist who dispensed the medication would have carefully explained the dosage. In considering the pharmacist's counselling function, the Coroner said:

> I ask ... when was it that a pharmacist last threw a bottle of tablets at you and simply said, 'Here it is'. It is not usual practice.[141]

This case demonstrates the critical role of a pharmacist in the drug distribution system, and in particular, the interventionist nature of that function.

XIX. CONCLUSION

The practice of pharmacy has undergone significant change and the evolutionary process continues, in Australia and elsewhere. These changes, some of which have been discussed above, are consistent with policy considerations inherent in statutory provisions governing pharmacists and the supply of medication. They are consistent also, with professional pronouncements concerning standards demanded of the profession. It appears likely that the pharmacist's professional function will expand further towards a greater emphasis on patient care.[142]

The profession has, to date, been enthusiastic in pursuing an expanded role in health care; its aim to provide better patient care by greater application of a pharmacist's expertise in drug therapy. That aim must remain the paramount concern of every health care profession. Given that courts in Australia will apply the standard of care demanded by the law,[143] pharmacists must maintain their professional pathway towards better patient care. Application of

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140 *Ibid* p 7

141 *Ibid*, p 5

142 Cf "Health Secretary to Expand Pharmacist's Role to Include Diagnosis, say press reports", (1997) 259 *The Pharmaceutical Journal* 200 and Editorial, "A Welcome Opportunity", *ibid* at 199.

143 Cf *Rogers v Whitaker*, note 2 *supra*.

appropriate risk management techniques in practice is part of better patient care and will assist in reducing a pharmacist's exposure to legal liability.

The message is clear.