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PHARMACEUTICAL SOCIETIES OF AUSTRALIA AND NEW ZEALAND

FIRST BIENNIAL CONFERENCE

HOBART, TASMANIA, 1 MARCH, 1982

PHARMACY AND LAW REFORM

The Hon. Mr. Justice M.D. Kirby
Chairman of the Australian Law Reform Commission

February 1982

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Mr. Justice Kirby is Chairman of the Australian Law Reform Commission. He will outline the relevance of some of the work of law reform in Australia, both in the Federal and State law reform commissions, relevant to pharmacists. Amongst items that will be dealt with are:

- Privacy : the Australian Law Reform Commission will, in 1982, recommend new Federal laws for the protection of privacy in Australia. These recommendations will cover the impact of computers on individual privacy. The growing use of computers for professional, medical and pharmaceutical services raises new problems for patient confidentiality.

- Class Actions : the Australian Law Reform Commission is also investigating whether class actions, such as exist in the United States, should be introduced in Australia. These legal procedures facilitate the bringing of any individual actions which might otherwise be defeated by the costs of litigation. The widespread impact of drug-induced defects (such as occurred with Thalidomide and is alleged to have occurred after exposure to Agent Orange) represent cases where class action-type procedures may be useful.

- Professionalism : the New South Wales Law Reform Commission is currently examining the professional rules of the legal profession in New South Wales. The implications of some of the work of that Commission, and of other Australian studies, for pharmacists, will be explored including advertising by professionals, competition, professional organisation and liability for professional advice.

The impact of rapid developments in science and technology on the law and legal institutions will be considered, as will the need for new institutional arrangements to help parliaments cope with the pressures of rapid scientific and technological changes.

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PHARMACY IN A TIME OF CHANGE

I must start by saying how conscious I am of the honour it is to receive an invitation to address this first biennial conference. I have read the abstracts of the papers of some of those who are to follow. I am sure that the conference will prove a relevant and informative occasion and will become an important event in the life of the pharmaceutical profession in this part of the world. The challenges that face the professions generally, and the pharmaceutical profession amongst them, are so profound that it will be of increasing importance to gather together representatives of the professions to consider the implications for their activities of a world of rapid change. The law and legal change are only one of the features of today's society that are bound to make the life of the pharmacist of the future more complicated and difficult than that of his forebears. Many of the laws governing pharmacists had their origins in an era when the pharmacist compounded medications, devised from natural products. Over the past 25 years, with the rapid development of the technology of potent synthetic drug products, the practice and responsibility of pharmacists have changed radically. Slowly, the laws of our country are being changed to reflect the changes that have come upon your profession.

The business I am in is legal change : change not for its own sake; but change for the better. Because what is 'better' is frequently a matter of controversy, the work of the Australian Law Reform Commission has been carried out in the open. The experts, the legal profession and the whole community have been invited to take a part in the work of the Commission and to understand its role. In a sense, that is why I am here in Hobart today. I will seek to relate the work we are doing, and the work we may come to do, to the concerns of your profession, and specifically to the theme of this session on pharmacy

and the law. I am delighted to join such distinguished fellow speakers as Mr. Gordon Applebee and Mr. Peter Carroll. Our concerns may overlap. However, we will be looking at different facets of the diamond. My concern is the national reform and renewal of Federal laws in Australia.

THE LAW REFORM COMMISSION

Let me start by telling you something about the Australian Law Reform Commission itself. It is a permanent body established by the Australian Federal Parliament. It works only upon projects specifically assigned to it by the Federal Attorney-General. Having received a project, it assembles a team of Commissioners, expert consultants and staff members to research the current law, to identify criticisms and defects in the law, to suggest options for change and to put forward tentative proposals by which legal change may be brought about. These proposals are widely distributed throughout the community and debated with the help of discussion papers, public hearings and seminars, talk-back radio and television programs. At the end of the day, a report is prepared, with draft legislation. This is delivered to the Attorney-General and he must table it in the Parliament, so that it becomes open to public debate.

Amongst the Commissioners of the Australian Law Reform Commission have been some of the most distinguished lawyers in our country. The Governor-General (Sir Zelman Cowen) was at one stage a part-time Commissioner. So was Sir Gerard Brennan, now a Justice of the High Court of Australia. Current part-time Commissioners include Mr. Justice Neasey of the Supreme Court of Tasmania and Mr. Justice Fitzgerald of the Federal Court of Australia. There are four full-time Commissioners and seven part-time Commissioners. They come from different parts of Australia and different branches of the legal profession : the judiciary, barristers, solicitors and legal academics.

A number of the reports have already been adopted in Federal and State law. One of the most pleasing features of the Commission's work over the past seven years has been the growing willingness of State Governments to look to the Commission's reports and to adopt them in the laws of the States. I note that one of the concerns of this conference is the procedure for securing more uniform laws to regulate the pharmacy profession and its operations. Although in the United States and Canada Uniformity Conferences have been established routinely to secure ready acceptance of uniform laws, where that is appropriate in the federation, no such equivalent mechanism has been developed in this country. Meetings of busy State and Federal ministers represent the best we can do. Such meetings, serviced by busy, often harassed and overworked public

servants, find it difficult to tackle in a coherent and dynamic way, the needs of uniform legislation in our federation. The work of the Australian Law Reform Commission can sometimes provide a vehicle for developing uniform laws. This can be done even in controversial topics of legal change.

One of our reports on Human Tissue Transplants[1] was delivered in 1977 to the Federal Government. The proposals were adopted shortly thereafter in the Australian Capital Territory. Since then they have been adopted in substance in Queensland and the Northern Territory of Australia. A Bill to adopt them was before the Victorian Parliament when it was dissolved for the election. The South Australian and New South Wales Ministers of Health have announced their intention to propose legislation based on the report. The Western Australian Government is also said to be about to act. The report dealt with such sensitive questions as:

- the definition of death;
- the regime for 'donating' organs and tissues;
- the suggested substitution of a system of presumed donation;
- the use of coroners' cadavers as a source of body parts for the development of useful serum;
- the possibility of legal minors consenting to the donation of non-regenerative tissue for siblings;
- the sale of human body parts.

No-one can say that this report covers simple topics. It required the Law Reform Commission to confront sensitive and difficult questions. This was done with the aid of the best experts in the country : medical, philosophical and theological. The result was a report which is now being adopted in law throughout the country. We can take heart from the experience of the Law Reform Commission's project on Human Tissue Transplants. It teaches us that difficult and sensitive questions raising issues of complex bioethical morality, can be tackled in a way that is compatible with a parliamentary democracy. I shall return to this theme.

It is enough for present purposes to indicate that the Law Reform Commission is a permanent body, with distinguished membership, working on projects of legal renewal identified as necessary by the first law officer of the Commonwealth. It has attracted a great deal of interest and support from Federal Parliament itself. Most Members of Parliament recognise the need for assistance in complex, controversial and technical areas of law reform. The reports of the Commission are being implemented. As I speak, three Bills based upon the reports of the Commission are before Federal Parliament. The exercise is therefore not a purely academic one. The work of the Law Reform Commission is the practical work of helping the democratic process to face up to the problems that might otherwise be put into the 'too hard' tray.

In addition to the Australian Law Reform Commission, there are State bodies, in every State, working in a similar way to help with the modernisation, simplification and reform of the law. All of these bodies are modestly funded. Whether it is the Australian Commission or the Tasmanian Commission, all of them have strictly limited manpower and resources. When I look at the amount of the community's resources that are (quite properly) devoted to medical and pharmacological research, and compare this to the amount available for improvement of the legal system, I sometimes despair. The Australian Law Reform Commission, which is the biggest in the country, has a staff of 19. It is a modest investment, to which citizens devote, on average, no more than ten cents each per year, for the improvement of the legal system. I hope I live to see a day in which the dedication to research and human improvement, that led to the establishment of the CSIRO in Australia, will find its way into the legal science. It is not much use grumbling about the state of the law, if, as a community, we are willing to do little and spend little upon the improvement of that activity (the law) which affects us all, at virtually all times of the day and all times of our life.

LAW REFORM AND PHARMACY

Concern as Citizens. Under the Australian Constitution, most of the laws governing the pharmacy profession and the activities of pharmacists, are State laws. They are not matters specifically assigned to the Commonwealth Parliament. Perhaps for this reason, none of the projects given to the Australian Law Reform Commission to date has been of specific and direct relevance to pharmacists. All of our projects affect pharmacists as citizens : whether we are working on the reform of laws governing complaints against police[2], criminal investigation[3], defamation law[4], the law governing compulsory acquisition of property by the Commonwealth[5] or the regulation of insurance brokers.[6]

Some projects have closer relevancy to the activities of pharmacists in their professional lives. I refer to the Commission's report on consumer indebteness based on the Commonwealth's insolvency power.[7] Similarly, because there have been unhappy cases involving prosecutions and convictions of pharmacists for offences against Federal laws in Australia, the recent report of the Commission on Sentencing of Federal Offenders[8], with its emphasis on the need for greater uniformity in the punishment imposed in different parts of Australia, will have an indirect relevance to members of the pharmaceutical profession. The well publicised article in the National Times at the beginning of last year titled 'Favourite Fiddles of the Crooked Chemist'[9] catalogued a list of activities, the common feature of which was a likelihood of prosecution, if detected, for breach of Federal law. The need to bring greater uniformity and

consistency in judicial punishment of persons convicted of such Federal offences is one which transcends pharmacists and medical professionals. It is a concern that is related to the ideal of equal treatment under the law.

I want, in this part of my paper, to identify a number of projects which are currently before the Australian Law Reform Commission which may be of more direct concern to pharmacists. I refer to the Commission's report on Alcohol, Drugs and Driving[10], and the current projects on class actions[11] and privacy.[12] I must deal with these briefly and superficially. In the time allotted to me, I also want to call attention to a number of other matters.

Alcohol and Drugs. One of your sessions later in the week will be devoted to a consideration of drugs and alcohol and their effect on driving and work performance. The 'keynote speaker', Dr. Joseph Santamaria, was a consultant to the Law Reform Commission in its report on Alcohol, Drugs and Driving in 1976. The report owes much to Dr. Santamaria's advice and informed opinion. The seemingly endemic problem of antisocial alcohol-impaired driving was examined by the Commission, with the benefit of overseas and local empirical research. The Commission was faced with the specific issue of whether 'random tests' should be introduced in the Australian Capital Territory. In the result, the Commission did not favour this facility for police because the best expert opinion at the time of the report suggested that random tests would not have a prolonged impact to diminish the road toll:

> It is traditional in British societies, before police intervention into the ordinary conduct of citizens is tolerated, that some reasonable cause to warrant suspicion on the part of the police officer is generally required. This tradition, which is at the heart of our liberties, ought not lightly to be sacrificed. It ought not to be sacrificed at all, in this context, without the clearest evidence that the results, in a diminished road toll, warrant the departure from time-honoured legal requirements. Far from supporting such a conclusion, the preponderance of expert opinion before the Commission is to the effect that no long-term diminution in the road toll could be anticipated. We should not sacrifice precious rights without assurance of the most substantial social gains.[13]

Since the report was written, the State of Victoria has introduced a 'random test' experiment. There has been very close attention to the results of the impact of random testing upon the road toll. It will be useful for this conference to consider the issue anew, with the benefit of Dr. Santamaria's report. Some other States have already moved towards introducing random breath tests. In the Australian Capital Territory, a recent report of a House of Assembly Committee urged that the time had come to introduce random tests there.

It is easier to lose liberties than to regain them. In the despair about the terrible loss of life and limb caused by alcohol-related motor vehicle accidents, it is quite natural for the community to look around for a magic solution that will cut the social and personal cost of road accidents. If the evidence of the Victorian tests indicates a significant or even an important impact of random breath testing on cutting the road toll, when compared to other States, it may well be that we should reduce the barrier which presently stands, in law, to prevent police intervention in the lives of citizens. The requirement of police to have 'reasonable cause' to intervene is a very important feature that distinguishes liberties in our form of society from those in other countries. This is an illustration of the controversial issues that can arise in considering the impact on society of alcohol, a legal intoxicant.

To cope with the growing problem of driving impaired by the consumption of drugs other than alcohol, the Law Reform Commission's report suggested the facility for medical examination and the taking of blood and other body part samples necessary to identify the presence of intoxicating drugs other than alcohol. Figures quoted in the report identify the growing use of cannabis, as reflected in criminal justice statistics, and the use of opiates, hallucinogens, cocaine, stimulants and sedatives as a source of intoxication, liable to be dangerous when mixed with activities requiring motor skills. Dr. Gerald Milner, another consultant to the Commission, was at pains in his submission to lay at rest the often repeated myth that cannabis is 'safer than alcohol' for driving:

> Dr. Milner asserts that cannabis 'alters the perception of time and distance, impairs psychomotor skills and judgment [and] interacts with alcohol. Research has shown that there is considerable potentiation between alcohol and ... the main psycho-active principle of marijuana. The evidence suggests that cannabis, especially when used, as it often is, in conjunction with alcohol, constitutes a significant danger when used by drivers. This may be so even though the amount of alcohol consumed is less than would otherwise significantly impair driving ability.[14]

Another major area of concern to which the Commission's report drew attention was the effect on drivers of the use of perfectly legal drugs. Reference was made to the effect of drugs prescribed by medical practitioners or those that can be bought over the counter in the pharmacy:

> The single small dose of barbiturates can, according to Dr. Milner, produce a measurable detriment during performance for up to 14 hours. It has been pointed out that a person is at risk if he drives a vehicle within 24 hours of even brief anaesthesia. Yet this is perfectly common in dental work. ... Another drug which potentiates the effect of alcohol (in this case its sedative and toxic effects) is chloral hydrate. Similarly anti-psychotic drugs may cause central sedative effects and potentiate alcohol. Anti-hypertensive drugs ... are also in wide use. Alcohol also increases the risk for a driver taking such drugs. It has been suggested that antihistamines should carry compulsory warnings about potential effects on driving, particularly as they greatly potentiate the effects of alcohol on driving ability. Some packets do; most do not.[15]

Since this report was written, the use of Barbiturates and Chloral Hydrate has declined significantly, both being subject to abuse and much safer alternatives being available. In fact, Barbiturates in Tasmania were rescheduled in December 1981 to place them in the same schedule as narcotic substances, in order to discourage the prescription of them and closely to monitor their use. For all this, the problem identified by the Law Reform Commission has not gone away. The two major sedatives prescribed in Australia, Diazepam (valium) and Oxazepam (Serepax) present risks, in interaction with alcohol, similar to those identifed in our 1976 report.

The Commission drew attention to the need for continuing education of the public and of the medical and pharmaceutical professions concerning the effects of drugs on driving, particularly drugs prescribed by medical practitioners or supplied over the counter. It was also suggested that consideration should be given to requiring drug companies to supply medical practitioners, pharmacists and the public with information concerning the effects of drugs on driving skills and compulsory labelling of drugs which may have an adverse effect on driving ability.[16] Although the general legislation based on this report of the Law Reform Commission has been implemented in the Capital Territory[17] and aspects of it copied in other jurisdictions, the proposals concerning compulsory drug information have not been acted upon. I shall return to the issue of labelling and patient information.

Class Actions. A project on which the Law Reform Commission is currently working and which may come to have relevance for the Australian pharmaceutical industry and profession is the inquiry into class actions in Australia. Although a discussion paper has been issued on this topic, the report has not yet been written. Rarely has a matter of legal procedure invoked such passionate argumentation. A class action is a legal procedure by which a person, or a group of persons, can bring proceedings claiming

damages, on behalf of all those who have suffered a common provable legal wrong. In our legal history, because courts did not want to get involved in the distribution of funds of money, actions for damages have, generally speaking, had to be brought individually. In the United States, the class action procedure developed to meet the problems of the mass production economy. Just as goods and services are mass-produced (and may therefore result in mass-produced legal problems, when things go wrong) so, it was considered, the delivery of legal justice should be 'mass-produced'. The vehicle was the class action.

Opponents in Australia have described the possibility of class actions as 'businesses' final nightmare'. On the other hand, supporters in the United States have described the procedure as the 'free enterprise answer to legal aid'. Opponents say it brings together people who would never pursue a legal claim, results in windfall verdicts, involves lawyers in 'drumming up business' and far from promoting the enforcement of legal rights, sets in train cases which are so large in their potential that settlement is virtually forced on the parties by a kind of 'legal blackmail'. Supporters of class actions say that all too many people in our society cannot afford to get to court, that aggregation of legal claims provides a means of equalising the ordinary consumer with the large and powerful defendant (perhaps a well funded drug company), permits issues to be thoroughly explored that could not be tackled in individual litigation and brings remedies to ordinary citizens who might otherwise have a legal claim which they simply could not afford to bring to court. It is noteworthy that a class action has been brought in the United States by veterans of the Vietnam War, alleging impairment from exposure to the pesticide Agent Orange. Australian veterans of the same war have been permitted to 'tack onto' the United States proceedings. Class actions do not yet exist in Australia. The Law Reform Commission has been asked to advise whether they should be introduced in Federal and Territory courts. When one thinks of the cases where it is alleged that particular drugs have caused widespread injury one can imagine the possible utility of class actions. These drugs include Agent Orange, Thalidomide or Diethylstilboestrol (DES) — the apparently safe drug used to diminish miscarriages which was found to produce carcinoma of the vagina in some female children born after the drug was administered. Legal, medical and pharmaceutical journals have taken much more interest in teratology[18] since the Thalidomide case. For example, in the May 1980 issue of Trial, a national legal magazine in the United States, a detailed article appears about the drug 'Bendectin', claiming that it causes deformity to the foetus in a small number of cases, causing an unidentified physician to declare:

> Most teratogens remain unknown. They are mysterious but often devastating assailants of our unborn children. They carefully guard their secrets, almost mockingly beckoning us to find them out.[19]

Bendectin is in some countries a prescription drug. In Australia it is so scheduled in all States that it is available on prescription only. In some countries, and in some parts of the United States, it is sold across the counter. Supporters of the class action procedure suggest that only by this procedure can the litigious battle between resourceful defendants and individual consumers be even partly equalised. I cannot say whether we will see class actions in Australia. However, it does seem likely to me that some form of aggregating claims for damages will be introduced. A world of mass production of legal problems cannot pass by the law and its procedures. Just as the pharmacy profession has embraced and adjusted to this new feature of the mass consumer society, so, as it seems to me, must the legal profession, its personnel and procedures. Class actions in the United States have certainly shown that country's legal procedures to be most ingenious. For example in the class action brought by daughters of women who had ingested the drug DES during pregnancy, the problem arose that it was impossible, 20 years later, to prove which drug company or companies had supplied the drug and so had a contractual or tortious relationship with the customer. This did not trouble the Californian Court. It simply adopted a market-share approach and divided liability according to market proportions at the relevant time.[20]

Privacy. A third project on which the Law Reform Commission is working relates to the protection of privacy in Federal laws. Discussion papers of the Commission have drawn attention to a number of problems, the most important of which, for my present purposes, is the impact on individual privacy of the growing computerisation of our society. The social and legal changes that will attend the revolution in information technology have attracted a great deal of concern throughout the western democracies. The concern about individual privacy is only one of these. It is, however, the concern that led the Federal Government to refer the issue to the Law Reform Commission. The computer can collect unprecedented quantities of individually identifiable information, can retrieve it at ever increasing speed and ever diminishing cost, can aggregate information supplied for many purposes, into a total 'profile' and is usually susceptible to centralisation of control.

It is likely that pharmaceutical records will increasingly move over to computerised format. This format will produce many efficiencies, not least in the operation of the costly Pharmaceutical Benefits Scheme. No-one questions that great advantages will attend the development of computerisation. However, it is the legitimate concern of society, and its laws, to ensure that the problems that can accompany such a profound change are equally addressed. As more and more intimate medical and like

personal information is kept in computerised format, increasing demands will be raised that protection should be given for the quality and security of that information. Specific issues that are being considered by the Law Reform Commission include:

- Should patients generally have a right of access to medical, hospital and pharmaceutical records about themselves and, if not, with what exceptions, according to what principle and with what alternative safeguards for the accuracy and up-to-dateness of personal health records as these are increasingly computerised?

- Should a parent have a right of access to medical and pharmaceutical information about a child and, if so, to what age and with what exceptions if the child claims a privilege to have advice on an intimate personal matter kept confidential, even from parents?

- Should courts have an unlimited right of access to the personal health files (medical and pharmaceutical) as is the case in most jurisdictions of Australia? Or should there be a privilege against disclosure to the court without the patient's consent? Should the court be required to weigh the competing interests of the administration of justice and the claims to privacy and confidentiality before requiring the production of such health records?

- Should police investigating medical and pharmaceutical fraud have access to personal health records of patients — and if so with what limitations to protect the privacy of patients and prevent the haemorrhage of personal data.

One of the possible advantages of the growing computerisation of personal pharmaceutical records may be the greater ease of epidemiological research, to study the incidence of side effects of drugs and to follow, more accurately, clinical trials by which new drugs are introduced. Research in the use of health records has already produced many benefits for mankind. Certain of the side effects that arise in the use of oral contraceptives were, for example, discovered primarily as a result of large-scale studies in which hospital, medical and pharmaceutical records were used. Those studies could not have been carried out had the actual consent of the patients involved been required. There is a competition here between the claim of the individual to the privacy of his health records and the advantage to the aggregation of all individuals in society that may attend the careful and respectful use of personal health records, even without the knowledge and specific consent of the subjects:

> Society has a vital stake in epidemeological research. We must ensure that the dignity and privacy of subjects will be protected without hindering the advancement of knowledge and disease. The social contract that facilitates the existence of individuals within social groups requires that each individual occasionally yields some of his rights, including privacy and freedom of action, for the benefit of society as a whole.[21]

At the moment the rules which balance the rights of the data subject and which protect him or her against misuse of data or sound the alert as to the possible harm that may be suffered, exist in the realm of fair practice or the conscience of the individual researcher. The potential coming together of so many sources of highly intimate personal information, as a result of the new computerised technology, and the spectre of the total 'personal data profile' will require better legal protection in the future than has been necessary in the past. The subject of protecting individual personal records, including in the course of epidemeological research, is not just a local concern. It is one that has attracted attention in many countries.[22]

Another aspect of the privacy debate relates to the growing power of officials to enter property and to search records, hitherto regarded as intimate and confidential. Because the Australian Law Reform Commission inquiry is directed at Federal operations, we have had a number of complaints about provisions of the National Health Act 1953 and the broad powers that are conferred upon persons authorised by the Minister of Health or the Director-General to enter, search and seize property.[23] The Law Reform Commission has proposed a uniform regime requiring, normally, judicial authorisation before any such powers are exercised.[24] In our enthusiasm to stamp out medical or pharmaceutical frauds we ought not to forget the traditional safeguards of our liberties nor the need for new protections as computer technology makes it easier to invade the medical privacy of innocent patients.

The use of computer records, assembled under the Pharmaceutical Benefit Scheme of the Commonwealth, has likewise caused anxiety in some quarters. Payments made under the scheme are undoubtedly substantial, running in excess of three hundred million dollars a year. There is a legitimate public concern to ensure that improper and fraudulent conduct under the scheme is speedily detected and promptly punished.

Special concern has been expressed about the analysis, with the aid of Federal computers, of the prescribing patterns followed by particular doctors. It is claimed that this use of personal medical information intrudes upon the confidentiality of the relationship that has existed until now between the patient, the medical practitioner and the pharmacist. On the other hand, the Federal Department of Health contends that it is useful to have readily available the analysis of the prescription of particular drugs. It can help comparison of prescription patterns against the average. Irregular patterns can at least raise the question of error or impropriety. Where unwanted systemic effects arise from particular drugs, prescription well beyond the average may properly be called to notice. On the other hand, practitioners have expressed anxiety both about the way in which investigations are carried out and about the potential control of prescription patterns that may follow any pressure, however subtle, towards 'averaging' in medical practice. There is a concern lest we see too much of the 'Modern Golden Rule' — which has been described as 'he who has the Gold makes the Rules'. On the other hand, the involvement of the public purse in the Pharmaceutical Benefits Scheme inevitably invites the attention of officials. We in the Law Reform Commission are seeking to establish machinery and principles which will balance the legitimate public concerns against the traditional expectation of confidentiality that has, until now, attached to health records. There is no doubt that computerisation will diminish that confidentiality somewhat. In the past, privacy of intimate personal maladies was guaranteed because they were often locked away in the safe crevices of the mind of the doctor and pharmacist. The advent of the new information technology, including in its relation to the pharmacy, will require new attention to the issue of patient confidentiality by individual pharmacists and their representative bodies. They will require a redefinition of legal rights and duties.

PROFESSIONALISM TODAY

New Inquiry. One of the tasks before the New South Wales Law Reform Commission requires it to examine the legal profession in that State with a view to proposing new laws and practices to make the profession more relevant to Australian society today. It is not appropriate for me to examine all of the issues that have been considered in the course of the New South Wales Law Reform Commission inquiry. Many of them are peculiar to the legal profession. The division between barristers and solicitors is one such issue, though one could doubtless draw parallels between the future demarcation of the role of the physician and the pharmacist.[25] I cannot think of any analogy in the pharmaceutical profession of the issue of whether barristers should continue to wear wigs and other court dress, inherited from the reign of Queen Anne. No

pharmacist of my acquaintance has yet suggested a revival of the powdered wig of earlier apothecaries. Nor is the special status of Queen's Counsel analogous to anything in the more democratic or commercial ranks of the pharmaceutical profession in Australia. Much of the debate, then, is irrelevant to your concerns. Some of it is not. Three issues stand out as transcending any particular profession and as warranting concern amongst all Australian 'professionals'.

Complaints and Discipline. The first relates to the question of complaints and discipline within the profession. In its first two discussion papers on this reference, the New South Wales Commission concluded that it was unsafe to leave resolution of conflicts and determination of disputes to the professionals alone. According to the Commission, an independent regulatory body was necessary to achieve satisfactory professional regulation. Effective public participation in such a body was considered necessary to ensure adequate communication between professionals and the broader community. In the light of these conclusions, the Commission recommended the appointment of two bodies, a Legal Profession Council and a Community Committee on Legal Services.

The examination of the handling of complaints against lawyers by the present professional bodies makes somewhat depressing reading. They are criticised for excessive reluctance to take action, inaction, particularly on complaints of delay and negligence, unhelpful attitudes to complainants, 'perfunctory' investigation of many complaints and excessive sympathy for and leniency to the professional. The infusion of a lay element into the handling of complaints is now well established within the legal profession. I am sure that this development has implications for professional organisations generally.[26]

Advertising and Specialisation. The second issue relates to one of the most recent discussion papers of the New South Wales Commission dealing with advertising and specialisation. This paper urges that solicitors should be allowed to advertise in all media, including on such matters as fields of practice, fees, the availability of credit cards, specific guarantees of speed of service and other listed matters. Limitations are imposed. For example, certain types of fee advertising is excluded. False, misleading, vulgar, sensational or disreputable advertising is forbidden. It is suggested that these limitations should be policed by the enhanced new professional bodies. The Commissioner responsible for this discussion paper, Mr. Julian Disney, is reported as saying that the main fear of those opposed to professional advertising was that costs would flow on to the public in the form of increased fees.[27] However, Mr. Disney said that this fear and the fear that

bigger firms would be at a greater advantage over smaller firms or individual practitioners had simply not been borne out by American experience. On the contrary, he said, competition caused by advertising had led to a general reduction in fees of about ten percent. I realise that pharmacists have not been quite so hidebound as the legal profession in advertising, partly because of the diversification of the activities of pharmaceutical professionals. On the other hand, the provision of informative advertising by professionals seems to be on the way to achieving greater professional and community acceptance. Restrictions on advertising can be anti-competitive and can diminish access by ordinary citizens to the professional services offered. I believe there would be much to be gained by pharmacists studying the discussion paper of the New South Wales Commission on advertising and specialisation.

Computerisation. The third matter of general significance relates to the impact of computerisation itself upon professional activities. Some professionals believe that the microchip will throw motor car assembly workers out of their jobs but somehow, miraculously, pass them by. I can share no such optimism. Within the legal profession, I am firmly of the view that computerisation will take over certain routine tasks, including routine land conveyancing. The potential of computerised checkout systems to monitor stock, order from warehouses, monitor employee activity, debit client accounts and so on have obvious potential for employment in the modern community pharmacy. I have seen no study of the impact of the microchip on the pharmaceutical profession. Doubtless such studies exist. The pharmacist, like the lawyer, should be looking to the implications of the microchip for the enhancement of his efficiency and professionalism (but, probably, the diminution of his work force). Wherever there is a routine task, the computer will have a place. Computers should be looked upon like electricity. Just as at the beginning of our century electricity began its process to permeate every aspect of our life, so will the computer in the century ahead. We have only begun to see the potential of its remarkable technology, including for the professions.

INFORMING PATIENTS

In the remaining time available to me, I want to address a few words at one area of legal activity affecting the pharmacy profession, where there does seem to be a possible need for law reform. I refer to the supply of information about drugs, both to the professional prescribing and dispensing them and the patient obtaining them. In December 1980 an interesting article on this topic by Mr. L.W. Darvall appeared in the Monash University Law Review. I commend this article, with its comparison of prescription drug information controls in Australia and the United States.[28]

So far as information to practitioners is concerned, legislation in the United States is both more detailed and more rigorous than anything applying in Australia. There are strict labelling requirements and controls over promotion of prescription drugs. Labels are required to contain, amongst other things, the established name of the drug, the name and address of its manufacturer, packer or distributor, together with ingredient and dosage details. Labelling on or within the package is required to bear 'adequate information' for prescribers (and dispensers).[29] This 'adequate information' includes a statement of indications, effects, dosages, roots, methods, frequency and duration of administration, together with any relevant hazards, contra indications, side effects and precautions. Labelling information must not be of a promotional nature or false or misleading in any particular.[30]

Advertising of prescription drugs in the United States is subject to the Federal Food and Drug Administration (FDA). Such advertisements must contain, amongst other things, a 'true statement' which briefly summarises side effects, contra indications and effectiveness.[31] Still further obligations were proposed by a Drug Regulation Reform Bill 1979, designed to require balanced summaries of promotional material and to permit the FDA to require corrective material to be issued where this requirement is breached. One interesting requirement of the 1979 Bill was to limit services and gifts that could be provided to medical practitioners, pharmacists and others in association with a promotion. A limit of $10 in value for such gifts was prescribed. In the United States, Congressional inquiries have revealed practices such as doctors and pharmacists being presented with gift catalogues and awarded bonus points to encourage them to prescribe or dispense certain quantities of designated drugs. Gifts listed in the catalogues included colour televisions, bicycles, radios and even fully-paid vacations in return for the practitioner attending a product briefing session.[32] It seems that in Australia this abuse has not gone so far as in the United States. The Commonwealth Department of Health in its submission to the Pharmaceutical Manufacturing Industry Inquiry, 1978, disclosed that the only gifts known to it have been pens, clocks, calculators, stethescopes, blood pressure measuring devices and financial assistance with overseas trips and conferences.[33] Although the 1979 Bill was not enacted by the United States Congress before the election of Reagan in Administration, and although that Administration does not propose to support it, the measure may yet come to pass and even its critics acknowledged that it addressed many important and unsatisfactory features of current United States law and practice. It is before the Australian community for our consideration of the relevance of its provisions to our circumstances.

Because of the Australian Constitution, controls in this country over prescription drugs and therapeutic substances is divided between the Federal and State authorities. The Federal regulations have tended to be confined to imported material. Notwithstanding the constitutional limits, the Federal regulation has been criticised because it does not extend to drugs manufactured in Australia from locally produced ingredients, because surveillance of promotional material is limited in time and extent and because advertising standards are 'wholly a matter of administrative discretion'. Pointing to the different quantity and quality of information supplied, both in promotional and labelling material, in the United States and Australia, Darvall has urged that:

> Instead of the present scheme, it is suggested that requirements governing the form and content of prescription drug advertisements should be enacted as legislative standards so that they are readily accessible to manufacturers, importers and consumers.[34]

He is not convinced of the effectiveness of the sanctions available to the self-regulatory bodies in Australia. Because of extensive reliance by medical and pharmaceutical professionals on advertising material as a source of prescribing information, Darvall contends that there is a need for a clear legal requirement for the disclosure of information in like manner as in the United States:

> A recent study has examined the effect of legislation and voluntary codes on the content of advertisements published in American, British and Australian medical journals. The findings suggest that after the implementation of legislation in the United States in 1962, the information content of prescription drug advertising rose markedly. The authors state that no comparable changes occurred in Britain following the adoption of a voluntary code ... in 1974 or in Australia following the implementation of the [National Media Medical Council] code in 1975. The conclusion is that 'it is difficult to identify clearly any impact attributable to the voluntary code' and that the 'overall pattern ... clearly shows that Australian and British doctors have received less information about potential dangers than their American counterparts'.

There does seem to be an important difference between the state of the law on the duty to provide balanced information to professionals handling drugs (especially doctors and pharmacists) in the United States, on the one hand, and Australia on the other. The basis for authorising doctors and pharmacists to administer drugs to the human patient is consent. That consent rests upon an assumption of expert knowledge. The expert

knowledge is diminished, if it is not based on a full, frank and up-to-date statement of drug effects, including adverse side effects and notes on contra indications and effectiveness. I realise that later in this session criticism will be voiced about the bureaucracy of the American system. But it does seem unsatisfactory, in principle, that the responsibility of providing medical practitioners and pharmacists with adequate prescribing information about drugs, should rest so heavily, as it does, in Australia, on the industry. There does appear to be a need for more independent drug information and regulations which will require more objective and comprehensive drug data. Self interested determination of standards, even by prosperous and responsible drug manufacturers, is not a sure foundation for critical information. There would seem to be no good reason of principle why our standards in Australia should be lower than those of the United States, where it comes to the supply of information about prescription drugs, especially new drugs.

In some countries, including Australia, it is not unusual for a pharmacist to remove bottle labelling or to superimpose a label of his own, with perfunctory information about dosage, substituting for more detailed information about side effects and cautions. So far as patient labelling is concerned, the Thalidomide disaster and the growing standards of education and knowledge in the community point to a greater need to supply patients with written information concerning the drugs they take and even the adoption of legislation to require this. Some professionals resist 'patient labels'. They point out that it is for the professional — the doctor or pharmacist — to warn the patient of adverse effects. A little knowledge, it is said, is a dangerous thing and patients should not be encouraged to the false confidence that may come from superficial and uninformed reading of package pamphlets.

On the other hand, the central principle of patient consent must always be remembered. It is, after all, the body of the patient to which the drug is administered. Many doctors and pharmacists do not have the time fully to explain side effects and contra indications. Some make little effort at all to do so. Even when they do, the information is usually given orally and sometimes in a language and at a speed which inhibits the patients' understanding. The time to read and absorb a pamphlet may provide a greater opportunity of truly exercising an informed consent to the medical treatment proposed.

In 1974 ten European countries adopted a resolution requiring information leaflets to accompany certain prescription drugs. Since the late 1960s, the FDA in the United States has required patient information with a number of drugs, including oral contraceptives. The FDA is currently proposing enhanced patient information, particularly the supply of a short statement in non technical language to summarise major indications, contra indications, severe adverse reactions and potential safety hazards.

In Australia there is no current Federal legislation requiring patient information labelling, although in evaluating certain imported drugs, discussions can take place concerning a 'product information' document. This is principally aimed at practitioners rather than consumers. The Director-General of Health may, in some cases, request manufacturers to prepare a patient information leaflet. Such requests already extend to oral contraceptives. However, because it is simply a request and is not supported by a number of State health authorities, this effort at patient information has not proved universally successful.[35]

Balancing the dangers, costs and problems of introducing increased patient information against the advantages of doing so in a community of higher educational and informational levels, it does seem likely that we will see more moves in the future to providing greater information to patients about prescription drugs. Doubtless the pharmaceutical profession will play its part in promoting informed drug use:

> The principal benefit of patient information labelling is that it will provide consumers with accurate information concerning the drugs they take. If such information is heeded, this should result in better therapy or refusal of a course of treatment where a particular drug is contra indicated, inappropriate or unnecessary. Informed drug use may be expected to reduce the number of hospital admissions for avoidable adverse reactions and possibly the number of worker disability days. Given the serious nature of side effects which may accompany drug use, coupled with the brief consultation periods between doctors and patients [and I would add pharmacists and patients] the provision of patient labelling is in the interests of public health and welfare.[36]

CONCLUSIONS

This review of the law, law reform and pharmacy was necessarily selective and idiosyncratic. I have sketched the establishment of law reform bodies, to help Parliament modernise and adjust the laws to a society that is rapidly changing. I have illustrated the work of the Australian Law Reform Commission, with particular reference to projects of relevance to pharmacists in Australia. The project on Alcohol, Drugs and Driving will receive specific focus in this conference, later in the week. The project on class actions seems specially relevant for the problem of providing effective legal redress where the widespread use of a drug has led to unforeseen complications.[37] The project on privacy protection is relevant to pharmacists both in respect of the growing computerisation of health records and the growing power of public officials to intrude upon those records, in defence of the public purse.

I have briefly sketched some of the changes that are occurring in my own profession, the law, and I have sought to draw attention to some of the developments here that may have implications for professionalism generally.

Finally I have called to notice the contrast that exists between legal obligations in the United States to supply information to professionals prescribing or dispensing drugs and to patients using them, and the regulation or lack of regulation in Australia on the same topics.

Pharmacy, like the law, will serve the highest ideals of professionalism, if it continues to scrutinise itself and its practices critically and to keep an open mind about the way in which it can best serve a rapidly changing world. Technology will force the pace of change. We in the established professions must adapt or like the dinosaurs we will perish because we would not or could not change to accord with our environment. The watchword for our time is change. If it is not as comfortable for professionals today as it was in earlier generations, we can perhaps take comfort from the fact that life is more challenging and exciting.

FOOTNOTES

1. The Law Reform Commission, Human Tissue Transplants, (ALRC 7) 1977.

2. ibid, Complaints Against Police, (ALRC 1) 1975; Complaints Againt Police : Supplementary Report, (ALRC 9) 1977.

3. ibid. Criminal Investigation, (ALRC 2) 1975 (Interim)

4. ibid, Unfair Publication, (ALRC 11) 1979.

5. ibid, Lands Acquisition and Compensation, (ALRC 14) 1980.

6. ibid, Insurance Agents and Brokers, (ALRC 16) 1980.

7. ibid, Insolvency : The Regular Payment of Debts, (ALRC 6) 1976.

8. ibid, Sentencing of Federal Offenders, (ALRC 15) (Interim).

9. D. Hickie, 'Favourite Fiddles of the Crooked Chemist', National Times 11-17 January 1981, 3.

10. The Law Reform Commission, Alcohol, Drugs and Driving, (1976).

11. ibid, Access to the Courts — II, Class Actions, (Discussion Paper 11), 1979.

12. ibid, Privacy and Intrusions, (Discussion Paper 13), 1980; id, Privacy and Personal Information, (Discussion Paper 14), 1980.

13. ALRC 4, xviii.

14. id, 99 (para. 229).

15. id (para. 230).

16. id, 166 (Recommendations 459, 460).

17. Motor Traffic (Alcohol & Drugs) Ordinance 1977 (ACT).

18. The study of the production of physical defects in offspring in utero.

19. Cited T.H. Bleakley and J.D. Peters, 'Bendectin' in Trial, May 1980, 56.

20. Sindell v. Abbott Laboratories 607 P.2d 924. 163 Cal Reptr 132 (1980). So far as Bendectin and Debendox are concerned, note the statement by Dr. S. Goulston, Chairman of the Australian Drug Evaluation Committee in The Medical Journal of Australia, 8 March 1980, 197. It is understood that Debendox has recently been again reviewed by the Australian Drug Evaluation Committee with advice by the Congenital Abnormalities Sub-committee.

21. L. Gordis and E. Gold, 'Privacy, Confidentiality and the Use of Medical Records in Research', Science, 207 (4427): 133, 206 (11 January 1980).

22. S. Simetis, 'Data Protection and Research : A Case Study on the Impact of a Control System', in Papers for the Tenth Council of Europe Colloquy on European Law, 23 September 1980, Scientific Research and the Law, mimeo (hereafter Papers). See also J. Visser, 'Control Mechanisms and Bodies with Special Reference to Medical and Genetic Research', in Papers, and P. Sieghart, 'Need for Control Systems and Interests Involved', ibid; Cf L.F. Bravo, 'International Aspects of the Control of Scientific Reseach', in Papers.

23. See eg s.104 National Health Act 1953 (Cwlth).

24. ALRC 2, 88ff; DP 13, 40ff.

25. NSW Law Reform Commission, Structure of the Profession (Discussion Paper). See [1981] Reform 110.

26. NSW Law Reform Commission, The Legal Profession : General Regulation (Discussion Paper 1), 1979; ibid, The Legal Profession : Complaints, Discipline and Professional Standards (Discussion Paper 2), 1979. See [1979] Reform 50.

27. J. Disney, reported the Age 23 November 1981. See [1982] Reform 27.

28. L.W. Darvall, 'The Pharmaceutical Industry : Prescription Drug Information Controls in Australia and the United States' (1980) 7 Monash Uni L.Rev. 39.

29. Federal Food Drug & Cosmetic Act 1938 (US) (as amended), s.201(K), (M). 21 Code of Federal Regulations (CFR) 202.1(1), (2). See Darvall, 41.

30. 21 CFR 201.56; 201.57.

31. 21 CFR 202.1(a), (b), (d), (e). Darvall, 42.

32. Statement of Senator E.M. Kennedy upon the introduction of the Drug Regulation Reform Act 1979 (Bill). (1979) 125 Congressional Record, s.5291, s.5304-8. See Darvall, 43.

33. Australia, Commonwealth Department of Health, Submission to the Senate Standing Committee on Social Welfare, Medication Inquiry, Hansard, 20 June 1979, 41-2. Darvall, 44.

34. Darvall, 45. See also id, 40.

35. id, 50.

36. id, 51. The words in brackets are added by the author.

37. For an examination of differing approaches to providing effective remedies for drug induced defects, see N.H. Hollenshead and M.R. Conway, 'International Products Liability', in Trial, November 1980, 50. Reference is made to the New Zealand Accident Compensation Act, 1972 and to the Japanese Drug Side Effect Injury Relief Fund Law, 1979.