THE AUSTRALIAN COLLEGE OF HEALTH SERVICE ADMINISTRATORS

VICTORIAN BRANCH

1983 POST-GRADUATE RESIDENTIAL SCHOOL

HEALESVILLE, VICTORIA, 7 APRIL 1983

BIOETHICS, MEDICAL PRACTICE AND LAW REFORM

April 1983

THE AUSTRALIAN COLLEGE OF HEALTH SERVICE ADMINISTRATORS

VICTORIAN BRANCH

1983 POST-GRADUATE RESIDENTIAL SCHOOL

BIOETHICS, MEDICAL PRACTICE AND LAW REFORM

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

BIOETHICS IN THE NEWS

The last few days has seen the usual spate of news items confronting our society including its legal and medical professions, with controversial and difficult issues of bioethics:

* In this week's issue of the Bulletin, there are 'fantastic photos' of how human life begins. Photographs of embryos during the first weeks of development show the fascinating way in which human form is assumed from shapeless matter.[1]

* A judge in the Supreme Court of British Columbia is reported to have over-ruled the wishes of parents and doctors, and ordered that a child, suffering from gross physical and mental disabilities, should be treated to ensure that it lived.

* From France comes the news that a 29-year-old French woman is fighting to be allowed to have a baby by artificial insemination with the preserved sperm of her dead boyfriend. French Government spokesmen were reported to have the case 'under study'. Legal and moral objections have been raised to her plan.[2]

* In Australia, we have seen, in the space of a week, a remarkable case, taken to the High Court of Australia, in which a lover sought an injunction to prevent an abortion from taking place. The application was rejected at first instance, by the Full Supreme Court of Queensland and then by the Chief Justice of the High Court, Sir Harry Gibbs. Sir Harry was reported in his judgment as saying that 'there are limits to the extent to which the law can intrude upon personal liberty or privacy'.

The unborn child was declared to have no legal rights until it had an existence separate from that of its mother.[3] He also declared that it was rare for injunctions in civil proceedings to be granted to enforce perceived breaches of the criminal law.

These and many other cases, some of which I will review, indicate the variety and complexity of issues of a medico-legal character that now press upon the community, its lawyers, doctors and health service administrators.

In the short time available, I propose to review some only of the issues that confront us. I propose to say something about the Australian Law Reform Commission. I will then mention a number of projects in which we have been or are involved that are of concern to health service administrators. Finally, I will list a few of the difficult subjects of bioethics that await community attention.

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 former 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. Mr John Cain, the Premier of Victoria, and Senator Gareth Evans, now Federal Attorney-General, are also past Commissioners. 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 eight 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. The new Federal Labor Government has offered many firm commitments to enacting law reforms — including as proposed by the ALRC. It has also promised a new commitment to uniform law reform. 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 itself 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[4] 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, the Northern Territory, South Australia, Western Australia, Victoria — and this week it was announced that New South Wales would follow suit. 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. The project 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, the Victorian Law Reform Commissioner (Professor Louis Waller) 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 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. Senator Evans has promised to increase it somewhat. But it will remain 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 HOSPITAL PRACTICE

Concern as Citizens. Under the Australian Constitution, most of the laws governing hospitals and the health service professions, 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 hospital administration as such. All of our projects affect you as citizens : whether we are working on the reform of laws governing complaints against police[5], criminal investigation[6], defamation law[7], the law governing compulsory acquisition of property by the Commonwealth[8] or the regulation of insurance brokers.[9]

Some projects have closer relevancy to the activities of hospital administrators in their professional lives. I refer to the Commission's report on consumer indebteness based on the Commonwealth's insolvency power.[10] Similarly, because there have been unhappy cases involving prosecutions and convictions of health care professionals for offences against Federal laws in Australia, the recent report of the Commission on Sentencing of Federal Offenders[11], 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 health care professions. The need to bring greater uniformity and consistency in judicial punishment of persons convicted of such Federal offences is one which transcends health care and medical professionals. It is a concern that is related to the ideal of equal treatment under the law. It was illustrated recently by the case of the so-called 'drug grannies'. There are many more such cases.

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 health care professions. I refer to the Commission's report on Alcohol, Drugs and Driving[11], 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. Drugs and alcohol and their effect on driving and work performance are a major preoccupation of health care in Australia. The Law Reform Commission prepared a report on Alcohol, Drugs and Driving in 1976. 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.[14]

Since the report was written, the States of Victoria, New South Wales, South Australia and the ACT have introduced a 'random test' experiments. There has been very close attention to the results of the impact of random testing upon the road toll. Early results in New South Wales suggest a real impact on the road toll. Results of some enquiries in Victoria suggest that this may not last.

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 long-term evidence of the legislative experiments indicate a significant or even an important impact of random breath testing on cutting the road toll, when compared to earlier times, it may well be that we should reduce permanently 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.[15]

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.

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.

Class Actions. A project on which the Law Reform Commission is currently working and which may come to have relevance for the Australian health care workers 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 health 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 Attorney-General 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 hospital records will increasingly move over to computerised format. This format will produce many efficiencies, not least in the operation of the costly Medical 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, hospital 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 is developing a uniform regime requiring, normally, judicial authorisation before any such powers are exercised.[24] In our enthusiasm to stamp out health care 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 Medical Benefit Scheme of the Commonwealth, has likewise caused anxiety in some quarters. Payments made under the scheme are undoubtedly substantial, running into many millions of dollars each 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 Medical 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 health care worker. The advent of the new information technology, including in its relation to hospitals, will require new attention to the issue of patient confidentiality by individual health care workers, including hospital administrators and their representative bodies. They will require a redefinition of legal rights and duties.

MAKING BIOETHICAL LAW : A NEW ISSUE

I now want to explore three areas in which there have been significant recent developments in medical technology. They are:

- in vitro fertilisation;
- genetic counselling (amniocentesis etc);
- genetic engineering;
- human tissue transplantation.

You may think it odd that a judge has taken such an interest in these topics. It is odd, in the sense that there are few present laws about these topics. But it was the recognition of the lack of law on the subject of human tissue transplants that brought me to a consideration of the interface between the law and modern medical technology.

We live in an age of social scientists and political scientists, economists and statisticians. These troublesome people have a tendency to examine our legal and institutional methodology. They tend to cast doubt upon assumptions long accepted. Increasingly they point to the great power that exists in some quarters not readily susceptible to legal regulation. Candidates often named are trade unions, powerful media interests and great international corporations with transnational interests. Certainly it is true that these three groups are not so readily submitted to legal regulation as the rest of us, humble citizens.

But now we have a new group who are candidates to join the list of those whose conduct is not easily submitted to legal regulation. I refer generally to technologists operating in the fields of 'high technology'. Their dazzling advances seem to have gone beyond the comprehension of ordinary people. The 'time cushion' that used to exist, within which lawmakers could prepare legal regulation to state society's standards, has virtually evaporated. Scientific and technological discoveries tumble out of the minds of these modern wizards. Slow-moving legal institutions find it hard to catch up. Occasionally the law is called on to provide a response. Instruments such as the Law Reform Commission are sometimes called into activity to help Parliament cope with the pressures of change. This is not an issue confined to the medical profession. It is the problem of adapting democratic institutions developed in the age of the long bow and the horse-drawn cart to the world of interplanetary flight, computications and bio-technology.

In the field of medical technology, we already have a few illustrations of what can happen, without any suggestion of evil or impropriety on the part of those involved. A scientific discovery may occur in an instant of time. Working out the legal and social consequences tends to take a great deal of time, particularly with the miniscule resources we are inclined, as a society, to devote to the effort. In the field of medical science, marvellous advances have been made in our century for the relief of pain and the treatment, cure and prevention of disease. We have, and should maintain, an optimistic spirit about the enormous value of medical science. But we should also be capable of providing the guidance and ground rules which the medical scientists themselves seek. This is not an appeal for a backward-looking, anti-science, Luddite approach to medical developments. I would have no part of such an attitude. It is, instead, an appeal for machinery to provide prompt social consideration of scientific advances. Unless interdisciplinary machinery can be developed, capable of consulting the experts and the general community and helping Parliament with the social and legal implications of medical developments, we must sadly face up to the inability of our democratic institutions to respond to the challenge of science. That may be a conclusion you will reach after this talk. You may believe that the problems are:

- too difficult and intractable to be addressed;
- too sensitive ever to be considered by parliaments comprising elected members, timorous of the special interest group and the passionate minority voice;
- too technological to be fully comprehended by the layman, whether in Parliament, the Cabinet or in the judiciary;
- too inevitable to be withstood and therefore virtually above the law and legal regulation.

All of these are conclusions of despair. I remain an optimist that our system of government, which we have so carefully nurtured and developed over 800 years, can adapt to the age of mature science and technology. But if this is to happen we will need new institutions. We will need more dialogue between scientists and the community and scientists and lawmakers. We will need more occasions such as this where thoughtful people come together to offer their views. We will need the support of the media and the interest of at least a few politicians who see more closely than most nowadays do that the great engine of our time is science and technology.

Unless these needs are fulfilled, scientists and technologists, including doctors, effectively will make the law. They will do so because the lawmaking institutions (out of incompetence, timorousness or just plain idle neglect) fail to respond adequately to the challenge which science and technology poses to the democratic order and the Rule of Law.

All of this may seem a bold claim. The best way to illustrate such a claim is to take the three examples I have mentioned. Necessarily they must be dealt with them briefly and superficially. They illustrate the fact that, whilst we must, of necessity, leave a wide scope for the exercise of professional judgment and professional medical discretion in the performance of the healing art, it remains for society to state its standards and the rules within which that performance is to proceed.

IN VITRO FERTILISATION

Take first in vitro fertilisation — the so-called 'test tube babies'. The first human born as a result of in vitro fertilisation was Louise Brown who came into this world in July 1978. Since then a small number of such babies have been born, many of them in Australia. We are amongst the leaders of the technology and this is a matter of pride. The pictures of the smiling parents and their offspring evoke natural human sympathy — especially because of the struggle these people have had to enjoy the pleasures and responsibilities of parenthood and family life.

In vitro fertilisation is a set of techniques which involves using human sperm and human eggs. It allows conception to take place outside the human body, on a piece of glass — hence 'in vitro'. The Victorian Attorney-General has established an interdisciplinary committee to examine legal and social implications of the technique. The Chairman of the committee is my colleague, Professor Louis Waller, the Victorian Law Reform Commissioner. Other inquiries have been established in other States. The Victorian Committee has already produced an interim report.

According to public opinion polls, the majority of Australian people support the in vitro program. Some ask : who could possibly oppose the technique that simply overcomes a physical obstruction and may bring parenthood to more than 30,000 couples?

It is now increasingly realised that there are problems to be addressed:

- Some commentators, particularly those starting from a traditional religious point of view, are absolutely opposed to the new techniques:
  - .. They are seen as 'laboratory procreation' — a dehumanised, unnatural manufacture of man as if he were a mere product : the elevation of the scientist to God-like power. This, roughly, is the reason that led Pope Pius XII to condemn the technique as absolutely illicit.
  - .. Other opponents point out that IVF requires masturbation to produce the sperm. It is said that this admittedly widespread practice is evil. In the absence of married love at the time of conception, it is thought that no good can come of it.
  - .. Other opponents fear the process of freezing of the human embryo — a technique utilised because of the wastage of embryos in the process of fertilisation — will all too readily lead on to experimentation with embryos and foetuses. The spectre of the foetal farm, developed to provide tissue for the relief of adult diseases, is one that horrifies some observers, but not others.
  - .. If embryos are frozen and not needed for future use, should they be discarded or would this act involve killing a form of human life?
  - .. Other opponents of the whole program simply say that, whatever your religion, there are better things to be done with the scarce medical dollars that would bring help to more fellow citizens. According to these people, this is an exotic, extremely expensive program benefitting relatively few.
- Even amongst those who positively support the IVF technology, there is now an increasing recognition of the need to consider particular social and legal consequences. Take the following, for example:
  - .. Should IVF be available only to married couples or also to single people, such as, say, a lesbian woman who wanted a child?
  - .. Should we permit surrogates, ie if a woman cannot carry a baby full-term, should her sister be permitted to do so? If so, who is the true mother? Who, if either of them, has the say in abortion decisions?
  - .. What happens to the law of incest? Could a daughter carry the child of her parents?

.. Should parents be able to chose the gender of the embryo they select?
.. Should it be lawful to retain a frozen human embryo for hundreds of years as is said to be technologically possible? If so, what is to happen to the distribution of property? Is the child's identity one of our generation or the generation into which he is born?
.. In the case of frozen embryos, what is to happen on the death or divorce of the donors?

These may sound exotic questions. Looking at the smiling babies we may prefer to put them out of our minds. But unless we provide the answers and the laws, we may be delivering our society to the Brave New World which Huxley wrote about, 50 years ago this year.

GENETIC COUNSELLING

Let me next turn to the issue of genetic counselling. So far, all of the 'test tube babies' have been genetically normal. But what about the position of people who have, or are likely to have, genetically abnormal children? A very high proportion of people who seek genetic counselling are couples who have already produced an abnormal child or know of one in the family. Genetic counselling involves doctors telling such people:

. whether a pregnancy should be undertaken at all;
. whether ante-natal diagnosis of abnormality (such as by the procedure of amniocentesis) would be useful;
. whether alternatives such as artificial insemination by anonymous donor should be used to avoid the risk of passing on genetic defects.

There are a lot of ethical problems here and most of them have to be faced by doctors and other health care workers, with only the vaguest guidance from the law:

. Should disclosure of a genetic defect be made to the parents or the child? At what age does the child with a genetic disorder become a separate patient entitled to separate, private advice?
. What are the limits of disclosure to third parties? For example, should a doctor tell a prospective spouse of the risks of genetic abnormality?
. What is the extent of the doctor's duty of frankness about mental disorder or retardation in a baby? If the doctor paints too pessimistic a picture, will the child be rejected by its parents and placed in an institution with consequences even worse than the genetic abnormality itself?

- What is the duty of a doctor who himself disapproves of abortion to advise pregnant women, especially those of mature years, to have amniocentesis, to test against the risk that the child may be mentally retarded or suffer other grave disabilities?
- Should every woman, or every woman over a given age, be entitled as of right to the amniocentesis test? Just in economic terms, would this not be much cheaper than keeping a retarded child in institutions for many years?
- Does the State which will otherwise have to fund the support of grossly disabled people have a legitimate interest to encourage abortion in such cases or is this the slippery path to unacceptable eugenics?

The legal situation in respect of the birth of grossly retarded and malformed children is only now being developed:

- Murder can include wilful failure to take necessary action. Yet the trial and acquittal in England of Dr. Leonard Arthur, who put a grossly retarded child in a corner and gave only sedatives until it died, shows how reluctant juries are to convict doctors in such circumstances.
- Doctors sometimes admit to causing the death of a grossly handicapped baby by giving it an injection at birth.[25] There can be little doubt that such positive action amounts to homicide. But it may be hard to detect. Some moral philosophers say it is quicker and kinder than murder by neglect -- leaving the child to die for want of nourishment.
- In America, there is already flourishing litigation surrounding this topic. Women sue doctors to recover the cost of maintaining a retarded child, because the doctor failed to advise amniocentesis. Some of these claims have succeeded. Will this risk force even opponents of abortion in the medical profession to advise the need for counselling of this kind, especially among women over 30 or 35?
- In America, actions have even been brought successfully by children against their parents claiming 'wrongful pregnancy', 'wrongful birth' and in one case 'wrongful life'. In essence, the claim is that parents ought to have had the ante-natal tests and not submitted the child to such a life of woe. A similar case in Britain in 1982 in the Court of Appeal failed. It was held that the common law of England did not recognise a cause of action against doctors for allowing the child to be born deformed.[26] Yet if a foetus is life and is owed duties by parents and doctors, are there ever cases where the mental retardation or physical disabilities are so gross that the birth should not be allowed to occur? If so, what are the precautions we would introduce against the misuse of the power to terminate life? Are we content to leave these decisions to be made by hospital committees or the unguided discretion of doctors on the spot?

GENETIC ENGINEERING

A third issue relates to genetic engineering. This is an expression that includes a number of techniques that involve scientific manipulation of the most basic forms of life. The life form may be plant, animal or human life. Without going into how they do it, scientists have been able by genetic engineering to achieve the cloning of plants and animals such as frogs and mice. Lately a good deal of attention has been given to the material that contained the genetic information of all living cells, the so-called DNA.[27] Scientific techniques are now available to enable recombination between molecules of DNA derived from different species of organisms. This technique of manipulating basic living matter is called recombinant DNA. There is a great deal of hope that experiments in this area will prove tremendously helpful in tackling pathology in human beings, including some forms at least of cancer. Furthermore, use of genetic engineering can have great economic consequences. New forms of plant life (and possibly new forms of animal life) could be bred. New energy forms may be developed. In a world of burgeoning population, food shortages and energy scarcity, genetic engineering may come to our rescue.

But here too problems arise:

- Some people just take a fundamentalist view that interference in the natural order is unacceptable and dangerous and may lead to consequences and risks we cannot perceive. According to this view we should just leave well alone.
- Some of the scientists involved in the early DNA experiments saw potential hazards. These included the possible production of new and highly pathogenic organisms which could escape from containment into the population spreading epidemics beyond our control. Subsequent research appears to have indicated that this risk is much less than was at first feared. Just the same, there are risks where experiments use genes derived from dangerous pathogens. Large-scale industrial genetic engineering may involve dangers to the environment, such as the escape of an unexpected virus or the spread of a fungus whose dangerous properties had not been contemplated.
- There is a further problem in medical treatment involving DNA. Doctors, anxious to help their patients, might be tempted to press on with experiments that involve the use of genetic engineering before it has been properly tested. In 1981 in the United States, Professor Martin Cline injected bone marrow containing genetically engineered DNA into two patients. He did this without getting permission under voluntary guidelines.

He has been reprimanded. Following criticism that the reprimand was too lenient, he has been 'fined' nearly $200,000 by the withdrawal of Federal research grants in that amount. He had tried unsuccessfully to treat people suffering from beta thalassaemi with cloned beta-globin genes which he had engineered in the laboratory.[28] A Nobel Prize if he had succeeded. Ignominy and rebuke on failure.

Professor Cline's case has raised questions about the effectiveness of voluntary guidelines on this form of genetic experimentation. In Australia until recently there was nothing more than a set of rules drawn up by the Australian Academy of Science. In 1981 the Federal Government established an advisory committee on recombinant DNA. The Chairman is Dr. Nancy Millis of Melbourne University. But questions remain:

- Given the risks of the kind of problems that can occur if genetic engineering goes wrong, should we have more rigorous legislative control? Is a reprimand from a voluntary committee an adequate sanction against the medical or scientific adventurist? With great profits to be made potentially out of genetic manipulation, do we need more legislation to protect the community against the risk that things go wrong?
- The committee established comprises scientists and industrials. Every one of them has a Ph.D. Only one (Professor Douglas Whalan) is not a scientist. He is a lawyer. Will the community's general interest be adequately protected by the scrutiny of such a committee? Is there any risk that such a committee of enthusiastic scientists and technologists may not be adequately sensitive to community opinion and needs?
- Even if there have been few accidents or mistakes so far, does the kind of potential risk of error with genetic engineering require more serious legislative sanctions? Is the criminal law needed to prevent the enthusiastic Dr. Clines of this world from taking risks with basic life forms that may endanger the species, however well motivated they may be?
- Can lay legislatures ever hope to cope with problems of this kind? Sir Gustav Nossal, in a recent lecture to the Australian Academy of Science, urged that:

  > Bio-technology is moving so rapidly that if we have a Royal Commission or introduce legislation now about recombinant DNA or in vitro fertilisation ... or anything else of this nature, the ground will have shifted before we have got through the mechanics; the action will have moved to the next level. It is much better to use soft-edged measures depending on human judgment and decency, such as strong ethnics committees including outside lay members to monitor research and treatment in laboratories and hospitals. In any case, the genie is out of the bottle and cannot be put back.[29]

Is this an admission of the ultimate defeat of our lawmaking institutions? Has the scientist and medical technologist gone beyond the wisdom of the whole community? Are we, the citizens and patients inevitably caught up in the chariot of science, liable to be taken wherever it goes? This is something our democracy has so far refused to acknowledge. But the crunch question must soon be answered.

Even if, as a society, we conclude that there is nothing much we can do to regulate the scientist, there will again be problems of detail to be sorted out:

- The former Commonwealth Government introduced a Plant Variety Rights Bill into Federal Parliament. The aim was to introduce a system where plant breeders can obtain exclusive property rights for commercial exploitation of new plant varieties.[30] Petitions were presented to Parliament protesting, claiming that life forms are 'a common heritage to all'.[31] It is not known if the new Government will reintroduce the Bill, amend or abandon it.
- In the United States a narrow 5:4 decision of the Supreme Court held that patent rights could be secured in bacteria developed to combat water-borne oil spills.[32] Should it be possible to patent life forms and if so under what circumstances? Can men and companies own life itself?
- Should cloning of human beings ever be permitted? A recent US report said we could have it within 10 to 20 years. The number of children in Australia who are named after their parents indicates that there is, at the very least, a risk that some people would think they should donate a clone of themselves to posterity. Is the law to stand idly by whilst this development occurs?

CONCLUSIONS

I have outlined a number areas in which medical technology has outstripped the law. In one of them, human tissue transplants, the Australian Law Reform Commission was called into aid. By interdisciplinary consultation and public discussion, we offered a report which is being accepted in all parts of the country, though not as yet in New South Wales. The other areas are, so far, neglected. In vitro fertilisation at last has a number of committees, though they are State committees and the prospect of differing recommendations must be anticipated. Genetic counselling stumbles along from one courtroom decision to another. Important issues of principle have to be determined by a criminal jury of 12 citizens in a provincial city or by busy judges in the midst of a heavy appeal docket. Genetic engineering has had little attention from the law.[33] The committee so far established at a national level is a committee of scientists and businessmen. Yet society's interests are at stake and there are legal implications.

My chief point is a simple one. Science and technology is advancing rapidly. If democracy is to be more than a myth and a shibboleth in the age of mature science and technology, we need a new institutional response. Otherwise, we must simply resign ourselves to being taken where the scientists' and technologists' imagination leads. That path involves nothing less than the demise of the Rule of Law as we know it. It is for our society to decide whether there is an alternative or whether t' e issues posed by modern science and technology are just too painful, technical, complicated, sensitive and controversial for our institutions.

FOOTNOTES

1. 'Hidden Life of the Unborn', the Bulletin, 12 April 1983, 56.

2. Melbourne Herald, 29 March 1983, 5.

3. Canberra Times, 31 March 1983, 1.

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

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

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

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

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

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

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

11. The Law Reform Commission, Alcohol, Drugs and Driving, (ALRC 4), 1976.

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

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

14. ALRC 4, xviii.

15. id, 99 (para. 229).

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. See eg Dr. P. Huntingford, Melbourne Herald, 20 March, 1982.

26. McKay v. Essex Area Health Authority & Anor, [1982] 2 WLR 890. See also S.C. Hayes and R. Hayes, Mental Health Law Policy and Administration, 1982, 44. The US case is Park v. Chessin, 46 NY 2d 401 (1978).

27. Deoxyribose Nucleic Acid.

28. New Scientist, 26 November 1981, 587.

29. G. Nossal, 1982 Lemberg Lecture, Australian Academy of Science, delivered at University of New South Wales, 27 January 1982, as reported AMA Gazette, March 1982, 24 ('The Genie is Out ...').

30. Statement by Mr. P. Nixon, Minister for Primary Industry, at the conclusion of the 113th Meeting of the Australiand Agricultural Council, Adelaide, 8 February 1982, mimeo.

31. See eg Commonwealth Parliamentary Debates (The Senate), 17 March 1982, 850.

32. Diamond v. Chakrabarthy, 447 US 303 (1979).

33. Interest is beginning. See eg D.E. Fisher, 'The Use of DNA and the Law in Australia', (1982) 56 Australian Law Journal 6.