JOINT COMMONWEALTH SECRETARIAT/WHO/UNICEF WORKSHOP
ON IMPLEMENTATION OF THE INTERNATIONAL CODE ON MARKETING
OF BREASTMILK SUBSTITUTES

HARARE, ZIMBABWE, 17-21 JANUARY 1983

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The Hon. Mr. Justice M.D. Kirby, C.M.G.*
Chairman of the Australian Law Reform Commission

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LAW AND THE COMMONWEALTH OF NATIONS

'A hundred years from now' said Arnold Smith, first Secretary-General of the Commonwealth of Nations, 'historians will consider the Commonwealth the greatest of all Britain's contributions to man's social and political history'.[1] This prediction will only be borne out if the succeeding generation of Commonwealth men and women make the most of the links that exist in the aftermath of Empire. Amongst those links is the English language and, in most parts of the Commonwealth, a common law system with many similarities in the approach to the role of the law and the instruments of its creation, interpretation and enforcement. Despite many differences in our societies, economies and cultures, we share much in common when it comes to law.

That this is so is in no way surprising. Until well into this century, many of our laws were made in London, either in the Westminster Parliament or in the Judicial Committee of the Privy Council. The result was not always satisfactory. One Act of Parliament of the State of Tasmania in Australia so faithfully copied its Westminster model that it solemnly proclaimed 'This Act is not to extend to Scotland'. The Minister of Justice and Constitutional Affairs of Zimbabwe, Mr. Mubako, speaking to law students at the University of Zimbabwe on 9 May 1980, reminded them of Lord Denning's warning:

> Lord Denning once likened the English common law in Africa to an oak transplanted to a foreign climate and went on to say that while the oak may survive, it is not likely to retain its sturdiness unless it is constantly tendered and pruned. These are wise words by a prominent English jurist. Yet in Africa, few people have called for radical reform of the foreign legal systems we teach. In addition to political self-determination and indigenisation of our economics, we need indigenisation of law, so that one day there will emerge the common law of Nigeria, the common law of Kenya, of Lososo, of Zambia or better still, one common law of Zimbabwe.[2]

We in Australia are developing our own common law and for a long time we have developed our own statute laws. One of the advantages of a Federation is that one can experiment with statutes in different parts of the same country. Despite the gradual development of different legal systems, it is likely that lawyers and law-makers throughout the Commonwealth of Nations will continue to feel at home in each others' company. This is because the common law today is less a body of specific and internationally agreed principles than a methodology for developing rules to meet new problems as they arise.

The days of Westminster statutes or Privy Council judgments bringing uniformity of law and of law reform throughout the Commonwealth of Nations have gone forever. But because our countries still share generally similar legal systems and because problems often occur on a worldwide scale, the need for common legal developments is still there. There are various ways in which this need can be met:

* Imitation of laws: The first was is the imitation throughout the Commonwealth of Nations of common law or statutory developments that have occurred in a particular jurisdiction. It is in this regard that the Legal Division of the Commonwealth Secretariat provides enormous assistance by the publication of the Commonwealth Law Bulletin. This highly practical publication brings a detailed abstract of major legal developments (legislative and case law) to all parts of the Commonwealth. It should be compulsory reading in all Ministries and by all senior judges for the simple reason that there are few entirely original ideas in this world today - especially in the law. We can all learn from developments to meet common problems in like legal systems. In September 1983, the Commonwealth Law Conference will convene in Hong Kong just as the previous Conference met in Lagos. As the Queen said in the fiftieth Christmas Message, the links between the professional groups in the Commonwealth of Nations are strong, practical, useful and enduring.

* Law reform reports: A second method of uniform law reform has now emerged on the scene. This follows the development in most of the nations of the Commonwealth of law reform agencies. In Australia, there are 10 such agencies at a State and Federal level. I am Chairman of the Australian Federal Law Reform Commission. From the establishment of the Indian Law Commission and the English Law Commission in the 1960's we have seen a proliferation throughout the Commonwealth of Nations of these remarkable agencies. They are set up in different ways, with different resources, tasks, methodologies and ratios of success. But there is an almost universal recognition that the modern legislature needs help in tackling difficult problems of law reform. Especially where consultation is required, with experts and with the community, a law reform agency can sometimes do the job better than the more formal and bureaucratic Departments of State. We have found in Australia that work done by law reform agencies can sometimes be picked up in other countries of the Commonwealth before they are actually implemented in Australia. I gather that proposals for reform of defamation laws suggested by the Australian Law Reform Commission have been adopted in Barbados, although they are still under consideration in Australia. Again, the Commonwealth Law Bulletin brings regular news of the major proposals of the law reform bodies throughout the Commonwealth. This is an invaluable service. It discloses how similar are the problems that we are all tackling. The latest task given to the Australian Law Reform Commission is a good case in point. We have been asked to examine and review the law on foreign State immunity.This is the law that exempts foreign governments and their agencies from having to submit to the jurisdiction of local courts. It is a situation where Australia still follows English common law, although England has itself adopted reform legislation based on a European Convention.[3] In all probability, in most part of the Commonwealth of Nations where no reform has been introduced, the law would be in the same situation as Australia. It is an ironic anachronism that we should follow old English cases when England itself has reformed its own laws. When the Australian Law Reform Commission delivers its report on the subject, with a draft statute attached to it for consideration by the Australian Parliament, it is likely that that report will provide a useful catalyst for reform legislation throughout the Commonwealth of Nations. At least, we will be working with that hope in mind. I have drawn to the attention of the Attorney-General of Australia the Commonwealth-wide implications of this project he has given us. He may well raise it at the forthcoming meeting of Commonwealth Law Ministers in Columbo, Sri Lanka.

* International Guidelines: A third development is one in which we are engaged here. I refer to the development of an early phase of international law by statements of internationally agreed principles captured in guidelines stated for international application. The World Health Organisation Code on Marketing of Breastmilk Substitutes[4] is one such statement of principles. Translating such broad and necessarily general statements into positive social action and actual reform of domestic law and administration is often a difficult process in which many considerations: political, economic, legal and cultural play a part. There are many sceptics, pessimists and critics in this world who would decry such efforts of international reform. But I am convinced that this generation stands on the threshold of major developments of international law. Through the agencies of the United Nations Organisation, the Commonwealth Secretariat and other international bodies, we are seeing the development of a whole host of interational rules on a wide range of issues of concern beyond the borders of domestic jurisdiction. Speaking at yet another workshop at the University of Zimbabwe this time on 8 February 1982, the Minister, Dr. Mubako rightly pointed out that lawyers brought up in the positivist tradition of English law 'still tend to regard international law as merely international politics, morality or comity'.[5] He urged the search of concretisation and improvement of the law so that international law could be carried beyond pious platitudes. One way to do this is to secure international agreements in binding conventions, in treaties. But the recent defections from the Law of the Sea Convention and indeed defections from support of the Breastmilk Substitutes Code on the part of important supplier nations, demonstrate that it is often difficult to get quick agreement on a treaty where perceived commercial or philosophical differences divide the nations. It is here that a lower order of international law development will have its place. It is the development of international statements of generally agreed principle, with the injunction that these should be reflected in domestic laws and machinery for monitoring and follow up.

I have previously been engaged in a similar enterprise in relation to some of the legal and social implications of the new information technology (computers linked by telecommunications). These implications include the need for privacy protection (data protection and data security). Between 1978 and 1980, I chaired a committee of another international organisation, the Organization for Economic Co-operation and Development (OECD) in Paris. The committee developed Guidelines which included a general statement

on privacy laws to be adopted in domestic jurisdictions.[6] Some commentators decried these Guidelines as a 'toothless tiger', unable to provide adequate protection against the activities of large and often transnational computing corporations. Such critics urged adherence to an international convention.[7] But whether a convention is or is not necessary or premature, the fact remains that many countries would not at this stage feel able to adhere to it. The Guidelines which the OECD Committee produced were adopted in the form of a recommendation to Member countries of the OECD by the Council of that organisation. There is a special need, because of the linkages of telecommunications techology to get compatibility in the laws controlling computerised movements of personal data.

When I left Australia, I was working on the report of the Australian Law Reform Commission on privacy protection. The OECD Guidelines are our guide posts in the development of our specific proposals for Australian laws on this subject. The Guidelines provide the framework of principle around which we are building the suggested Australian statute. So, though it takes time and there is not the satisfaction of immediate enforceability, we should not for that reason dismiss international guidelines and statements. With an appropriate measure of follow up, they can stimulate domestic lawmakers into the development of generally compatible laws. They provide for a degree of flexibility and adaption to home conditions. They are just as important in a matter of universal concern involving the human body and nutrition of infants (breastmilk substitutes) as they are in my previous field of interest (informatics, privacy and trans border data flows). It is illuminating to read the national reports to this workshop to see the way in which the WHO Code is being implemented in differing ways and in different Member countries. As a stimulus to our thinking and to concentrate attention on specifics, the Secretariat has produced a draft 'model' statute.[8] One Member country of the Commonwealth has already enacted legislation, namely Papua New Guinea.[9] Others have legislation under current consideration. An important address delivered to the Annual Scientific Meeting of the Australian Society for Medical Research in mid-December 1982 urged that Australia should follow the example of Papua New Guinea and make feeding bottles available only on prescription.[10]

The preparation of a model statute has some disadvantages.

* Legal mosaic: it makes no allowance for the differing legislative background against which such a statute must be placed and the variety of the legal mosiac into which it must be positioned in each jurisdiction;

* Legislative styles: it does not allow for diffent modes of legislative expression followed in different jurisdictions, though it must be admitted that this is a relatively small consideration in the countries of the Commonwealth of Nations which have generally followed that rather peculiar and much maligned style of statutory drafting inherited from Britain.

* Economic interests: it makes insufficient allowance for differing political and economic interest and for the strong moves that are now very much in evidence in developed countries at least to reduce the size of the public sector and the extent of government interference in the operation of the market. We, in the Australian Law Reform Commission have seen recent evidence of this attitude in the rejection by the Australian Government of a proposal for regulation of insurance brokers. Despite proved cases of millions dollars of default, the Government accepted Treasury advice that regulation of insurance broker misconduct should be left to market forces.[11] There is more than a suggestion of this attitude in the resistance by the United States and some countries of Western Europe to rigorous legal regulation of breastmilk substitutes. I will be disclosing no secrets when I say that there is, in the current serious economic downturn afflicting many countries, strong political and economic pressure to reduce government interference in business operations. It is part of the avowed economic philosophy of the Reagan Administration in the United States and the Thatcher Administration in the United Kingdom. The same approach has also been taken in Australia, as I have said, and doubtless in many other countries of the Commonwealth of Nations and beyond. So a statute which comtemplates detailed regulation of market forces and the creation of an administration, however small, to police the system[12] is bound to attract opposition in some quarters.

Having said all this, it must be acknowledged that drafting a Bill also has major advantages. It is a technique which is always followed in the Australia Law Reform Commission:

* Focus on specifics: it helps focus attention on specifics, particularly the machinery that it proposed to implement principles which are agreed in their vague generality. It is often when one gets down to specifics that important problems, difficulties and points of difference emerge for the first time.

* Bureaucratic obstacles: draft legislation can also help to overcome an important bureaucratic obstacle to action. This is the complaint, common in all our countries, that Parliamentary Counsel are too busy with urgent tasks of government priority to give attention to complex matters of social and moral importance. The preparation of a draft statute will often overcome this administrative barrier.

* Lawmakers' methods: furthermore, lawmakers of our tradition find it easier to see precisely what is being suggested if they can examine a draft statute. Administrators, experts, lobby interests and the like, find it much simpler to consider proposals when they are in orthodox legislative form, rather than when they are lost in the always voluminous papers that emanate from the United Nations and its agencies, with obscurity of language which is the price of compromise between texts worked on in many tongues.

MEDICO-LEGAL ISSUES IN AUSTRALIA: PUBLIC PARTICIPATION

Despite the call for Australian legislation to which I have just referred[13], it does not appear that Australian legislation on the subject of the marketing of breastmilk substitutes, either within Australia or by Australian agencies or companies out of Australia is under contemplation of the Australian Government. At the end of 1981, the Federal Department of Health indicated that it had agreed that the Australian industry's compliance with the WHO Code, should be based on voluntary self-regulation. This agreement was reached after consultation with the Federal Department of Primary Industry and representatives of the five major Australian manufacturers of breastmilk substitutes. The Federal Department of Health has co-ordinated the drafting of an industry-wide voluntary regulation code which is based on the 'aims and principles' of the WHO Code recommendations. According to Nestlé Australia Limited that code is 'near completion and adoption'.[14] Nestlé was established in Australia in 1908. Soon after it began exporting sweetened condensed milk to South-East Asia. By the 1920's the Australian company was exporting Lactogen, an infant formula in powder form. Lactogen has been used extensively throughout South-East Asian and in China and Nestlé is still the major exporter of infant milk powder from Australia.[15]

There has been some discussion in Australia on the problems of Aboriginal infant mortality arising from the trend away from breast feeding.[16] The Australian National Health and Medical Research Council has endorsed, generally, the WHO Code, whilst stressing the need for the availability of formulating appropriate cases.[17] Current data indicates a steady increase in breast feeding in Australia with a

co-incidental increase of the duration of breast feeding. 82% of Australian infants are breast fed at the time of hospital discharge, 75% at the age of 6 weeks and 10% at 12 months.[18] There is established in Sydney an Infant Formula Action Coalition which is active. It issues a newsletter and captures media attention. Serious journals have included critical items on the involvement of the Australian Dairy Corporation in selling inadequately labelled and unsuitable sweetened condensed milk as babyfood in South-East Asia.[20] However, it seems unlikely, at present, that Federal legislative intervention in the marketing and sale of breastmilk substitutes in and from Australia will ensue. Co-inciding with 'womens' liberation' there has been a marked turn-back in Australia at least to breast feeding. There is little popular pressure for legislation, the relevant government department is working towards voluntary guidelines. The introduction of more specific legislation would be out of line with the present Australian Government's general approach to the role of the law in controlling corporate activity in the market place. It favours voluntary self-regulation and this approach is being actively pursued. I would only add that Australia has consistently supported and voted for the WHO Code both in the World Health Assembly and in other organs of the United Nations Organisation.

Against this background, it will not be apparent to you what an Australian judge has to offer to this international conference. I am here primarily to speak of the ways in which we in Australia have tackled other medico-legal issues. I believe that our techniques in this regard may be a more welcome export to developing countries than Australian exports of unnecessary breast milk substitutes. Because of the universality of the human body and its problems, the international nature of much scientific and medical technology and the commonality of many of man's moral perceptions, it is likely that, at some stage of other, most countries of the Commonwealth of Nations will have to face issues of the kind I will mention. I fully realise that in the developing countries of the Commonwealth issues such as transplantation and in vitro fertilization may seen exotic - or at least of less relevant concern than issues such as alleged 'commerciogenic malnutrition'.[21] It has been said that 10 million babies in the world suffer from malnutrition and hundreds of thousands of them die every year from this cause.[22] Critics of breastmilk substitutes certainly claim very high levels of infant morbidity and fatality attributed to breastmilk substitutes.[23] Some claim millions of such cases.[24] Whatever the number, the issue at stake is at once urgent, widespread and affects very large numbers.

Governments comprising lay politicians and administrators are confronted by competing and sometimes conflicting demands in debates tinged by ethical and philosophical passions. Powerful economic and professional forces are involved. How, in

these circumstances, are such issues to be tackled by a lawmaking process which finds such questions unconfortable and puzzling? In countries where the government must answer periodically to the people at the ballot box, where strongly conflicting views are held, how are such issues to be resolved in a way that is informed, not unduly dominated by emotionalism and appropriately sensitive to the values of the community, popular opinion and the processes of parliament?

These were the questions which the Australian Law Reform Commission confronted when in 1976 it received a reference to enquire into the law governing human tissue transplantation. I must admit to you that when the then Australian Attorney-General, Mr. R.J. Ellicott, gave this project to the Commission, I thought he had taken leave of his senses. With many pressing tasks of law reform and small resources available to tackle them, I considered that he had got his priorities wrong. In retrospect, I must confess that the Attorney-General was right and it was I who had the priorities wrong. For in asking a body such as the Law Reform Commission to provide Parliament with laws on human tissues transplants, he was essentially saying here is a species of a new problem which confronts our legal system. It is the problem of tackling bio-ethical questions, of which there will be many in the future. If Parliamentary Government and the rule of law are to survive, it will be essential for our legislatures to make laws on such topics. Being laymen, they find it difficult to understand the issues. Yet the issues must not be neglected nor must they be turned over entirely to experts and scientists. Where moral questions are involved, the community's moral voice, through its lawmakers must be heard. In the past many such issues would have been dealt with by the judiciary. But in today's world, the judiciary will defer on them to the legislature. Furthermore, it is undesirable that highly complex matters of bio-ethics should be resolved as between particular parties in the court setting. We must find new machinery to make the process of lawmaking work and work better.

The Australian Law Reform Commission was fortunate to have, as participants in this project a number of very fine and thoughtful lawyers. Sir Zelman Cowen, later Governor-General of Australia and now Provost of Oriel College, Oxford, was a Commissioner. So was Sir Gerard Brennan, now a Justice of the High Court of Australia, Australia's highest court. The Commission gathered around it a nucleus of interdisciplinary expertise to assist in the identification of the moral and legal problems of transplantation and to help provide the solutions. There was a professor of anatomy, experts in transplant surgery, a professor of moral philosophy and theologians from the major faiths. But the team was still small and it set to work examining local practices, overseas writing, medical and legal, and community opinions.

Throughout the country a series of public hearings was held in which law commissioners listened to ordinary citizens expressing their experiences and concerns. These hearings were accompanied by seminars with the medical professions and health care. As the hearings and seminars tended to be covered in the press, they generated a great deal of popular discussion. Invitations were extended and accepted to appear to television, to participate in radio programs, talkback radio and print media conferences. In the end, there would probably have been few interested people in Australia who were not aware that the enquiry was proceeding, that the issue was important and complicated and that their opinions were being sought. Public opinion polls were conducted by the major newspapers and by other interests. At the end of this process, a report was drafted. To it was attached draft statute on human tissue transplantation.

You will not be surprised that, in an enquiry which was examining puzzling dilemmas of medicine and ethics, differences of view arose between members of the Law Reform Commission. These were thoroughly debated with consultants and finally amongst the Commissioners. At the end of the day, it was not possible to get unanimity on all points. The Commission did not seek to disguise the disagreements. On the contrary, the differing viewpoints were candidly and vigorously stated. The report dealt with such topics as:

* the definition of 'death' in terms of brain function;
* whether a regime of donations should be maintained or, to increase the supply of organs and tissues, a presumed donation should be enforced by thelaw;
* whether young persons should be ever able and if so under what precautions, to donate paired non-regenerative organs, say to a sibling;
* whether organs should be taken from coroners' cadavers for production of serum of great social utility;
* whether wishes of the deceased should ever be overridden by surviving relatives concerning the use of a body for its parts.

Because vital issues of life and death were touched upon in the enquiry, and because strongly held religious, philosophical and professional opinions did not always co-incide, lawmaking in this area in Australia had been long neglected: the law failing to keep up with surgical and technological advances. The Law Reform Commission provided the catalyst. The report ultimately produced, proved of practical value. It has been followed by legislation in four of the eight Australian jurisdictions. Legislation is before Parliament in one other and in promised in two others. In some cases, the legislation as introduced varied the precise language of the Law Reform Commission's draft Bill. But a fair measure of uniformity has been maintained. Above all, the draft Bill we offered focused attention on the key issues. The report outlined the basic hard policy questions which administrators and law makers had to address.

Another point must be made. It is all too easy, whatever the form of Government, to postpone and delay indefinitely legislative responses to problems involving complex and sensitive bioethical issues. In Australia, the special difficulties include the federal system of government which sometimes decides responsibility for action, strongly held religious convictions in minority but influential circles and powerful professional opinions in the practising medical profession. In other countries, the problems may be communal factionalism on specific issues or securing legislative priority, when so many other social and economic questions compete for legislative attention and scarce funds. It is here that the technique of open enquiry, involving frank discussion of issues in the whole community, is of great benefit. It has numerous advantages:

* Public information: it informs the community about complex issues, many of which ultimately get back to community perspections of right and wrong. For most people, there is no absolutely right answer to the debate whether there should be an 'opting in' or 'opting out' regime in the law governing human tissue transplantation. It is a matter upon which sincere people of goodwill, even when fully informed, can differ because of differing fundamental values.

* Public experiences: a second reason is that public discussion illicits public experience. As the Zimbabwe Minister of Justice has inferred, lawyers, even in Africa, tend by their vocation and training often to be less critical of the law and less sensitive to its injustices than non-lawyers. It is a healthy corrective to lawyers' complacency to listen carefully to the experiences and needs of citizens. Their experiences personalize and concretize the problems which the law reformer must address. As in breastmilk substitutes, they can also motivate the law reformer and galvanise him or her into an appreciation of the need for urgent action.

* Political stimulation: and action is the third reason. I cannot speak for other countries. But in Australia, the resistance to law reform is often not the result of frank political opposition, or deeply felt philosophical objection. All too frequently it is an unhappy combination of community apathy, legal professional resignation, administrative and bureaucratic inertia, ministerial distraction by other issues and the sheer cumbersome procedures enacting legislation. Add to these, the opposition of powerful lobby interests with local economic and commercial advantages to defend, the shrill voices of this or that religious viewpoint and the Babel of conflicting scientific opinion and you have a most potent formula for inaction and no reform. One must either accept this situation,

particularly in countries with parliaments facing an election every few years, or one must try to find means to help cut the Gordian knot. This, I believe, is where an effective law reforming agency can come in. Its very procedures of public consultation can attract publicity. Publicity can provide the impetus for political action. Its procedures of public deliberation and justification can provide the means of resolving differences of scientific and lay opinion. Its reasoned reports and use of the modern means of communications (radio and television) can ensure that it educates the community and the politicans in the issues before it. Attracting community attention in turn builds up expectations for reform action which are less readily able to be pushed to one side. If it is a respected body of integrity, which has approached its problem with an open mind, seeking out a true and just solution to the matters before it, its public operations will, more likely than not, galvanise even a lethargic political process into reform action - and even on a controversial and sensitive matter about which people differ. On bioethical questions, it is impossible to attain absolute unanimity of opinion. In a free society, such consensus is rarely achieved. But it is possible to give all points of view the reality and the appearance of being publicly heard and the satisfaction of a reasoned report which accepts or rejects competing facts and opinions.

The British system of public administration which we inherited in all of our countries had many virtues. These included general incorruptability, competitive entrance examinations and high ideals of public service. But British public administration had at least one major defect which is damaging in today's world of better educated and more informed citizens, volatile political movements and many states recently come to self-government. It was a highly secretive and closed system, performed by an elite. Such a system is ill-suited to tackling many bioethical questions which now present themselves for moral judgement, and in some cases, legislative action. The way of the future is a more open administration and more public discussion of the ramifications of medical problems having social and legal relevance. The experience of the Law Reform Commission of Australia in its project on human tissue transplants is both instructive and reassuring. It shows that, if you go about the task in the right way, avoiding the sensational and the trivial, it is possible, with the help of experts and lobbys to assess competing opinions. It is reassuring because, at the end of the process there has been a great deal of legislative activity in an area long neglected. Now, in saying all this I do not ignore:

* the special and rather limited nature of the issues raised by human tissue transplants;
* the absence of well-established economic and commercial interests, such as exist, with great power, in the area of breastmilk substitutes;
* the difficulty in developing countries especially of communiticating complex issues to a mass audience;
* the urgency and priorities that must attach to competing social questions, especially when it comes to scarce media time.
* the limited manpower of highly talented people who are available to make decisions and the limited resources that can be devoted to public consultation, securing opinions, printing reports and so on.

All of these considerations have to be weighed. No two countries of the Commonwealth of Nations will have precisely the same needs or problems. But I do suggest that all of us are going to face in the near future the need for legislation on highly controversial medical practices which raise moral and ethical questions as well legal and medical professional ones. If I have one simple message, it is that the safest course to follow in tackling such issues is the procedure of open discussion. It should be open discussion that goes beyond the experts out to the community. For if laws are to be made which touch the fundamental questions of life and death, those laws must satisfy not only the views of lawyers and scientists. They must be in tune with the views of the citizenry.

The Australian Law Reform Commission's project on human tissue transplants tackles but one issue in the bioethical sphere. Many remain to be attended. In Australia, at present there are three State enquiries into the moral and legal implications of in vitro fertilization (test tube babies). The Victorian State enquiry has produced an interim report which follows public hearings and a great deal of serious media debate.[25] In Parliament recently, the Federal Attorney-General was asked whether he intended to refer other questions having a bioethical content to the Australian Law Reform Commission. Matters instanced, were the law on:

* embryo implantation;
* surrogate parenthood;
* artificial insemination;
* genetic engineering.[26]

But the list might have been much longer. It could, for example, have included other legal questions which are presented by new medical techniques or by changing community opinions in Australia. Such questions include:

* the law on abortion and the use for treatment or experimentation of foetal tissue;
* euthanasia, the so-called right to die and the right to make a 'living will' excluding extraordinary medical care in the case of a terminal condition;
* the rights of young children and their parents, where a child is born grossly, physically or mentally disabled. Should an operation be required in such cases, or such 'nature be left to take its course'?[27] If such a child is sustained, should it have a claim for 'wrongful birth'?[28]
* human cloning is said to be but 20 years off.[29] Should the law permit cloning? Should it permit cloning to produce an embryo as a source of replaceable body parts for the clone donor, desperately needing a compatible kidney or pancreas?
* and what of the legal position of long-neglected minorities: The mentally ill? The mentally retarded?[30] The very old? The new born? The embryo?
* should we permit implantation of computers in the human brain to supplement or to substitute for natural brain power?

These and many other questions are either with us now or shortly will have to be faced. Though in many Commonwealth countries the basic problems of human survival, preventitive community medicine and macro issues of aggregate national health, loom large and the issues I have listed may seem exotic or of remote significance, experience teaches that developments of medical science begin in one part of the world and soon spread else as the pursuit of medical excellence and local demands put pressure on the local professions to acquire skills and supply specialist services.

Within the Commonwealth of Nations, because of our generally similar legal systems, we do well to pay attention to the studies that are going on in other Member countries. Though the social base is often different, though religious and cultural factors may vary, our common language and common governmental and professional traditions and above all commonality of the human body all make it appropriate that we should heed closely developments in other Commonwealth countries. This very conference is an illustration of the way things happen. Papua New Guinea, enacted as long ago as 1977 the Baby Food Supplies (Control) Act which forbids the sale of bottles and teats except on prescription. This was done in recognition of the perceived dangers of uncontrolled sale of breastmilk substitutes.[31] This legislation and the follow-up of its impact has attracted a great deal of attention throughout the Commonwealth of Nations including, as I have said, in Australia. A question is posed by such a legal development. What is the problem it seeks to tackle? Is that problem common to other countries? Is it tackled

the right way? Have there been unexpected effects? Are there distinguishing factors at home? All of these are legitimate questions. The fact that we in the Commonwealth Nations share so many features in common in law, medicine and government, makes it appropriate and convenient that we should study this innovation and consider its implication for our own countries. The methodology of the Australian Law Reform Commission suggests that we will do this best if the home consideration is conducted in the open, if expert and citizen are heard, and if at the end of the day a report is prepared which tackles the basic issues and suggests the way ahead for legal action. I am aware that in Zimbabwe a report, which have attracted a great deal of attention overseas, has already been produced, is publicly available and suggests reform legislation.[32]

BREASTMILK SUBSTITUTES: THE DISADVANTAGES

I now turn to make a few remarks about the breastmilk substitutes issue. These are personal remarks because the subject has not been and is not likely to be referred to the Australian Law Reform Commission for examination and report. It seems clear beyond doubt that the phenomenon of bottle feeding, which has been a feature of this century with the advent of breastmilk substitutes, is as serious a problem for community health, particularly in developing countries, as a great epidemic or the current problems of narcotic drug abuse in Western countries. Everyone, including the manufacturers of breastmilk substitutes agree that 'Breast is best'.

* Composition: breastmilk substitutes are based on cows milk and though high degress of compatibility with human milk have been achieved, there remain abiding differences.[33]

* Dilution and contamination: because of the cost of breastmilk substitutes, the formulae are often diluted. Because of the difficulties of instructions incorrect mixtures are sometimes offered. The net result, universally agreed, is an exacerbation in developing countries of the already serious problem of malnourishment. One can argue about the numbers and whether it is thousands, hundreds of thousands or as some claim, millions of babies malnourished because their mothers have chosen the bottle rather than the breast. Whatever the precise numbers, the problem is one of serious proportions.[34] Mothers deplete the capacity to provide milk by depriving themselves of food to pay for the formula.[35] Provision of incorrect food can cause permanent brain damage in neonates.[36]

* Infections: the chances of infection are greater on average for bottle fed than for breast fed babies. This can be attributed in part to poor home hygiene[37], in part to the unreality in underdeveloped communities of instructing sterilisation, boiling water, washing of hands and other rituals, piously urged on the labels of formula products.[38] The absence of uncontaminated water in many developing countries makes the mixture sometimes lethal. It certainly explains the high number of cases of serious diarrhoea - rare among breast fed babies, but even in Britain, high amongst those on the bottle.[39]

* Contraception: the value of breast feeding as an effective means of contraception is now well established.[40] Transfer to the bottle has a significant effect on community birth rates which is especially serious in developing countries where other forms of contraception are less readily available but where contraception is, possibly, more socially needed.

* Psychological bonding: the psychological bonding between mother and baby achieved through neonatal contact is increasingly recognised as important in combating cases of child abuse on the part of the mother and emotional deprivation on the part of the child.[40] It is also important for the confidence of the mother and her capacity to produce milk readily. Early transfer to the bottle may greatly diminish lactation.

* Economics: quite apart from the reasons of public health, there are reasons of economics. At the micro level, within families, very high proportions (sometimes 50%) of average income is being spent by people who can ill afford it on formula.[43] This is occuring when, in a great majority of such cases, it is simply not needed and would be better spent on feeding the mother and other members of the family. At a macro level, large sums must be found in hard-pressed budgets and limited foreign exchange resources to meet the cost of imported baby formulas. These sums runs into billions of dollars in aggregate.[44]

BREATMILK SUBSTITUTES: MOVES FOR REFORM

The problem presented in summary above is now recognised throughout the world by world organisations such as the World Health Organisation and the Commonwealth of Nations. Indeed, it is acknowledged in general terms by the major producers of breastmilk substitutes. The pressure for reform action began amongst tropical nutritionists in the 1950's[45] and amongst womens' movement organisations in developed countries at the same time.[46] Initial legal responses focused on permitting working women the legal right, under legislation or industrial awards to breast feed their infants during work time.[47] As one mother plaintively asked through

the pages of The Lancet, 'Would you like to eat your meal in a toilet?'[48] In too many countries, that remains the only facility and opportunity for breast feeding of infants by working mothers. The spread of malnutrition amongst children of office workers in developing countries is identified as a specially serious problem of our time.[49]

Moves on the international scene gathered pace in the 1960's and the temperature was distinctly raised when in 1974 War On Want published The Baby Killer.[50] The effort of the World Health Organisation General Assembly began in earnest in May 1974. But frustration at apparent lack of action led in 1977 to the Nestle boycott. This stimulated the United States Senate and the World Health Organisation into more positive action. In 1979, the Year of the Child, focused more attention on the problem. The major companies agreed to stop promoting milk substitutes formula publicly. They formed the International Council of Infant Food Industries to develop a marketing practice Code.[51] In October 1979, WHO issued its statement calling on governments in Member countries to take steps to address the issues and to ensure that undue promotion of milk substitutes was controlled. In May 1981, a draft International Code on the Marketing of Breastmilk Substitutes was adopted by WHO. It is in the form of a recommendation, It therefore depends on Member countries to follow it up. It calls for a response by Governments of Member countries. It was overwhelmingly supported.

In February 1982, the largest manufacturer Nestle gave written instruction for compliance by its employees with the Code, though these instructions were later analysed and criticised in The Lancet.[52] Nestle also established the Nestle Infant Formula Audit Commission chaired by former Senator Muskie of the United States designed to examine complaints and make suggestions. All members of the Commission are appointed by Nestle. In offering his resignation from the Audit Commission, Bishop Ramirez of New Mexico urged that he should be replaced by 'someone representative of the Nestle boycott network in order that there be a possibility for eventual reconciliation'.[53] So far this has not occurred. In June 1982 the World Health Assembly instructed the Director General of WHO to offer recommendations to 'deal with' persisting market practices. The debate continues. This international workshop is a practical endeavour, by analysis of developments in differing countries, to chart the way ahead for response by goverment to the continuing major public health problems presented by persisting unnecessary use of baby formula rather than the breast.

THE COMPANIES: CRITICS AND DEFENDERS

Criticisms: I do not have to recount the criticisms that have been voiced on the companies engaged in the sale of breastmilk substitutes, particularly in the developing countries where opportunities of corrective public education are less than in countries such as my own. The companies have been accused of action harming the babies of millions of mothers. They have been accused of questionable tactics in meeting the objections raised against their commercial practices.[54] They have been accused of persisting, despite public utterances to the contrary, with undesirable practices. These include:

* distribution of free samples of formula to nurses in hospitals;
* failure to print warnings in local languages;
* provision of sponsorship for hospital tea parties;
* distribution of 'educational' leaflets by agents posing as 'nurses'[55];
* provision of prescription forms, health cards and other documents prominently bearing the name and brands of baby health foods[56];
* provision of glossy posters in hospitals;
* hiring of private investigators to enquire into vocal opponents[57].

Many other objections are voiced against the companies. These include the unnecessary drain on local economies, the underpayment for labour and raw materials used by local branches in the production of formula [58] and the adoption of public relations tactics to defend a market and to head off what is essentially a moral question of world dimension. Though economic issues are truly involved, most observers would agree with the editorial in The Lancet that we can surely not justify jeopardising any nation's infants for commercial advantage.[59]

Defences: The other side of the case is vocal in defence.

* It is pointed out that the lives of many babies have been saved this century by substitutes where they might otherwise have died. Certainly, one must be careful, in providing any legislative response to the problem, not to exclude the useful purposes to which breastmilk substitutes can be put. The cases where the mother has died, where there have been multiple births or where the baby fails to thrive on breastmilk or where the mother is at work and simply cannot provide suckling are all instances where formula may be justified.[60]

* As well, growing evidence of the damage that can be done to the embryo and to neonates by mothers who inbibe alcohol, nicotine or other narcotics may sometimes justify early transfer of some babies to formula. The growing penetration of third

world countries by tobacco interests is another major public health problem that needs to be addressed. It is yet another case of unnecessary occidental lifestyles with grave health implications being inflicted on others.

* The occidental lifestyle, the growth in the number of working mothers, the desire to keep one's figure and Western emphasis on the erotic features of the breast have all encouraged many young women in developing countries to abandon breast feeding. Some of them might insist on the right to do so as an attribute of their new found freedom. So long as they can provide appropriate nourishment to the child, they and their supporters might argue that the State has no right to intervene in their personal lives. On the other hand, public education must seek to meet, combat and compete with this public psychology of the bottle. If efforts of public education do not or cannot succeed something more rigorous may be required.[61]

* The issue of personal freedom is often raised in this debate. The Lancet in 1979, voiced the caution that WHO should not become 'too authoritarian and restrictive' in its approach.[62] Freedom of choice and attention to exceptional cases, the right to local and personal variation are usual attributes of a free society. But at the heart of any medical or quasi medical relationship is informed consent of the patient. This legal principle upholds the rights of patients to control their own destiny, including, ultimely, their medical destinies. In the area of breastmilk substitutes one suspects that all too often there is no informed choice by many users - certainly not by the ultimate user - the baby. Sometimes it is simply a matter of hospital routine to provide the bottle, even before the baby is born. Sometimes the mother and the family, out of a desire to do the very best for the child, in imitation of perceived Western 'medicine', wrongly believe that formula is best and breast second best. The only way this misapprehension will be removed, is by community education. If this fails, administrative and possibly legislative controls will be needed to reinforce it.

* Some Western commentators suggest that developing countries are, by their effort to put the whole blame on formula manufacturers detracting attention from the 'real issues' of poverty, contaminated water and undernourishment.[63] Whilst it is true that many larger issues are involved and that most malnourishment in babies cannot fairly be traced to infant formula, in the short run at least we must take the world as it is. Pending the Millenium, when the broader questions will be tackled, there is a man-made problem which most observers agree needs positive government response.

* Defenders of the companies point to the complication of the impact of action on the supporting industries, including in the underdeveloped world. The civil service tends, in advising on action, to balance employment and economic effects of legislation against the public health reasons for action.[64] Especially in times of economic downturn, action having a harmful economic effect is likely to come slowly. On the other hand, the appeal of The Lancet to our moral duty to the next generation and the reminder of Dr. Sai that in this debate the 'major players are powerless'[65] cast a special responsibility on governments and those who advise them concerning the action that should be taken.

THE PROPER RESPONSE? VOLUNTARY CODES v LEGISLATION

Voluntary codes: There are some who say it is enough to proceed with voluntary codes. They mount this argument on practical and philosophical grounds. They say that government should get out of the market place as its interferences cause inefficiencies and public cost. They speak in terms of freedom of choice, including the choice of the bottle rather than breast. They urge conciliation rather than confrontation[66] and say this is more likely to occur with flexible guidelines than with inflexible of legislation. They suggest that 'at the workface' voluntary guidelines in which the industry has been involved are more likely to work in practice because of the industry participation and involvement.

On the other hand, the critics of voluntarism are many and vocal. In Papua New Guinea the legislation was only enacted in 1977 when distributors of baby bottles and teats resisted invitations to voluntary self-regulation. Critics of the voluntary approach say it encourages evasion by interested parties who are not members of the code.[67] It encourages a search for the lowest common denominator that sometimes falls short of what some participants regard as appropriate. It usually provides no neutral supervisor to monitor conduct and complaints.[68] It provides inadequate sanctions.[69] It permits too many breaches and exceptions in a serious and urgent social operation. The appearance of action without a real response is condemned as dangerous 'cosmetics'.

Administrative changes: The next line of regulation is change of administrative practice. Governments can step in to forbid imports of certain products within the rubric of 'dangerous goods'. They can encourage hospitals to change bottle feeding practices. They can control their own corporations, agencies and employees and enforce good practices in government run or government funded hospitals.

Legislation: But when measures of education, voluntary guidelines and administrative practices fail or operate inadequately and too slowly, the sanctions of the law may be appropriate. This was the view taken in Papua New Guinea.[70] It is the conclusion reached in the Zimbabwe report.[71] It was the message contained in the speech by Professor Short in December 1982 at the Australian National University.[72] It is the policy that is under consideration in numerous Commonwealth countries, both those represented at this conference and others.

The range of options for legislative action are many. They include banning of advertising, banning distribution of free samples, restricting availability of bottles and teats to the complete control of the importation and distribution of breastmilk substitutes and its supervision as a potential killer of young human beings: as dangerous in the wrong hands in developing countries as narcotic drugs are in Western countries. The need for legislation will differ from one jurisdiction to another. The precise design of the legislation may differ from jurisdiction to jurisdiction, in the light of experience and of the perceived practices that need to be controlled.

With a loud voice: Whatever the differences, this is undoubtedly a major health problem especially of the developing world. It is recognised as such by WHO, UNICEF and the Commonwealth of Nations. It is acknowledged implicitly or explicitly by most of the manufacturers of breast milk substitute products themselves. This conference is a timely opportunity for colleagues in the Commonwealth of Nations to pool their knowledge and experience. May our labours contribute to the protection of the new born children of the world. They cannot speak in their own interests. They require the informed, civilised world to do so on their behalf. And to do so with a clear, loud voice.

FOOTNOTES

* The views expressed are personal views. The visit of Mr. Justice Kirby to Zimbabwe was made at the invitation of the Commonwealth Secretariat, London and funded by the Commonwealth Foundation.

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12. See sub-clause 7(1) of Model Bill noted in fn 8 above.

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33. D.B. Jelliffe and E.F. Jelliffe, 'Breast is Best: Modern Meanings' in New Eng J Med, 27 October 1977, 912 (hereafter Jelliffe and Jelliffe)

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36. ibid, 1592.

37. Jelliffe and Jelliffe, 913.

38. Muller, 10.

40. Jelliffe and Jelliffe, 913.

41. ibid, 914

42. George 1597.

43. Jelliffe and Jelliffe, 914.

44. George, 1592; Jelliffe and Jelliffe, 914.

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Sai, 13; Jelliffe and Jelliffe, 915.

48. 'Choice of Infant Feeding in the United Kingdom' in The Lancet, 17 April 1982, 918.

49. Sai, 2.

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54. George, 1596.

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58. ibid, 1600.

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64. Schwab, 280.

65. Sai, 2

66. Schwab, 281.

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69. ibid; The Lancet, 25 May 1982, 1196.

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