# THE ROLE OF LAW REFORM IN BIOETHICS: THE CASE OF BREASTMILK SUBSTITUTES

BY
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In 1977 Papua New Guinea enacted the Baby Food Supplies (Control) Act 1977 (P.N.G.) to control the sale, without prescription, of baby formula (breastmilk substitutes), feeding bottles and teats. This legislation anticipated the 1981 World Health Organisation International Code on Marketing of Breastmilk Substitutes. The W.H.O. Code was developed, with support from Australia, to control marketing practices concerning breastmilk substitutes, particularly in developing countries. The widespread sale of these products has produced many problems. In January 1983, a conference of lawyers, health workers and public administrators convened in Harare, Zimbabwe, to consider ways in which the law could be used to reduce the unnecessary promotion and sale of such products. The Chairman of the Australian Law Reform Commission was invited to participate in the conference. In this paper he reviews the methods used by the Commission in the preparation of its report on Human Tissue Transplants as an illustration of the ways in which controversial, bioethical problems can be tackled. The paper includes some comments on the regulation of the sale of breastmilk substitutes: a matter of growing concern in developing countries of the Commonwealth of Nations and beyond.

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#### I. INTRODUCTION

In 1981, the World Health Organisation (W.H.O.) implemented a code on the marketing of breastmilk substitutes. This code was a broad and general statement of principle, but translating it 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. The recent 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 nations. In addition, in the current serious economic downturn afflicting many countries, strong political and economic pressures exist to reduce government interference in business activity. Nonetheless, Law Reform Commission Reports and International Guidelines can bring pressure to bear on nations to conform to such statements of principle. 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 adaptation 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 other areas such as informatics, privacy and transborder data flows.

## II. MEDICO-LEGAL ISSUES IN AUSTRALIA: PUBLIC PARTICIPATION

It is illuminating to see the way in which the W.H.O. Code is being implemented in differing ways in different member countries. As a stimulus to our thinking and to concentrate attention on specifics, the Commonwealth Secretariat has produced a draft "model" statute.1 One member country of the Commonwealth of Nations has already enacted legislation, namely Papua New Guinea.2 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.3 Despite this call for Australian legislation, 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 W.H.O. 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 coordinated the drafting of an industry-wide voluntary regulation code which is based on the "aims and principles" of the W.H.O. Code recommendations. According to Nestle

Infant Foods (Marketing) Act 1983 appended to BMS/38/L/2, papers for Harare workshop.

Baby Food Supplies (Control) Act 1977 (PNG).

<sup>3</sup> Professor R. Short, Monash University, A. W. T. Edwards Memorial Oration, Australian National University, 14 December 1982, Canberra Times, 16 December 1982, 6.

Australia Limited that code is "near completion and adoption". Nestle was established in Australia in 1908 and soon afterwards began exporting sweetened condensed milk to South-East Asia. By the 1920s, the Australian company was exporting Lactogen, an infant formula in powder form. Lactogen has been used extensively throughout South-East Asia and in China and Nestle' is still the major exporter of infant milk powder from Australia.<sup>5</sup>

There has been some discussion in Australia on the problems of Aboriginal infant mortality arising from the trend away from breast-feeding.6 The Australian National Health and Medical Research Council has generally endorsed the W.H.O. Code whilst stressing the need for the availability of formulating appropriate cases. Current data indicates a steady increase in breast-feeding in Australia with a coincidental increase of the duration of breast-feeding. 82% of Australian infants are breast-feed at the time of hospital discharge, 75% at the age of six weeks and ten per cent at twelve months.8 There is an active Infant Formula Action Coalition established in Sydney. 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 milk as babyfood in South-East Asia.9 However, it seems unlikely at present that Federal legislative intervention in the marketing and sale of breastmilk substitutes in and from Australia will ensue. Coinciding with "women's liberation" there has been a marked turn-back in Australia 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 recent approaches to the role of the law in controlling corporate activity in the market place. These approaches favour voluntary self-regulation and such an approach is being actively pursued. It should be added that Australia has consistently supported and voted for the W.H.O. Code, both in the World Health Assembly and in other organs of the United Nations Organisation.

Against this background it may be asserted that the techniques used in Australian law reform to tackle other medico-legal issues could be of considerable relevance. 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 or other, most countries of the Commonwealth of Nations will have to face these issues. Problems concerning transplantation and in vitro fertilisation may well seem exotic or at least of little relevance when compared with issues such as alleged "commerciogenic malnutrition".<sup>10</sup>

<sup>4</sup> Letter by Nestlé Australia Limited to the author, 10 December 1982, 4. On 9 May 1983 the new Federal Minister of Health, Dr N. Blewett M.P. announced the Australian Government's voluntary code (Australian Code of Practice for Marketing of Infant Formulas). It is to be reviewed in two years when other measures will be considered.

<sup>5</sup> Ibid.

<sup>6</sup> I. Darnton Hill, "The Worst of Both Worlds: Changing Patterns of Aboriginal Disease and Nutrition" Paper presented at the ANZAAS Congress, Adelaide, S.A. (May 1980) mimeo 6-7.

<sup>7</sup> Resolution adopted at the 92nd Session of the Australian National Health and Medical Research Council (Oct. 1981). See also the Resolution on Infant Formulas adopted at 93rd Session (June 1982).

<sup>8</sup> In Australian comments on the implementation of the W.H.O. Code by Australia for presentation to the 21st Session of the Executive Board (January 1983) made available to the author.

<sup>9</sup> See e.g., "The Baby Food Scandal" (Feb. 1980) Choice 42.

<sup>10</sup> M. Muller, The Baby Killer (1974) 10.

It has been said that 10 million babies in the world suffer from malnutrition and hundred of thousands of them die every year from this cause. 11 Critics of breastmilk substitutes certainly claim very high levels of infant morbidity and fatality attributed to breastmilk substitutes. 12 Some claim millions of such cases. 13 Whatever the number, the issue at stake is at once urgent and widespread. However, the methods by which more esoteric medico-legal problems have been tackled could provide a useful analogy for legal reform.

Governments comprising lay politicians and administrators are confronted by competing and sometimes conflicting demands on 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 uncomfortable 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. When the then Australian Attorney-General, Mr R. J. Ellicott, gave this project to the Commission, he was essentially saying: here is a new species of problem which confronts our legal system. It is the problem of tackling bioethical 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 tend to defer 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. Accordingly, new machinery should be found to make the process of lawmaking work and work better.

The Australian Law Reform 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.

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. As the hearings and seminars tended to be covered in the press, they generated a great deal of popular discussion. Public opinion polls were conducted by the major newspapers and

<sup>11</sup> Editorial, "Stop the Babymilk Pushers" (April 1982) New Internationalist 7.

<sup>12</sup> S. George, "Nestlé Alimentana S.A.: The Limits to Public Relations" (1978) 13 Economic and Political Weekly 1592.

<sup>13</sup> E. F. P. Jelliffe, "When the answer is not a bottle" (undated) UNICEF News 3.

by other interests. At the end of this process a report was drafted to which was attached a draft statute on human tissue transplantation.

It is not surprising that, in an enquiry which was examining 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. 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 coincide, lawmaking in this area in Australia had long been neglected: the law was failing to keep up with surgical and technological advances. The Law Reform Commission provided the catalyst. The report ultimately produced proved to be of practical value; it 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 divides 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. 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 inherited throughout the Commonwealth of Nations had many virtues. These included general incorruptibility, 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 generally controlled 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 Australian Law Reform Commission of Australia in its project on human tissue transplants is both instructive and reassuring. It shows that if one goes about the task in the right way, avoiding the sensational and the trivial, it is possible, with the help of experts and lobbies, 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. Every State and Territory of Australia, except Tasmania, has adopted legislation based on the Commission's report on transplant law. No two countries will have precisely the same needs or problems. But all 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 as legal and medical professional ones. The safest course to adopt in tackling such issues is the procedure of open discussion. It should be open discussion that goes beyond the experts, to the community. 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, but must be in tune with the views of the citizenry.

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, 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. One such development is that seen in Papua New Guinea, when in 1977 the Baby Food Supplies (Control) Act was enacted to forbid the sale of bottles and teats except on prescription. This was done in recognition of the perceived dangers of uncontrolled sale of breastmilk substitutes. This legislation and the follow-up of its impact has attracted a great deal of attention throughout the Commonwealth of Nations, including Australia.

#### III. BREASTMILK SUBSTITUTES: THE DISADVANTAGES

The following remarks are personal remarks because the subject of Australian legislation on breastmilk substitutes has not been referred to the Australian Law Reform Commission for examination and report. The phenomenon of bottle feeding, which has been a feature of this century with the advent of breastmilk substitutes, is as serious a community health problem, particularly in developing countries, as a great epidemic or the current problems of narcotic drug abuse in Western countries.

- Composition Breastmilk substitutes are based on cows' milk and though high degrees of compatibility with human milk have been achieved, there are abiding differences.<sup>15</sup>
- Dilution and Contamination Because of the cost of breastmilk substitutes, the formulae are often diluted in developing countries. Because of the difficulties of understanding instructions, incorrect mixtures are sometimes offered. The net result, universally agreed, is an exacerbation 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 to bottle feed rather than breast-feed. Whatever the precise numbers, the problem is one of serious proportions. Mothers deplete the capacity to provide milk by depriving themselves of food to pay for the formula. Provision of incorrect food can cause permanent brain damage in neonates.

<sup>14</sup> J. Aidou et al, "Bottle Feeding and The Law in Papua New Guinea" (21 July 1979) Lancet 155.

D. B. Jelliffe and E. F. Jelliffe, "Breast is Best: Modern Meanings", (1977) New Engl. J. Med. 912.
 World Health Organisation, Opening statement by Dr. F. Sai, Chairman W.H.O./UNICEF Meeting on Infant and Young Child Feeding, Geneva, 9 October 1979, 2.

<sup>17</sup> Note 12 supra, 1596.

<sup>18</sup> Id., 1592.

- Infections On average, the chances of infection are greater for bottle fed than for breast-fed babies. This can be attributed in part, to poor home hygiene, <sup>19</sup> and 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. <sup>20</sup> 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 bottle fed babies.
- Contraception The effect of breast-feeding on contraception is now well established.<sup>21</sup> 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 or acceptable 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.<sup>22</sup> 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 incomes is being spent on formula by people who can ill afford it.<sup>23</sup> 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 run into billions of dollars in aggregate.<sup>24</sup>

#### IV. BREASTMILK SUBSTITUTES: MOVES FOR REFORM

The problem presented in summary above is now recognised throughout the world by 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<sup>25</sup> and amongst women's movement organisations in developed countries at the same time.<sup>26</sup> Initial legal responses focused on permitting working women the legal right, under legislation or industrial awards, to breast-feed

<sup>19</sup> Note 15 supra, 913.

<sup>20</sup> Note 10 supra.

<sup>21</sup> Note 15 supra, 913.

<sup>22</sup> Id., 914.

<sup>23</sup> *Ibid*.

<sup>24</sup> Note 12 supra, 1592; note 15 supra, 914.

<sup>25</sup> Note 15 supra, 914.

<sup>26</sup> Ibid.

their infants during work time.<sup>27</sup> In many countries this remains the only opportunity for breast-feeding of infants by working mothers. The consequential spread of malnutrition amongst children of office workers in developing countries is identified as an especially serious problem of our time.<sup>28</sup>

Moves on the international scene gathered pace in the 1960's and the temperature was distincly raised when in 1974 War On Want published *The Baby Killer*.<sup>29</sup> 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 campaign 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.<sup>30</sup> In October 1979 W.H.O. 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 W.H.O. 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 *Lancet*<sup>31</sup>. 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". So far this has not occurred. In June 1982 the World Health Assembly instructed the Director General of W.H.O. to offer recommendations to deal with persisting market practices. The debate continues.

#### V. THE COMPANIES: CRITICS AND DEFENDERS

#### 1. Criticisms

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

<sup>27</sup> Note 16 supra, 13; note 15 supra, 915.

<sup>28</sup> Note 16 supra.

<sup>29</sup> Note 10 supra, 1591.

<sup>30 &</sup>quot;Campaign Against Malnutrition" (20 October 1979) Lancet 833. Cf. M. G. Schwab, "The Rise and Fall of the Baby's Bottle" (1979) 33 J.Hum. Nutr. 276, 279.

<sup>31 &</sup>quot;Response by Nestlé to the W.H.O. Code on breast-milk substitutes" (22 May 1982) Lancet 1196.

<sup>32</sup> Nestlé Co-ordination Centre for Nutrition Inc. and Nestlé Infant Formula Audit Commission, Press Conference with Hon. E. S. Muskie et al, Washington D.C., 24 October 1982, Transcript of Proceedings, 52.

raised against their commercial practices.<sup>33</sup> 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 and instructions in local languages;
- provision of sponsorship for hospital tea parties;
- distribution of "educational" leaflets by agents posing as "nurses";34
- provision of prescription forms, health cards and other documents prominently bearing the name and brands of baby health foods;<sup>35</sup>
- provision of glossy posters in hospitals;
- hiring of private investigators to enquire into vocal opponents.<sup>36</sup>

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<sup>37</sup> 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 *Lancet* that we can surely not justify jeopardising any nation's infant for commercial advantage.<sup>38</sup>

### 2. Defences

The producers of breastmilk substitutes point out that the lives of many babies have been saved this century by substitutes where they might otherwise have died. In providing any legislative response to the problem, one must be careful 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, where the baby fails to thrive on breastmilk or where the mother is at work and simply cannot breast-feed the baby are all instances where formula may be justified.<sup>39</sup> As well, growing evidence of the damage that can be done to the embryo and to neonates by mothers who imbibe 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 inflicting grave health implications 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

<sup>33</sup> Note 12 supra. 1596.

<sup>34 &</sup>quot;Promotion of Breastmilk Substitutes" (20 Feb. 1982) Lancet.

<sup>35</sup> See Ministry of Health of Zimbabwe, "Baby feeding: Behind and Towards a Health Model for Zimbabwe" (1982), referred to in Lancet (20 Feb. 1982).

<sup>36</sup> Note 12 supra, 1596.

<sup>37</sup> Id., 1600.

<sup>38 &</sup>quot;Choice of Infant Feeding in the United Kingdom" (17 April 1982) Lancet 918.

<sup>39 &</sup>quot;The Role of Artificial Feeding and Food Supplementation in Infant Feeding in Developing Countries", Nutrition in Developing Countries, a seminar for German technical assistance personnel, Kenya, December 1977, 383; M. G. Schwab, note 30 supra, 281.

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.<sup>40</sup>

The issue of personal freedom is often raised in this debate. Lancet in 1979 voiced the caution that W.H.O. should not become "too authoritarian and restrictive" in its approach. 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 the informed consent of the patient. This legal principal upholds the rights of patients to control their own destiny, including their medical destiny. 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 and in imitation of perceived Western "medicine", wrongly believe that formula is best and breast-feeding 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.<sup>42</sup> 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 Millennium, when the broader questions will be tackled, there is a manmade 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 those in the underdeveloped world. The civil service tends, in advising an action, to balance employment and economic effects of legislation against the public health reasons for action.<sup>43</sup> Especially in times of economic downturn, action having a harmful economic effect is likely to come slowly. On the other hand, the appeal of *Lancet* to our moral duty to the next generation and the reminder of W.H.O. leader Dr Sai that in this debate the "major players are powerless"<sup>44</sup>, cast a special responsibility on governments and those who advise them concerning the action that should be taken.

# VI. THE PROPER RESPONSE? VOLUNTARY CODES v. LEGISLATION

#### 1. 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 the government should get out of the market place as its interferences cause inefficiencies and public

<sup>40</sup> Note 12 supra, 1592; note 16 supra, 2.

<sup>41 &</sup>quot;Uneasy Prelude to Meeting on Infant Feeding" (29 September 1979) Lancet 680.

<sup>42</sup> Editorial in Washington Post quoted in International Herald Tribune, 6-7 November 1982.

<sup>43</sup> M. G. Schwab, note 30 supra, 280.

<sup>44</sup> Note 16 supra.

cost. They speak in terms of freedom of choice, including the choice of bottle feeding rather than breast-feeding. They urge conciliation rather than confrontation<sup>45</sup> and say this is more likely to occur with flexible guidelines than with the inflexibility 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. 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. It provides inadequate sanctions. 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".

## 2. Administrative Changes

The next method of regulation is change of administrative practice. Governments can step in under present laws 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.

# 3. Legislation

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.<sup>49</sup> It is the conclusion reached in a recent Zimbabwe report.<sup>50</sup> It was the message contained in the speech by Professor Short in December 1982 at the Australian National University.<sup>51</sup> It is the policy that is under consideration in numerous Commonwealth countries.

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 and 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 needs for legislation will differ from one jurisdiction to another. The precise design of the legislation may differ from jurisdiction to jurisdiction, in the light

<sup>45</sup> M. G. Schwab, note 30 supra, 281.

<sup>46</sup> Note 9 supra, 44-45.

<sup>47</sup> Note 12 supra, 1596.

<sup>48</sup> *Ibid.*; note 31 *supra*.

<sup>49</sup> J. Lambert, "Bottle-Feeding Legislation in Papua New Guinea" (1980) 34 J. Hum. Nutr. 23. See also J. Lambert, "To Encourage Breast-Feeding We Banned Bottles" (20 July 1979) Papua New Guinea Post Courier.

<sup>50</sup> Note 34 supra.

<sup>51</sup> Professor R. Short, note 3 supra.

of current legislation, experience, and of the perceived practices that need to be controlled.

Whatever the alternatives, the marketing of breastmilk substitutes is undoubtedly a major health problem, especially for the developing world. All nations should make a concerted effort to protect the rights of the newborn children of the world.