

A34/INF.DOC./9

INDEXED

14 May 1981

THIRTY-FOURTH WORLD HEALTH ASSEMBLY

Agenda item 23.2

1 B M C CHERRE

## DRAFT INTERNATIONAL CODE OF MARKETING OF BREASTMILK SUBSTITUTES

The Director-General has the honour to transmit to the Thirty-fourth World Health Assembly for its information a letter from the Delegation of Kuwait together with an article on "The International Code of Marketing for Breastmilk Substitutes: Consensus, Compromise and Conflict in the Infant Formula Controversy", published in: The Review, International Commission of Jurists, No. 25, December 1980.

Annex.

ANNEX

Wednesday, 13 May

Dear Dr Mahler,

I should be grateful if you would transmit to the Thirty-fourth World Health Assembly, for its information, the attached article: "The International Code of Marketing for Breastmilk Substitutes: Consensus, Compromise and Conflict in the Infant Formula Controversy".

I consider that this article contains very useful background information for the discussion on Agenda Item 23.2 Draft international code of marketing of breastmilk substitutes. There is, however, one point in it that requires updating. The article was written in December 1980 and still raised as a question whether the Code might be adopted as a recommendation or a regulation. In the meantime, the Executive Board at its Sixty-seventh Session in January 1981 has proposed to the Health Assembly that it adopt the Code as a recommendation in the sense of Article 23 of the Constitution.

Yours sincerely,

Dr A. R. Al-Awadi Minister of Public Health Chief Delegate Kuweit Delegation to the 34th World Health Assembly

Dr H. Mahler Director-General

#### RECENT ICJ PUBLICATIONS

#### The West Bank and the Rule of Law

A study by members of Law in the Service of Man (LSM), a group of Palestinian lawyers affiliated to the International Commission of Jurists (ICJ), published jointly by the ICJ and LSM, Geneva, October 1980, 128 pp. (ISBN 92 9037 005 X) Available in english. Swiss Francs 10 or US\$ 6, plus postage.

The study is the first survey and analysis to have been made of the charges in the law and legal system introduced by Israeli military orders during the 13-year occupation. It is a task which could only be undertaken by West Bank lawyers as the military orders, which number over 850, are not available to the general public and not to be found in libraries. The study is divided in three main parts: the judiciary and the legal profession, restrictions on basic rights and Israeli alterations to Jordanian law. The authors of the study argue that the military government has extended its legislation and administration far beyond that authorised under international law for an occupying power, thus ensuring for the State of Israel many of the benefits of an annexation of the territory.

### Human Rights in Nicaragua: Yesterday and Today

Report of a mission by Professor Heleno Claudio Fragoso of Brazil, and by Dr. Alejandro Artucio, a legal officer of the ICJ Secretariat, Geneva, September 1980, 86 pp.

Available in english or spanish. Swiss Francs 6 or US\$ 4, plus postage.

The report describes the legal framework and major human rights violations under Somoza's regime and discusses the human rights situation under the present regime. It comments favourably on the new government's commitment to the rule of law and the legal protection of human rights, but it urges the government to resolve the problem of the 7,000 "somocistas" still in detention by accelerated releases and improved trial procedures.

# \* \* \* The Trial of Macias in Equatorial Guinea

Report of an observer mission by Dr Alejandro Artucio, legal officer of the International Commission of Jurists, Geneva, December 1979, 70 pp.

Available in english or spanish. Swiss Francs 4 or US\$ 2.50, plus postage.

The report includes a description of the nature of the repression under Macias and the economic and social conditions of the country resulting from it. Criticisms are made of certain legal aspects of the trial, but the observer found most of the charges fully proved.

# \* \* \* C.I.J.L. Bulletin

Twice yearly bulletin, available in english, french and spanish.

Annual subscription: 10 Swiss Francs (surface mail) and 15 Swiss Francs (airmail).

This bulletin describes the activities of the Centre for the Independence of Judges and Lawyers, founded by the ICJ. It contains notes and articles on the persecution and harassment of members of the legal profession arising from their prefessional activities, and gives background information on legal developments relevant to the independence of the judiciary and of lawyers.

Publications available from:

ICJ, P.O. Box 120, CH-1224 Geneva

or from:

AAICJ, 777 UN Plaza, New York, N.Y. 10017

#### For the Pule of Law

## THE REVIEW



### INTERNATIONAL COMMISSION OF JURISTS

	_	1
HE WORLD	)	
2	India	16
10	Iran	20
14	Zimbabwe	23
UN Sub-Commission		26
Copenhagen Conference on UN Decade for Women		34
nd Common I	aw Systems	
J.F. Garner		39
stmilk Substit	utes	
James E. Post and Edward Baer		52
ON OF TH	E RULE OF LAW	
		6:
uct		6
	2 10 14  UN Decade for the straight of the str	10 Iran 14 Zimbabwe  UN Decade for Women  Ind Common Law Systems  Istmilk Substitutes  If Baer  ION OF THE RULE OF LAW  International Law

No 25 December 1980

Editor: Niall MacDermot

### The International Code of Marketing for Breastmilk Substitutes: Consensus, Compromise and Conflict in the Infant Formula Controversy

by
James E. Post and Edward Baer\*

#### Introduction

In May 1981, the World Health Assembly, the 155 member governing body of the United Nations' World Health Organization (WHO), is expected to adopt a resolution formalizing an International Code of Marketing of Breastmilk Substitutes. This action will cap over 10 years of often acrimonious conflict in which a group of health professionals, consumer advocates and their allies have sought to halt the aggressive promotion of powdered infant milk formulas. especially in developing countries of the world. While the code is far from complete. the process leading up to the decision by the World Health Assembly to proceed with its development raises some important questions about the role of international institutions in mediating conflict between transnational industries and consumer groups.

In this paper, we shall review the nature of the health and economic problems caused by the replacement of breast-feeding by bottlefeeding, examine the role of industry promotion within the multitude of forces fostering this trend, and summarize the

main themes and currents of the infant formula controversy. Then we shall examine more closely the role of the World Heahth Organization and UNICEF (United Nations Childrens Fund) in the process of developing this international code of marketing. and discuss a number of particularly crucial issues raised by the code, and the code process. Finally, we shall draw some conclusions and make some predictions about this process, based on information at present available, and suggest the lines along which future analysis of this and analogous cases must proceed in order to understand the capacity - and limits - of such quasi-legal processes to encourage progress on what are commonly thought to be intractable social ills.

#### "Breast Is Best, but..."

For the last ten years or more, a growing number of health workers have been trying to attract attention to what has been called the "greatest change in human behavior in recorded history," the shift from breastfeeding to artificial feeding of young

infants.1 This trend, which took place in the Western world in the 1950's and 1960's in relatively acceptable conditions of sanitation, income, and literacy, is now spreading to the Third World long before the conditions required for safe bottlefeeding are possible for the vast majority of citizens in those nations. When bottlefeeding is practiced in the absence of clean water. safe sterilization facilities, sufficient income to purchase the proper amount of an expensive product, and the education needed to comprehend and follow complex mixing instructions each time the bottle is prepared, the result can be disastrous for the baby, the family, and the emerging nation.

While it is extraordinary difficult to estimate the magnitude of the problem, one of the world's leading experts on pediatric nutrition. Dr. Derrick Jelliffe, estimates that there occur some 10 million cases per year of infectious disease and infant malnutrition directly attributable to improper bottlefeeding. Virtually every study that has compared breastfed and bottlefed populations demonstrates clearcut advantages for the breastfed child for nutritional, biochemical, psychological, emotional, immunological, economic, and contraceptive reasons. Especially in poverty environments, breastmilk's ideal combination of proteins. calories, vitamins and minerals assures optimal nutrition, along with important antibodies that defend against the very infections that are the greatest killers of infants under one year of age. Even the manufacturers of infant formula products acknowledge that breastmilk is the perfect infant food. And since it requires no sterilization. preparation, or out-of-pocket expenditures. breastmilk has also been called the "original convenience food."

Not only has the decline of breastfeeding accelerated the rate of population growth (breastfeeding increases birth inter-

vals), but it has enormous financial implications for the economies of emerging nations. Mothers can produce adequate supplies of breastmilk with relatively small increases of nutritional intake and consequent expense. Infant formula products, in contrast, are quite expensive, with adequate supplies costing more than US\$100 during the six months an infant needs such nourishment. For many families, such expenditures may exceed 50 percent of household income: for the nation, it represents a use of scarce foreign exchange for importation of a product that is inferior to breastmilk. Furthermore, bottlefed infants get more seriously ill more frequently, thereby imposing high costs of medical treatment on the family and the community. While precise economic estimates of these social costs are lacking, analysis of available data makes clear the immense financial burden that widespread bottlefeeding places on a developing nation.

What causes this massive shift away from natural feeding, especially in light of the many advantages that it confers? Like any other form of human behavior, the infant feeding decision is complex and not easily explained at the individual or societal level. Nevertheless, the reasons most commonly cited are: urbanization; increasing female employment in jobs incompatible with breastfeeding; the widespread belief that "West is Best" when it comes to feeding babies; increasing number of women in contact with Western style health personnel and facilities that often discourage breastfeeding through hospital routines: replacement of the breast's nurturing function by its erotic role in society; and the general desire to emulate the habits of the upper classes. Finally, and inextricably linked with all of the above factors is the widespread marketing and promotion of infant formulas by the international infant food industry.

<sup>\*</sup> James E. Post is Professor of Management and Public Policy at Boston University, Boston, Massachusetts, USA. Edward Baer is Associate Director, Infant Formula Program, Interfaith Center on Corporate Responsibility, New York, New York, USA.

#### The Industry at Bay

The sales of infant formula products in the Third World countries expanded greatly during the 1960's and 1970's. Declining birth rates in Western nations, coupled with available capital and the entrepreneurial drive to develop Third World marketing opportunities, significantly increased the active presence of infant formula sellers. Established food companies (e.g. Nestlé) were joined by Unigate, Morinaga, and Borden in the promotion of milk products for infants, and by pharmaceutical manufacturers such as Bristol Myers, Abbott Laboratories, and American Home Products which introduced new forms of formula and marketed them to the medical professions. The wide open marketing environments in many nations led to intensive competitive battles. At public hearings by a United States Senate committee in 1978, every industry executive who testified acknowledged that the industry had borne no responsibility to investigate who was actually buying and using their products, or what effects those products had on infant health and nutritional status.<sup>2</sup> That denial of responsibility is the ultimate source of the infant formula controversy.

Public interest began in the early 1970's with the publication of a pamphlet called the Baby Killer (1974) by a British charity organization, War on Want. When the Swiss based Third World Action Group translated it into German, they retitled it, "Nestlé Kills Babies." to call attention to the industry's largest member. Predictably. Nestlé sued for libel, and the ensuing trial placed "infant formula malnutrition" in the international spotlight. Soon the Interfaith Center on Corporate Responsibility (ICCR), a coalition of Protestant and Catholic groups that hold stock in American companies, took up the struggle by filing a series of shareholder resolutions calling for review

and revision of corporate marketing practives. Lawsuits, public education, Congressional action, and community organizing followed to increase public pressure on industry to revise its behaviour. In 1977, the Infant Formula Action Coalition (INFACT) came together and began organizing a boycott of all Nestlé products. The Nestlé Boycott spread further and faster than either its organizers or the firm could have anticipated; today, there are active campaigns in a half dozen countries, with support groups in another dozen. The International Baby Food Action Network (IFBAN) was recently formed to coordinate actions on an international scale.

#### Industry Behaviour

The industry's response to this mounting public pressure has generally been to deny all charges that they are contributing to infant malnutrition, and to point, instead, to the underlying conditions of poverty, lack of sanitation, and illiteracy as circumstances beyond their control. Moreover, the companies argue that their purpose is to sell only to those mothers who need, can afford, and are able to use formula products properly. The gap between the manufacturers' intentions and the effects of their actual practices is a large one. however, and their inability to segment the market carefully in a way that confines the use of formula products only to those who are able to use them properly is a major problem.3

The infant formula industry will sell more than (U.S.) \$2 billion of products in 1980, including more than fifty percent in developing nations. Future growth depends heavily on the industry's ability to sell in the developing world, where annual market growth is often 15-20 percent compared to 5-10 percent growth in industrialized

nations. The size of this stake, and its importance to the multinational companies involved, explains much of their unwillingness to retreat from all promotional activity.

During the ten years of this controversy, the industry has responded to its critics by de emphasizing direct consumer advertising to mothers, and by shifting its resources toward promotion to health professionals. Radio slogans, billboards, and company personnel in nurses carb ("milk nurses") are less frequently used to promote formula products. In their places are medical sales personnel, known as detailmen, who visit hospitals, clinics, and physicians, and Who leave posters, weight charts, and free samples of formula behind. Such promotion, the manufacturers assert, does not mislead mothers and does allow medical professionals to provide counsel and advice to mothers on appropriate feeding practices.

Voluntary codes of conduct have been adopted by many of the firms in the industry as a means of demonstrating their commitment to responsible behaviour. In 1975. while the Nestlé trial was pending, the International Council of Infant Food Industries (ICIFI) was formed by industry members accounting for about 80 percent of world sales. ICIFI announced adoption of a marketing code that established non-binding standards or marketing conduct for members. The weakness of the provisions. however, led Abbott Laboratories to denounce the code as too weak and to withdraw from ICIFI. Abbott later adopted its own, more stringent code.

The voluntary codes which the industry members have adopted reflect both the industry's structure and the competitive strategies of the various companies. Particularly important is the distinction between food companies, which tend to sell their products via consumer advertising, and

pharmaceutical companies, which normally promote to the medical community. The ICIFI Code, for example, permits direct contact with consumers by sellers of formula products. Such provision serves the interest of Nestlé, the industry's largest firm, which had a relatively small medical marketing staff in 1975 when the code was first adopted.

Today some five years later, Nestlé is capable of promoting to the medical community on an equal basis with the pharmaceutical firms, and no longer insists on a direct consumer advertising provision.

Taken together, the public pressure on the industry, and the ability of the industry members to adapt to new competitive and political realities over time have produced changes in marketing behaviour. While this change has yielded some positive results, such as diminished consumer advertising, it has not affected the fundamental circumstances in which infant feeding decisions are made. Thus, the question of the commercial sellers' appropriate role in the infant feeding decision remains at issue. It is to this fundamental relationship that the WHO has addressed its efforts.

#### WHO/UNICEF Code

International organizations have been concerned with the infant formula marketing issue for more than a decade. In 1970, WHO and UNICEF convened a meeting in Bogota, Columbia to focus on the problem of infant malnutrition. Industry representatives were invited to attend along with prominent pediatricians and nutritionists. During the meeting, allegations of unconscionable marketing conduct arose, and great diplomatic skills were required to achieve a measure of reconciliation by the end of the meeting.

The 1970 meeting was followed by an-

other meeting in 1972 under the auspices of the U.N.'s Protein Calorie Advisory Group (PAG) and a statement was drafted with regard to the promotion of special foods, namely infant formula and powdered milks. This statement, PAG No. 23 was revised and issued in November 1973. It was hoped it would generate a consensus among nutrition experts, the industry, and national governments about action that would resolve the problems. This line of activity continued when in 1974 the World Health Assembly, governing body of the World Health Organization, unanimously adopted a resolution which identified misleading sales promotion as a cause of declining breastfeeding and urged nations to take action to review and regulate marketing practices. In 1975, the International Pediatric Association passed a resolution calling for controls on the promotional activities of manufacturers.

The public pressure against the industry resulted in a U.S. Senate hearing in May, 1978, chaired by Senator Edward Kennedy. Having heard from many of the interests involved, Kennedy requested that the Director-General of WHO undertake to bring the parties together to find a new path toward solution of the problem. Because the request coincided with WHO's own interest in the matter, the Director-General organized a meeting in October, 1979, which was designed to produce a new level of dialogue on the issue.<sup>4</sup>

The WHO Secretariat commissioned distinguished researchers and consultants to prepare background statements on various aspects of the problem, including medical and nutritional aspects, marketing practices, and social legislation.<sup>5</sup> The October, 1979 meeting was then organized into working groups that addressed contributing factors. The working group which focused on marketing activities was most volatile, requiring great political skills to maintain

decorum and discussion. At the conclusion of the meeting, the participants called upon the Director General to take steps to produce a code of marketing conduct. This led WHO to begin the drafting process in late 1979.

#### The Code: Context and Content

The desirability of having the WHO Secretariat draft a code of marketing rested on different sets of expectations in the minds of the parties about the central question: "What is the code expected to accomplish?"

The infant formula industry wants the code to provide an orderly frame of reference that will allow them maximum flexibility to sell their products while at the same time outlawing certain objectionable forms of promotion so that "less ethical" firms do not have competitive advantages. This will deal with the problem of industry members who have refused to abide by the voluntary code provisions.

The code will also be of value to the industry in providing a means to deflect public criticism by officially pronouncing certain marketing practices as "acceptable." More importantly, in our view, the legitimization of marketing practices will serve to endorse the industry's role as a legitimate actor in the process of nourishing infants during the first year of life. In the longer term, this may be the most valuable aspect of the code for established sellers of breastmilk substitutes.

In the view of the various consumer groups, the industry's appropriate role in providing infant nutrition is the primary issue to be adressed by such a code. If the code development process is one of political negotiation and compromise, rather than adherence to a set of principles based on notions of "equity," "social justice," or "what is best for infants," then legitimiza-

tion is inevitable and the code may serve the interests of the industry more than the populations in whose interests the code development process was undertaken. These concerns have led critics to argue for a code based on principles that are truly designed to protect mothers, infants, and health workers from inappropriate commercial pressures. A code which falls short of providing optimal guidelines, it is felt, will allow the industry room for "interpretations of convenience" that will nullify the practical effects of the code's restrictions.

The WHO and UNICEF secretariats, and the international experts who have assisted them, are sensitive to the concerns of both groups. The question they are asking is: "How strict can the code's provisions be and still retain the participation and commitment of the industry?" They obviously believe that more progress can be achieved by gathering industry support, even if it means weakening the code, than by adopting a code that would be "ideal" but unacceptable to the industry.

Given this orientation, much of the eventual impact of the code hinges on questions of the code's level of specificity, legal status, universality of application, enforcement and monitoring mechanisms, and approach to the regulation of conduct. We shall devote the next sections to a brief discussion of these issues.

#### Key Issues

### 1. General Guidelines or Specific Provisions?

The industry has steadfastly maintained that the code should consist of "general guidelines" and "flexible principles" rather than specific provisions. General guidelines provide room (and the need) for interpretation, and the industry has the staff, resources, and expertise to engage in debates.

discussion, and lobbying at both the international and national levels over interpretation of what general guidelines actually mean (or should mean). For example, the industry has been holding firm to a demand that "educational advertising" be treated as permissible practice in the code. But such a phrase lacks the specificity that would distinguished between billboards, posters in hospital waiting rooms, and information on tins of formula about when and how to use the product. Each has an effect on potential users that is arguably "educational." If such general language is used in the code. national governments will then be forced to determine which practices are "educational" and to be permitted, and which are "promotional" and to be barred. The industry is able, and prepared, to use its resources in case-by-case bargaining and negotiation, with the full knowledge that its critics are unable to Provide countervailing pressures in each national setting. The governments of South Africa, Malaysia, Singapore, Peru, and Costa Rica have been persuaded by the industry to create codes that include much of the permissive language found in the industry's voluntary codes.6 It is axiomatic that the more specific the provision, the more clearcut the criteria for determining what practices are and are not permissible. For policymakers seeking to apply the WHO/UNICEF code at a national level, the resolution of this issue will virtually determine whether or not real change will occur in marketing conduct.

#### 2. Legal Basis of Code: Recommendation or Regulation?

One of the most hotly debated aspects of the code development process is the legal basis for the code. The WHO Constitution provides for three possible bases: convention, regulation or recommendation. The formality of a convention makes it extraordinarily time-consuming and impracti-

cal; thus the debate has focused on the other two options, which are embodied in Articles 21 and 23, respectively, of the WHO Constitution.

If the code is interpreted as a recommendation it appears that member nations would not be obligated to implement the terms of the code. The permissiveness of a recommendation has, understandably, considerable appeal to the exporting nations which are not anxious to see stringent standards of conduct in important markets. Thus, on this issue the industry and the exporting nations stand together.

The implications of interpreting the code as a regulation are unclear. Some experts believe that WHO's Constitution gives its regulations real binding power, on a par with the terms of an international treaty. This is true, however, only if the adopting country does not file any objections to the regulations as a whole, or to any part with which it does not intend to comply. At the time of writing, it appears that the Director-General of WHO will not take any formal position on this issue, nor will the Executive Board of the World Health Assembly which is due to review the code in January, 1981. Apparently, the matter will be referred for debate and decision to the whole Assembly at its May, 1981 meeting.

#### 3. Universality of Application

Another point of controversy is whether this code is intended to apply universally to all countries, and equally to all population groups within those countries, or whether distinctions will be made according to "level of development" or other indicators of "risk of misuse." The industry has long argued that conditions in, for example, Sweden and Papua New Guinea, are so different that a single code of marketing would be inappropriate. Consumer organizations have long argued, on the other hand, that optimal standards of infant care

- including protection from commercial pressures - should be universally applied. While the risk of misuse in Papua New Guinea is certainly higher than in Sweden, there is no reason to assume that it is more ethically defensible to try to persuade the Swedish mother to abandon breastfeeding. Moreover, in every society, there will be some segments of the population for whom the risk of misuse is higher because of income levels or social circumstances.

Certainly the principle of universality is endorsed by the United Nations, thereby making it impossible for WHO/UNICEF to endorse officially a double standard of protection. What is more likely, is that the code will be advanced as a minimum basis for a national action, with the encouragement that any country that wishes can go beyond the code in its regulations.

#### 4. Enforcement

Enforcement of international codes represents a thorny problem for governments and industry alike. In addition to national action to implement the breastmilk substitute code, effective enforcement will require that an apparatus be created to monitor company behaviour in the field and initiate proceedings to investigate, prosecute, and penalize violators. The experience of national governments with alternative enforcement mechanisms (e.g., self-reporting by manufacturers versus data collection by government agency) must be considered by policymakers, and it is to be expected that companies to be affected by the code will press for the least threatening option.

The necessity of national government action with respect to the codes underscores the concomitant need for WHO/UNICEF to provide technical assistance in the development of legislation regulations, and enforcement mechanisms. The need for such technical assistance was recognized in the initial draft of the breastmilk substi-

tutes code. A set of provisions called for the establishment of a Central Office at WHO which would collect information on marketing practices, hear complaints by parties of code abuses, and make decisions regarding the propriety of specific behaviour within the framework of the code. It was further proposed that the Central Office collect information from all nations on code compliance, and prepare regular reports for WHA members.

The Central Office provisions were deleted in subsequent drafts of the code because of the inherent administrative and political problems. But the proposal underscored the obvious need that exists for providing expert advice to governments that wish to act on the code. Given that there are relatively few experts inthe world on infant formula marketing practices and strategies, and still less on regulatory actions that have successfully affected the behaviour of transnational firms in the food and pharmaceutical industries, a need exists for organizing this expertise in a technical assistance office of WHO/UNICEF. The failure to do so will leave government officials at the mercy of industry executives, lawyers, and lobbyists, all of whom have a pecuniary interest in seeing the weakest form of enforcement adopted at the national levels.

#### 5. Regulating Conduct: Intentions and Effects

In a broad context, the WHO/UNICEF code is intended to alter types of marketing behaviour that are widely believed to affect infants adversely. A vital question, which bears heavily on the ability of governments to implement the code, is whether the intention of a manufacturer in marketing its products should mitigate liability when injury to the public occurs. In terms of tort liability, the difference between a standard based on intent or effect is substantial. Yet.

there has been continuing ambiguity on this point in the code drafting process.

A brief example from Draft §3 illustrates the problem. In Section 1.3, the drafters provide that "The printing on the container or label should not contain pictures or other graphic material designed to increase the saleability of the product." (Emphasis added:) The emphasis on intent in Section 1.3 contrasts with other code language that emphasized the effect of promotional activity. In Section 1.2, for example, it is expressly stated that "No product... should be marketed or publicly referred to... in a way that implies, or could create a belief, that bottlefeeding is equivalent or superior to breastfeeding." (Emphasis added.) Normal rules of construction and interpretation would suggest that Section 1.3 is an exception to Section 1.2. Thus, a manufacturer would be liable where its promotion had the effect of leading customers to believe that bottlefeeding is equal or superior to breastfeeding except in the case of labelling, where the manufacturer's intention would have to be proven.

It is important that the code language be presented in a manner that emphasizes that manufacturers and sellers are liable for any actions which have the effect of promoting, advertising or educating consumers toward the use of breastmilk substitutes.

#### 6. Burden of Proof

According to the language of Draft §3, the burden of monitoring industry behaviour rests with governments, consumer and professional groups, and the manufacturers themselves. This approach draws on recent research studies of corporate social performance that emphasize the likelihood of corporate compliance with new standards when multiple parties are empowered to monitor performance. National legislation should, therefore, allow private parties (e.g., consumer groups) as well as public

agencies to initiate legal action for code deviations.

National laws and regulations must also deal with the burden of proof in hearings and enforcement proceedings, a matter on which the WHO/UNICEF code is silent. Just as it is difficult for a person outside a large organization to determine the intention that led to a specific action, so too is it difficult or impossible for an outsider to prove where the breakdown in organization occurred that resulted in a code deviation. That is a burden best borne by those who know and understand the organization, and who are in a position to have the information - namely, the managers of the enterprise. It is desirable for national governments to consider the creation of a standard of absolute liability in which the manufacturers are held liable for any deviation from the code standards. This will serve to place responsibility where authority rests, and where access to information is most likely to result in compliance.

#### Conclusions

The WHO/UNICEF Code development process represents an unprecedented step by UN agencies to solve a major public health problem by controlling marketing practices of private corporations that are widely believed to be exacerbating this problem. The utility of the code now depends on two factors: the text of the final draft, and the extent to which each member state marshalls the political will and resources to transform the international code into practical, substantial steps at the national and local levels. The text of the code will be decided by the World Health Assembly in May 1981; until then, consumer groups, the infant food industry, experts, government officials and WHO/UNICEF staff members will continue to quarrel over the wording of each significant passage. But the real challenge will lie in implementing the code.

Effective implementation of the code will be the product of more complex interactions of political and economic forces than those at work during the code development process (October 1979 to May 1981). National governments will emerge as the primary forum for further action. Adaptation of the international code to national needs and local circumstances will require the leadership of officials in Ministries of Health, Economic Planning, and Social Welfare. The role of WHO and UNICEF will be crucial in providing technical assistance to governments, both for developing marketing codes and monitoring systems, and for determining what additional steps are needed to protect and promote breastfeeding and timely supplementation with local foods.

To counter the industry strategy of pressing national governments to adopt permissive codes, consumer organizations will have to provide countervailing information, and call public attention to discrepencies between industrial practice and government policy. Without such indigenous watchdog activity, few countries are likely still to have an effective regulatory mechanism in place in a decade or two.

Finally, the real usefulness of the code may lie not in its becoming a piece of consumer legislation, but in raising the underlying issues before government officials and health workers. It is to be hoped that it will foster a critical examination of the impact of food and drug promotion on the determination of health policies and practices. Only to the extent that doctors and nurses begin to say "no" to corporate promotion will this problem ever be solved, because it is clear that most government regulation can never reach the community level. It behoves the medical profession, in particular,

to undergo a fundamental reexamination of its responsibilities to its patients and to society, in view of the blandishments offered by industry to engage in practices – such as routine dispersal of infant formula samples to all mothers – that have no medical justification, and may indeed actually harm health.

The outcome of the code text itself must be seen as a product of a process of

negotiation and political bargaining. In the international arena, this is called consensus. But since it ultimately depends on power, it is really a process of compromise. The WHO/UNICEF code has shaped the dynamics of the conflict, but not eliminated the conflict itself. The appropriate role of the commercial food industry in influencing decisions about infant and young child feeding is still at issue.

### References

- International Pediatrics Association, "Recommendations for Action Programs to Encourage Breast-feeding," Bulletin of International Pediatrics Association, Vol. 4 (October 1975) pp. 18-22.
- United States Congress, Senate Committee on Human Resources, Subcommittee on Health and Scientific Research. The Marketing and Promotion of Infant Formula in the Developing Nations, 1978, 95th Congress, Second Session (May 23, 1978).
- James E. Post and Edward Baer, "Demarketing Infant Formula: Consumer Products in the Developing World," Journal of Contemporary Business 7, 4 (Fall 1978).
- WHO/UNICEF, Meeting on Infant and Young Child Feeding, October 9-12, 1979, Statement and Recommendations (Geneva: WHO, 1979).
- 5. WHO/UNICEF, Background Paper for Meeting on Infant and Young Child Feeding, Part 2, "Themes for Discussion." (Geneva: WHO, 1979).
- 6. E.W. Saunders (President of ICIFI), "Letter to the Editor," Lancet July 5, 1980, p. 42.
- 7. World Health Organization, Basic Documents, "The Constitution of WHO." Articles 21 and 23, pp. 7-8.