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NOTES AND COMMENTS

Formulating Customary International Law: An Examination of the WHO International Code of Marketing of Breastmilk Substitutes

I. INTRODUCTION

As the network of transnational corporations (TNCs)¹ continues to extend over national boundaries, nations need new international agreements to govern the conduct of TNCs.² Host countries³ often cannot adequately regulate TNCs as these nations frequently are unable to exert the same type of supervision and regulation over TNCs as over their domestic enterprises.⁴ At the same time, national regulations that do exist severely overlap because home countries can

1. For the purposes of this discussion, a TNC is:

a business enterprise composed of a parent company and one or more subsidiaries implanted in two or more countries and organized for the conduct of profitable international production and provision of goods and services. It is characterized by its large size, ability to rapidly shift capital and resources, reliance on technological innovations which, in turn, often results in an oligopolistic control of markets, tightly-knit management group which is highly integrated and centralized, and international approach to business operations.

Coonrod, *The United Nations Code of Conduct for Transnational Corporations*, 18 HARV. INT'L L. J. 273, 274-75 (1977) [hereinafter cited as Coonrod]. Although authors have used a variety of terms to describe the transnational corporation (i.e., multinational corporation, multinational enterprise) the United Nations has consistently employed the term "transnational corporation" since 1974. *Id.* at 275 n.5. For a discussion of the debate surrounding the definition of the TNC, see Aharoni, *On the Definition of the Multinational Corporation*, 11 Q. REV. ECON. & BUS. 27 (1972); Hadari, *The Structure of the Private Multinational Enterprise*, 71 MICH. L. REV. 731 (1973). For a listing of various definitions that have been employed, see U.N. Department Economic and Social Affairs, *Multinational Corporations in World Development*, Annex II, at 118, U.N. Doc. ST/ECA/190 (1973).

2. Coonrod, *supra* note 1, at 274-76.

3. The term "host country" refers to the nation in which subsidiaries or branches of the TNC are located. "Home country" refers to the state where the parent company is located. *Id.* at 276 n.15.

4. For example, a nation may be able to assert jurisdiction over foreign TNCs making decisions regarding their subsidiaries within that nation's territory. However, the limits of enforcement jurisdiction would restrict the host country's control. *Id.* at 276 & nn. 11-12 & 14. The regulation of TNCs by developing nations is even more difficult because of the "developing country's relatively weak position vis-a-vis the multinationals, the country's lack of information on the multinational's business activities outside the host country, and the country's initial lack of expertise in regulatory matters." Note, *Influencing Multinational Corporations: The Infant Formula Marketing Controversy*, 10 N.Y.U. J. INT'L L. & POL. 125, 163 (1977) [hereinafter cited as *Influencing Multinational Corporations*]. A detailed discussion of the concerns facing a host country is beyond the scope of this Comment. For a thorough treatment of this topic, see generally Coonrod, *supra* note 1, at 274-85.

control TNCs on matters which influence the host country and other nations.⁵ In light of the inability of host countries to effectively control TNCs, nations have begun to use codes of conduct⁶ to harmonize and supplement existing national laws, to offer models for new legislation, and to promote an alternative method of regulating TNCs.⁷

The major codes of conduct⁸ currently in existence or close to formal adoption are neither treaties nor multinational conventions.⁹ Instead, nations approve codes as "declarations"¹⁰ or "recommendations"¹¹ which are policy statements that are not legally binding.¹² However, while the codes are not legally binding per se, their exact status in international law is unclear.¹³ Codes of conduct can remain as non-binding recommendations, or according to one theory, codes of conduct can have great significance in international law,¹⁴ especially if nations comply with the code provisions in such a way as to create customary international law.¹⁵ The Statute of the International Court of Justice¹⁶ defines customary international law as "international custom, as evidence of general practice

5. Coonrod, *supra* note 1, at 276 & n.17, 277. See also Baade, *The Legal Effects of Codes of Conduct for Multinational Enterprises*, 22 GER. Y.B. INT'L L. 11, 12 (1979) [hereinafter cited as Baade].

6. In 1972 the U.N. established the Group of Eminent Persons to discuss the problems of transnational corporations. ECOSOC Res. 1721, 53 U.N. ESCOR Supp. (No. 1) at 4, U.N. Doc. E/5209 (1972). The Group defined a code of conduct as "a consistent set of recommendations which are gradually evolved and which may be revised as experience or circumstances require. Although they are not compulsory in character, they act as an instrument of moral persuasion, strengthened by the authority of international organizations and the support of public opinion." U.N. Department of Economic and Social Affairs, *The Impact of Multinational Corporations on Development and on International Relations* 55 E/5500/Rev. 21 ST/ESA/6, (1974) cited in R. WALDMANN, *REGULATING INTERNATIONAL BUSINESS THROUGH CODES OF CONDUCT* 20 (1980) [hereinafter cited as WALDMANN].

7. WALDMANN, *supra* note 6, at 23-24.

8. See OECD, *Guidelines for Multinational Enterprises, DECLARATION ON INTERNATIONAL INVESTMENT AND MULTINATIONAL ENTERPRISES* (1976), reprinted in 15 INT'L LEGAL MATS. 967, 969 (1976) [hereinafter cited as OECD DECLARATION]; ILO, *TRIPARTITE DECLARATION OF PRINCIPLES CONCERNING MULTINATIONAL ENTERPRISES AND SOCIAL POLICY*, reprinted in 17 INT'L LEGAL MATS. 423 (1978) [hereinafter cited as TRIPARTITE DECLARATION]; UNCTAD, *Report of the Intergovernmental Group of Experts on a Code of Conduct on Transfers of Technology*, U.N. Doc. TD/B/C.6/1 (1975), U.N. Cod. TD/B/600 (1976); Thirty-Fourth World Health Assembly, *International Code of Marketing of Breastmilk Substitutes*, Res. WHA34.22, Annex WHO Doc. A34/VR/15, (Fifteenth Plenary Meeting, May 21, 1981) [hereinafter cited as Code of Breastmilk Substitutes].

9. Baade, *supra* note 5, at 13-14.

10. See OECD DECLARATION, *supra* note 8; TRIPARTITE DECLARATION, *supra* note 8.

11. Code of Breastmilk Substitutes, *supra* note 8.

12. Baade, *supra* note 5, at 13, 19.

13. WALDMANN, *supra* note 6, at 20.

14. Coonrod, *supra* note 1, at 297.

15. Baade, *supra* note 5, at 15; Davidow & Chiles, *The United States and the Issue of the Binding or Voluntary Nature of International Codes of Conduct Regarding Restrictive Business Practices*, 72 AM. J. INT'L L. 247, 255 (1978) [hereinafter cited as Davidow & Chiles].

16. The International Court of Justice is the judicial body of the United Nations. The Court has jurisdiction to give advisory opinions on matters of law and treaty construction and it has the power to settle legal disputes between nations when voluntarily submitted to it. See Stat. I.C.J. arts. 34-36.

accepted as law."¹⁷ Thus, while the codes themselves are not "instant international law,"¹⁸ but rather pronouncements of policy, an application of policy through state action¹⁹ and an acceptance of the practice as required by law may lead to the creation of customary international law.²⁰

This Comment focuses on the legal effects of a code of conduct for TNCs through an examination of the World Health Organization (WHO) "International Code of Marketing of Breastmilk Substitutes" (Code of Breastmilk Substitutes). After reviewing the WHO authority to formulate a code of conduct, the author analyzes the provisions of the Code of Breastmilk Substitutes and discusses the current legal effects of this Code. The author then examines the process required to form customary international law and suggests how this Code may become international law.

II. THE FORMULA MARKETING CONTROVERSY

On May 21, 1981, the World Health Assembly (WHA)²¹ passed the "International Code of Marketing of Breastmilk Substitutes."²² This Code is a response by a U.N. organization to the international baby formula controversy.²³ Previous

17. Stat. I.C.J. art. 38(1)(b).

18. Baade, *supra* note 5, at 22. Codes are not "instant" international law in that codes are not international law upon passage. The author uses the word "instant" to contrast with the long, evolving process of law formation as in customary international law, which is the subject of this Comment.

19. State actions includes physical acts and possibly statements and declarations by a state from which other nations can infer the state's views on international law. Akehurst, *Custom as a Source of International Law*, 47 BRIT. J. INT'L L. 1, 10 (1974-75) [hereinafter cited as Akehurst]. For a detailed discussion of the meaning of state action, see § V.B.1 *infra*.

20. Davidow & Chiles, *supra* note 15, at 255.

21. The WHA is "the highest governing body of the [World Health] [O]rganization." *Marketing and Promotion of Infant Formula in Developing Nations, 1978: Hearing Before the Subcomm. on Health and Scientific Research of the Senate Comm. on Human Resources*, 95th Cong., 2d Sess. 104 (1978) (statement of Dr. Manuel Carballo, M.D., Maternal and Child Health Division, WHO) [hereinafter cited as *1978 Hearing*]. "Member States of the World Health Organization through its governing bodies, which are the World Health Assembly, the Executive Board and the Regional Committees, determine health policies and doctrines in international health work." *Id.* at 103-04.

The World Health Organization is one of the specialized agencies of the United Nations system. It is composed of its 151 Member States. Its objective is the attainment by all peoples of the highest possible level of health. The World Health Organization is the UN agency responsible for planning and coordinating health activities on a global basis, promoting technical cooperation with and among its Member States, and the exchange of scientific information. At the request of Member States it assists in planning and coordinating health programmes, strengthening health services and training health workers. It promotes medical and health-related research, develops health regulations, undertakes surveillance of communicable diseases, collects and disseminates data on health and health-related issues, sets standards for the quality control of drugs, vaccines, and other substances relating to health. The position of the World Health Organization on the question of infant feeding has been, and continues to be, that breast feeding is ideally suited to the overall health and well-being of the young infant, and that breast milk is the food of choice during early infancy.

Id.

22. Code of Breastmilk Substitutes, *supra* note 8.

23. Helpful to an understanding of the infant formula controversy is an examination of the role of

efforts by private groups,²⁴ industry,²⁵ and individual nations²⁶ to deal with the

international formula producers in encouraging the use of breastmilk substitutes. One source estimated that formula sales rose to more than \$2 billion in 1980, including more than 50% of the sales in developing nations. Post & Baer, *The International Code of Marketing for Breastmilk Substitutes: Consensus, Compromise and Conflict in the Infant Formula Controversy*, REV. INT'L COMM'N JURISTS, 52, 54 (1980) [hereinafter cited as Post & Baer]. Nestlé, a Swiss based corporation, dominates the Third World market with a 50% share. The three American producers — Ross, Mead Johnson and Wyeth Laboratories — account for 15% of the market in developing nations. Industry spokesmen estimate that sales are growing at the rate of 20% per year in the United States and 12% abroad. N.Y. Times, May 22, 1981, § IV, at 1, col. 3. While infant formula corporations are enthusiastic about this growth, others are concerned by the coinciding decrease in breast feeding. Note, *Innocents Abroad: Infant Food Technology at the Law's Frontier*, 20 VA. J. INT'L L. 617, 623 (1980) [hereinafter cited as *Innocents Abroad*].

General agreement on the superiority of breastmilk over formula exists. Representatives of industry do not deny that "breast feeding is best" and agree that breastfeeding should be actively protected and encouraged. *Marketing and Promotion of Infant Formula and Trade in Developing Countries: Hearings Before the Subcomm. on International Economic Policy and Trade of the House Comm. on Foreign Affairs*, 96th Cong., 2d Sess. 26 (1980) (statement of David Cox, President, Ross Laboratories) [hereinafter cited as *1980 Hearings*]; *Id.* at 22 (statement of Gary W. Mize, Vice President, Mead Johnson). Most authorities claim that breastmilk provides better nutrition than does any substitute. *Influencing Multinational Corporations*, *supra* note 4, at 128-29. However, bottlefeeding is adequate and acceptable if prepared under sanitary conditions and administered in sufficient quantity. *1980 Hearings*, *supra*, at 103 (excerpt from Background Paper for Meeting on Infant and Young Child Feeding, prepared by WHO and UNICEF).

Proper use of infant formula requires sanitary conditions, clean water and sufficient income to pay for an adequate amount of formula. In many developing nations, these requirements are difficult for inhabitants to satisfy. As Senator Edward Kennedy (D. Mass.) rhetorically asked: "Can a product that requires clean water, good sanitation, adequate family income and a literate parent to follow printed instructions be properly and safely used in areas where water is contaminated, sewage runs in the streets, poverty is severe and illiteracy is high?" *A U.S. Vote on Baby Formula that Stirred a Storm*, U.S. NEWS & WORLD REP., June 1, 1981, at 60-61. In some nations, infant formula products cost \$100 per infant during the first six month period of use. Such an expenditure may exceed 50% of the household income. Post & Baer, *supra*, at 53. In view of these factors, formula misuse is common in developing nations. "Some 10 million infants and young children annually suffer from malnutrition and diarrhea associated with inadequate breastfeeding and the use of artificial feeding." 127 CONG. REC. E2405 (daily ed. May 19, 1981) (Memorandum from the Deputy Assistant Secretary for International Health).

Many factors contribute to the shift away from breast feeding, including urbanization, female employment and a desire to emulate the West. Recently many government officials and private groups have criticized the marketing techniques of the infant formula producers, claiming that the producers idealize bottlefeeding and discourage women from breastfeeding. See *Influencing Multinational Corporations*, *supra* note 4, at 130-31. Companies use direct radio and billboard advertisements and give free promotional materials, such as calendars and totes, to new mothers. "Milk nurses," women employed by the companies and dressed as health workers, give health and nutritional advice to women in maternity hospitals. Companies have also organized the "indiscriminate" distribution of free formula and bottle samples in hospitals and clinics. *Id.* One baby book, distributed by Wyeth, claimed that their formula S-26 "nourishes babies like mother's milk." *1980 Hearings*, *supra*, at 55 (joint prepared statement of Leah Margulies, Director, Infant Formula Program, Interfaith Center on Corporate Responsibility, and Douglas Johnson, Chairperson, Infant Formula Action Coalition). Critics of these marketing practices claim that they contribute to the use of formula. These critics also fear that the marketing techniques are especially effective in the unsophisticated markets of developing nations. Manufacturers deny these charges and claim that they abide by a voluntary code of self-restraint. "But a report by health professionals, Peace Corps workers and others in the field last year found at least 700 individual instances of abuse." 127 CONG. REC. S5313 (daily ed. May 20, 1981) (remarks of Sen. Mitchell).

24. Within the United States, shareholders have used proxy solicitations successfully to present their views on specific corporate policies regarding the marketing of infant formulas. See *Influencing Multinational Corporations*, *supra* note 4, at 142-52.

baby formula problem left many of these groups believing that only a coordinated international plan could achieve an effective solution.²⁷ Therefore, the WHO and the United Nations International Children's Emergency Fund (UN-

The first major international discussions regarding the marketing practices of the infant formula industry involved "a series of pediatrician/infant food industry seminars sponsored by the United Nations Protein Advisory Group (PAG), UNICEF, the International Pediatric Association, and the World Health Organization in Bogata (1970), Paris (1972), New York (1973), and Singapore (1974)." *Id.* at 137. UNICEF is "an agency, created by the United Nations General Assembly in 1946, concerned with improving the health and nutrition of children and mothers throughout the world." *RANDOM HOUSE DICTIONARY OF ENGLISH LANGUAGE* 1552 (1st ed. 1967). No more meetings took place after 1974 due to the lack of both an enforcement mechanism and agreement on the type or effectiveness of industry self-regulation. Nevertheless, in 1974 the WHA adopted a resolution which identified misleading sales promotion as a cause of declining breastfeeding and urged nations to take action to review and regulate market practices. In 1975, the International Pediatric Association passed a resolution calling for controls on the promotional activities of manufacturers. Post & Baer, *supra* note 23, at 56. Public pressure against the industry resulted in the joint WHO-UNICEF meeting in 1979. *See* note 29 and accompanying text *infra*.

25. Following the Singapore Conference of 1974, industry representatives met to organize the International Council of Infant Food Industries (ICIFI), a self-regulatory council. Industry members accounting for approximately 80% of world sales joined this group. Post & Baer, *supra* note 23, at 55. The ICIFI formulated a voluntary Code of Ethics and Professional Standards for Advertising, Product Information and Advisory Services for Breast-Milk Substitutes. While critics of the infant formula industry first saw this Code as a positive step, the weaknesses of the provisions soon became obvious. For a detailed analysis of this Code, *see Innocents Abroad*, *supra* note 23, at 630. Many companies formulated individual codes, such as the Nestlé Infant Food Policy. The codes of Abbott and Bristol-Meyers contained more explicit, stringent directives than did the ICIFI Code. *Influencing Multinational Corporations*, *supra* note 4, at 139.

26. Several governments have taken steps to regulate the marketing of infant formula products within their borders. In Papua New Guinea, formula as well as bottles, nipples (teats) and pacifiers can only be obtained by prescription. The law forbids formula advertisements but encourages breastmilk advertisements. 127 CONG. REC. E2335 (daily ed. May 13, 1981) (statement by Rep. Schroeder introducing into the Record an article by Patricia Jelliffe, entitled *When the Answer is not a Bottle*). In Nigeria and Jamaica strict controls on the promotion of canned baby milk exist as law. *Influencing Multinational Corporations*, *supra* note 4, at 163. In Zambia only the nationalized powdered milk is available and the labels encourage a mother to "BREAST FEED YOUR CHILD." *Id.* (emphasis in original). The Philippines controls infant formula marketing by the provisions of an act similar to the U.S. Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-392 (1976 & Supp. II 1978); *Innocents Abroad*, *supra* note 23, at 638-39.

Rep. Michael Harrington (D. Mass.) who introduced an "Infant Feeding Resolution" led a U.S. Congressional movement to limit the promotion of infant formula in developing nations. H.R.J. Res. 1095, 94th Cong., 2d Sess., 122 CONG. REC. 30,175 (1976) (remarks of Rep. Harrington). This resolution called on the President to sponsor a study of worldwide formula use, its health effects, the effects of advertising, the extent of U.S. government promotion of breastmilk substitutes in developing nations, and the possible use of bribes to insure formula sales. *Id.* Following this, in 1977 Congressman Harrington introduced an amendment to the International Development and Food Assistance Act of 1977 which codified the policies presented in the 1976 joint resolution. 22 U.S.C. § 2151(o) (Supp. I 1979). The Congressional conference committee to which the bill was referred agreed that businesses in the infant formula industry have the responsibility not to jeopardize the health of children. However, the committee's redraft — which Congress enacted — merely encourages the President to respond to these issues. As a result of the modified provisions of the Act, it gained little notice. *Innocents Abroad*, *supra* note 23, at 641. For a detailed discussion of congressional activity, *see id.* at 639-46.

27. *Innocents Abroad*, *supra* note 23, at 627-28.

ICEF)²⁸ sponsored a joint meeting in Geneva in October 1979,²⁹ to discuss the role of breastfeeding and the appropriate marketing of breastmilk substitutes. The Thirty-Third World Health Assembly³⁰ endorsed the recommendations resulting from this meeting and instructed the Director-General of the WHO to draft an international code.³¹ As a result of meetings with representatives of governments, industry, the scientific community, and international organizations,³² the Director-General produced several code drafts. The Thirty-Fourth WHA adopted the final Code with 118 nations voting in favor of the Code.³³ Only the United States voted against the resolution.³⁴

28. For a description of UNICEF, see note 24 *supra*.

29. WORLD HEALTH ORGANIZATION, JOINT WHO/UNICEF MEETING ON INFANT AND YOUNG CHILD FEEDING: STATEMENT, RECOMMENDATIONS, LIST OF PARTICIPANTS (1979), cited in *Innocents Abroad*, *supra* note 23, at 637.

Since WHO had a definite interest in the regulation of marketing of breastmilk substitutes, the Director-General organized the October 1979 meeting. The invited participants at this meeting were:

government representatives from eighteen countries including India, Japan, Malaysia, New Zealand, Papua New Guinea, the Philippines, the U.S. and Britain. Also among the participants were experts from U.N. and other agencies such as the Food & Agriculture Organisation (FAO), the World Bank's Rural Development Department, the International Labour Organisation (ILO), the U.N. Conference on Trade & Development (UNCTAD), the U.N. FUND for Population Activities (UNFPA), the World Food Programme and the U.N. Industrial Development Organisation (UNIDO). Among the participants from the infant-formula industry itself were executives from Bristol-Myers, Mead Johnson, Abbott, Wyeth and Gerber (U.S.), Friésland and Nutricia (Holland), Dumex (Denmark), Meiji Milk Products and Snow Brand (Japan) and Nestlé (Switzerland).

127 CONG. REC. S6487 (daily ed. June 18, 1981) (statement by Sen. Leahy introducing into the Record an article from ASIA WEEK, entitled *Sabotage: Breast vs. Bottle: A New Battlefront*).

30. The Thirty-Third World Health Assembly was held in Geneva during May 1980. See *Innocents Abroad*, *supra* note 23, at 632 n.89.

31. In 1980, the Thirty-Third World Health Assembly, in resolution 33.32, requested the Director-General inter alia to

"prepare an international code of marketing of breastmilk substitutes" and to "submit the code to the Executive Board for consideration at its sixty-seventh session and for forwarding with its recommendations to the Thirty-fourth World Health Assembly, together with proposals regarding its promotion and implementation, either as a regulation in the sense of Articles 21 and 22 of the Constitution of the World Health Organization or as a recommendation in the sense of Article 23, outlining the legal and other implications of each choice."

Thirty-Fourth World Health Assembly, Draft International Code of Marketing of Breastmilk Substitutes, Report by the Director-General, WHO Doc. A34/8 (67th Session of Executive Board, December 10, 1980).

32. *Id.* See 1980 Hearings, *supra* note 23, at 53.

33. World Health Assembly, Provisional Verbatim Record of the Fifteenth Plenary Meeting 9, WHO Doc. A34/VR/15 (prov. ed. 1981) [hereinafter cited as Fifteenth Plenary Meeting].

34. In light of the idea of a WHO code for regulating the infant formula, industry practices originating in the United States are ironic. Senator Kennedy requested that the Director-General of the WHO take action following the U.S. Senate hearings on the subject. J. of Commerce, May 7, 1981, at 4, col. 1. See generally 1978 Hearing, *supra* note 21.

The U.S. government affirmed that it strongly supported efforts to promote and protect breastfeeding and remained "committed to improving infant and child health around the world." Thirty-Fourth World Health Assembly, Committee A, Provisional Summary Record of the Fourteenth Meeting 9, WHO Doc. A34/A/SR/14 (prov. ed. 1981) [hereinafter cited as Fourteenth Meeting]. In spite of this commitment, the United States maintained that it could not support the Code. In voting against the Code, Gerald Helman, U.S. Ambassador to the WHO, claimed that the Code would cause serious legal and constitutional problems for the United States. The central basis for opposition to the Code results

III. THE INTERNATIONAL CODE OF MARKETING OF BREASTMILK SUBSTITUTES

A. Authority to Formulate a Code

The aim of the Code of Breastmilk Substitutes is to contribute to the safe and adequate nutrition of infants "by the protection and promotion of breastfeeding, and by ensuring the proper use of breastmilk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution."³⁵ In order to accomplish this purpose, the Code provides a specific set of directives for the infant formula industry regarding the marketing of breastmilk substitutes.³⁶ In addition, the Code provides guidelines for individual governments encouraging the promotion of breastfeeding.³⁷ The authority to formulate such a code comes from the WHO Constitution.³⁸ As stated in Article 1 of its Constitution, the objective of the WHO "shall be the attainment by all peoples of the highest possible level of health."³⁹

The WHO and the WHA have broad powers with which to attain their health objectives. Some of the functions of the WHO include:

(k) to propose conventions, agreements and regulations, and make recommendations with respect to international health matters and to perform such duties as may be assigned thereby to the Organization and are consistent with its objectives;⁴⁰

(l) to promote maternal and child health and to foster the ability to live harmoniously in a changing total environment;⁴¹ [and]

. . . .

(v) generally to take all necessary action to attain the objective of the Organization.⁴²

The WHA also has the power under Article 18 "to take any other appropriate action to further the objective of the Organization."⁴³ In addition, the constitution specifically authorizes the WHA to adopt conventions and regulations⁴⁴ and

from WHO's involvement in a commercial code, especially one with the "overall effect of prescribing a rigid set of rules applicable to companies, health workers, and health care systems in all parts of the world." *Id.*

35. Code of Breastmilk Substitutes, *supra* note 8, art. 1.

36. *See id.* arts. 4-11.

37. *Id.*

38. "The [WHO] Constitution was adopted by the International Health Conference held in New York from 19 June to 22 July, 1946, and signed on 22 July 1946 by the representatives of 61 States." CONSTITUTION OF THE WORLD HEALTH ORGANIZATION, in BASIC DOCUMENTS 1 n.1 (1978) [hereinafter cited as CONSTITUTION].

39. *Id.* art. 1.

40. *Id.* art. 2(k), at 2-3.

41. *Id.* art. 2(l).

42. *Id.* art. 2(v).

43. *Id.* art. 18(m).

44. *Id.* art. 21.

to make recommendations.⁴⁵ The WHA adopted the Code of Breastmilk Substitutes pursuant to Article 23 which authorizes the WHA to make recommendations "to Members with respect to any matter within the competence of the Organization."⁴⁶

B. Code Provisions

Before considering the legal effects of the Code of Breastmilk Substitutes, an understanding of the scope of the Code provisions is necessary. The Code of Breastmilk Substitutes applies to the marketing of breastmilk substitutes, feeding bottles and nipples, and to the availability of information concerning the use of these products.⁴⁷

The Code suggests that producers of breastmilk substitutes should not engage in direct advertising or other promotions to the general public regarding breastmilk substitutes.⁴⁸ Specifically, the Code provides that manufacturers and distributors should neither give free samples to the general public⁴⁹ nor provide for "special displays, discount coupons, premiums, special sales, loss-leaders,⁵⁰ and tie-in-sales⁵¹ for products within the scope of the Code."⁵² Under the Code, marketing personnel may receive sales bonuses, but corporations may not include the volume of sales of breastmilk substitutes when calculating bonuses.⁵³ Company marketing personnel should restrict their personal contact with pregnant women or mothers of young children to prevent "educational" programs aimed at pregnant women.⁵⁴ According to the Code provisions, formula companies should limit the information they provide to health professionals to "scientific and factual matters."⁵⁵ Manufacturers and distributors should not give

45. *Id.* art. 23.

46. *Id.*

47. Specifically, the Code applies to the following products:

breastmilk substitutes, including infant formula; other milk products, foods and beverages, including bottle-fed complementary foods when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breastmilk; feeding bottles and teats. It also applies to their quality and availability and to information concerning their use.

Code of Breastmilk Substitutes, *supra* note 8, art. 2.

48. *Id.* art. 5.1.

49. *Id.* art. 5.2.

50. The Code does not define the terms generally used in commercial circles. A loss leader is an "[i]tem sold by a merchant at a very low price and sometimes below cost in order to attract people to [a] store with the hope that they will buy additional items on which a profit will be made." BLACK'S LAW DICTIONARY 852 (5th ed. 1979).

51. A tie-in-sale is "allowed by a seller only on condition of attendant purchase of another product or fulfillment of an attendant agreement." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE 2391 (3rd ed. 1976).

52. Code of Breastmilk Substitutes, *supra* note 8, art. 5.3.

53. *Id.* art. 8.1.

54. *Id.* art. 8.2.

55. *Id.* art. 7.2.

inducements to health workers⁵⁶ to promote the products.⁵⁷ While formula companies may give health workers free samples to be used for research purposes, they may not give samples to pregnant women or families of young children.⁵⁸

A central theme of the Code is that information on infant feeding should stress the superiority of breastfeeding over bottle feeding.⁵⁹ Labels on breastmilk substitutes should "provide the necessary information about the appropriate use of the product . . . so as not to discourage breastfeeding."⁶⁰ The information on the label should not idealize the use of formula and advertisers may not use pictures of infants on the label.⁶¹ The product itself should meet the quality standards of the Codex Alimentarius Commission⁶² and manufacturers should list all ingredients on the label.⁶³

In addition to providing directives for private industry,⁶⁴ the Code calls for government action to achieve the objectives of the Code: "Governments should take action to give effect to the principles and aim of this Code, as appropriate to their social and legislative framework, including the adoption of national legislation, regulations or other suitable measures."⁶⁵ For example, the Code urges

56. The Code defines a "health worker" as "a person working in a component of such a health care system, whether professional or non-professional, including voluntary, unpaid workers." *Id.* art. 3.

57. *Id.* art. 7.3.

58. *Id.* art. 7.4.

59. *Id.* art. 1.

60. *Id.* art. 9.1.

61. *Id.* art. 9.2.

62. *Id.* art. 10.2.

The purpose of the work of the Codex Alimentarius Commission [a sub-group of the WHO] . . . is to protect consumers against health hazards in food and against fraud, to ensure fair practices in the food trade, and to facilitate international trade in foods. The eleventh session of the Codex Alimentarius Commission, held in April 1976, adopted 21 international food standards, including standards for infant formulas, canned baby foods, cereal-based foods for infants and children

BIENNIAL REPORT OF THE DIRECTOR-GENERAL TO THE WORLD HEALTH ASSEMBLY AND TO THE UNITED NATIONS, THE WORK OF THE WHO 1976-1977 § 11.57 (1978).

63. Code of Breastmilk Substitutes, *supra* note 8, art. 9.4.

64. Since international law is formed only by state actors, it can only apply directly to state actors. Baade, *supra* note 5, at 16. However, "[t]he present century has seen a growing tendency to admit that individuals — and companies — have some degree of international personality, but the whole subject is extremely controversial." M. AKEHURST, A MODERN INTRODUCTION TO INTERNATIONAL LAW 94 (1970). Although TNCs are non-state actors, the Code can set forth guidelines directly for industry because the Code recommends rather than requires actions by TNCs. The Code does not become international law upon passage and no mechanics of enforcement which apply to either states or TNCs exist. Thirty-Fourth World Health Assembly, Draft International Code of Marketing of Breastmilk Substitutes, Report by the Director-General 4, Annex, WHO Doc. A34/8, EB67/20 (67th Session of the Executive Board, December 10, 1980) [hereinafter cited as Draft International Code] (This document includes an explanatory section written by the Director-General followed by two draft codes.). However, nations can adopt these guidelines in national legislation and thus, the Code can indirectly govern the behavior of TNCs.

65. Code of Breastmilk Substitutes, *supra* note 8, art. 11.1.

governments to take more responsibility for providing information about infant and young child feeding;⁶⁶ in particular, member states should encourage breastfeeding and emphasize its superiority.⁶⁷ According to the Code, manufacturers and distributors should use neither health care systems⁶⁸ nor displays for breastmilk substitutes to promote formulas.⁶⁹

Finally, governments have the responsibility of monitoring the application of the Code.⁷⁰ The Code also calls upon non-governmental organizations, manufacturers, professional groups and consumer organizations to work with governments in this implementation and monitoring.⁷¹ Member states are responsible for reporting to the Director-General of the WHO on the "action taken to give effect to the principles and aim of the Code."⁷² The Director-General will make his first report to the WHA on the implementation of this Code in 1983.⁷³ The Code is not legally binding but it has political and moral force;⁷⁴ this particular provision probably permits member states to bring political and moral pressure against each other in order to give effect to the Code.

C. *Strengths and Weaknesses of the Code*

The Code of Breastmilk Substitutes represents an unprecedented step by any U.N. agency to deal with a public health problem through the control of the marketing practices of private industry.⁷⁵ In the past, the WHO has never become involved directly with the activity of TNCs.⁷⁶ However, in the present case, the WHO is attempting to correct a public health problem by controlling the behavior of TNCs. Unlike other codes designed to influence the behavior of TNCs generally,⁷⁷ this Code only applies to a single industry⁷⁸ and a single theme unifies the Code: the superiority of breastmilk over any substitutes. Because of its single industry application and unified theme, the Code can outline specific guidelines.⁷⁹ Thus, the Code provides private industry with a

66. *Id.* art. 4.1.

67. *Id.* art. 4.2.

68. *Id.* art. 6.2.

69. *Id.* art. 6.3.

70. *Id.* art. 11.2.

71. *Id.* art. 11.4.

72. *Id.* art. 11.6.

73. *Id.* art. 11.7.

74. See text accompanying note 107 *infra* regarding the political and moral force of a code.

75. Post & Baer, *supra* note 23, at 60.

76. See *id.*

77. See OECD DECLARATION, *supra* note 8; TRIPARTITE DECLARATION, *supra* note 8.

78. See Code of Breastmilk Substitutes, *supra* note 8, art. 2.

79. Compare the general language of OECD DECLARATION, *supra* note 8, with the detailed recommendations of the Code of Breastmilk Substitutes, *supra* note 8, arts. 4-11.

clear directive for corporate action and offers governments a detailed model for national legislation and action.⁸⁰

While some proponents of the Code regard the Code's establishment of clear guidelines in support of breastfeeding as its chief strength,⁸¹ formula industry officials criticize the Code's specificity. For example, industry officials argue that nations should give health professionals more discretion over promotion of breastmilk substitutes by refusing to limit promotion by these individuals to "scientific and factual matters."⁸² As previously noted, the Code does not permit health professionals to "give samples of infant formula to pregnant women, mothers of infants and young children, or members of their families."⁸³ Since physicians are included within the definition of "health professional," even they should not provide free samples of infant formula to their patients.⁸⁴

American critics contend that the Code is so restrictive that it undermines free speech, free press and competition.⁸⁵ One American politician also criticized the Code's specificity, saying that the Code "regulates with complete, drastic, and totalitarian precision every aspect of marketing, distributing, and using infant products . . . and defines with equal precision every permissible activity of every person involved in any way in such transactions."⁸⁶ Critics not only regard the Code as a "totalitarian document" in itself, but also fear that it is "a dangerous

80. See Code of Breastmilk Substitutes, *supra* note 8, arts. 4-11.

81. 127 CONG. REC. S5312 (daily ed. May 20, 1981) (statement by Sen. Leahy introducing into the Record an article by Richard Harley, entitled *Bottle-Feeding, Good or Bad? UN Agency Takes Critical Vote*); 127 CONG. REC. H2950-51 (daily ed. June 16, 1981) (remarks of Rep. Bedell).

82. 1980 Hearings, *supra* note 23, at 37 (statement of David Cox, President, Ross Laboratories); Code of Breastmilk Substitutes, *supra* note 8, art. 7.2.

83. Code of Breastmilk Substitutes, *supra* note 8, art. 7.4.

84. See *id.* arts. 3, 7.4.

85. 127 CONG. REC. E2367 (daily ed. May 14, 1981) (statement by Rep. Michel introducing into the Record an article by Sam J. Ervin, Jr., entitled *A Totalitarian Grab for Baby's Bottle*); 127 CONG. REC. H2946 (daily ed. June 16, 1981) (remarks of Rep. Lagomarsino); 127 CONG. REC. H2950 (daily ed. June 16, 1981) (statement by Rep. McClory introducing into the Record an editorial from the Chicago-Tribune, entitled *The Politics of Breast-Feeding*).

86. 127 CONG. REC. E2367 (daily ed. May 14, 1981) (statement by Rep. Michel introducing into the Record an article by Sam J. Ervin, Jr., entitled *A Totalitarian Grab for Baby's Bottle*). See *Implementation of the World Health Organization (WHO) Code of Infant Formula Marketing Practices: Hearings before the Subcomm. on International Economics Policy and Trade and on Human Rights and International Organizations of the House Comm. on Foreign Affairs, 97th Cong., 1st Sess. 18 (1981)* (statement of John R. Bolton, General Counsel, Agency for International Development) [hereinafter cited as *1981 Hearings*]. Regarding the Code, Mr. Bolton stated:

I don't know of any other international agreement into which the United States has entered that contains proscriptions as sweeping as this one in the area of the first amendment. . . . The focus of my concern is article 5 of the code as drafted that contains a complete prohibition on advertising.

Id. at 18. For a detailed critique of the specific Code provisions, see *1981 Hearings, supra*, at 129-42 (statement of George Graham, Division of Human Nutrition, Department of International Health, School of Hygiene and Public Health, John Hopkins University).

precedent of worldwide control over the advertising, labeling, and marketing of infant products."⁸⁷ U.S. Secretary of Health and Human Services Richard Schweiker explained that "[t]he administration [of President Ronald Reagan] honestly does not believe the WHO should be an international Federal Trade Commission."⁸⁸ Reagan officials contend that the WHO should not involve itself in commercial regulation and the WHO should refrain from telling private industry how to conduct business, especially since the WHO is a health organization.⁸⁹

IV. THE LEGAL EFFECT OF THE CODE OF BREASTMILK SUBSTITUTES

A. *Legal Background of the Code of Breastmilk Substitutes*

During the process of developing an international code of marketing of breastmilk substitutes, the Director-General of the WHO formulated several draft codes.⁹⁰ Under the provisions of the WHO Constitution, a draft code can be approved as a convention,⁹¹ a regulation⁹² or a recommendation.⁹³ Since the formality of a convention is time-consuming and inflexible,⁹⁴ the Director-General focused on the latter two options.⁹⁵ A major source of controversy among member states in the code development process was the debate over the legal status of the Code.⁹⁶ One important focus of this controversy was the legal distinction between a regulation and a recommendation and the legal implications of each.⁹⁷

87. 127 CONG. REC. E2367 (daily ed. May 14, 1981) (statement by Rep. Michel introducing into the Record an article by Sam J. Ervin, Jr., entitled *A Totalitarian Grab for Baby's Bottle*). See also notes 34 & 85 and accompanying text *supra*.

88. *A U.S. Vote on Baby Formula that Stirred a Storm*, U.S. NEWS & WORLD REP., June 1, 1981, at 60.

89. *Id.* While the Reagan administration has spoken out against the Code, members of Congress have rallied to the Code's support. The House passed a joint resolution supporting the "implementation of the World Health Organization voluntary code on infant formula" by a vote of 301 to 100. H.R.J. RES. 287, 97th Cong., 1st Sess., 127 CONG. REC. H2944 (daily ed. June 16, 1981) (statement of Rep. Zablocki).

90. See Draft International Code, *supra* note 64, at 1. This document contains one draft code in the form of a recommendation and one draft in the form of a regulation.

91. CONSTITUTION, *supra* note 38, art. 19.

92. *Id.* art. 21.

93. *Id.* art. 23.

94. Baade, *supra* note 5, at 13.

95. Post & Baer, *supra* note 23, at 57-58. In fact the Thirty-Third World Health Assembly requested the Director-General to draft codes in the form of a recommendation or a regulation. See note 31 and accompanying text *supra*.

96. Post & Baer, *supra* note 23, at 57. For a discussion of the U.S. position, see Fourteenth Meeting, *supra* note 34, at 9 (statement of Gerald Helman, U.S. Ambassador to the WHO); U.S. NEWS & WORLD REP., June 1, 1981, at 60-61; 127 CONG. REC. H2952 (daily ed. June 16, 1981) (copy of State Department telegram).

97. See Draft International Code, *supra* note 64, at 3-4.

B. *Legal Implications of a Regulation*

One of the draft codes prepared by the Director-General was in the form of a regulation.⁹⁸ Article 21 of the Constitution of the WHO confers authority to adopt regulations.⁹⁹ Article 22 outlines the procedure by which member nations adopt regulations.¹⁰⁰ According to the WHO interpretation, any code in the form of a regulation adopted pursuant to Article 22 would have a "binding effect without the need for ratification, acceptance or approval by each member."¹⁰¹ Regulations come into force for all members after the Health Assembly gives due notice of their adoption.¹⁰² However, the WHA cannot require compliance from members who notify the Director-General of rejection or reservations within the period stated in the notice.¹⁰³ To implement the regulation, each member state bound by the regulation would be free to determine the legal process by which the state would give effect to the regulation.¹⁰⁴ By simply requiring that states give "effect" to the regulation and by granting nations discretion as to the method of implementation, the WHA does not seem to require a word for word adoption of the regulation within the member states.

98. *Id.* at 5.

99. Article 21 of the WHO Constitution provides:

The Health Assembly shall have authority to adopt regulations concerning:

- (a) sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease;
- (b) nomenclatures with respect to disease, causes of death and public health practices;
- (c) standards with respect to diagnostic procedures for international use;
- (d) standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce;
- (e) advertising and labelling of biological, pharmaceutical and similar products moving in international commerce.

CONSTITUTION, *supra* note 38, art. 21.

100. Article 22 of the WHO Constitution provides: "Regulations adopted pursuant to Article 21 shall come into force for all Members after due notice has been given of their adoption by the Health Assembly except for such Members as may notify the Director-General of rejection or reservation within the period stated in the notice." CONSTITUTION, *supra* note 38, art. 22.

101. Draft International Code, *supra* note 64, at 3.

102. *See* CONSTITUTION, *supra* note 38, art. 22.

103. *Id.* "The WHO Survey of the First Ten Years . . . defined the Regulations as constituting 'a new departure in International Law by laying obligations on States without signature and ratification of a formal treaty.'" C. ALEXANDROWICZ, *THE LAW-MAKING FUNCTIONS OF THE SPECIALISED AGENCIES OF THE U.N.* 55 (1973) [hereinafter cited as ALEXANDROWICZ]. Article 22 outlines a "quasi-legislative" procedure in that a regulation comes into force for all members immediately upon passage and notice. Once the regulation has come into force, states can then contract out of their legal obligation if they so choose. *Id.* at 50-51.

104. States would be free to enact statutes, regulations or any other appropriate measures to give effect to the Code. Draft International Code, *supra* note 64, at 3. The use of the word "bound" by the Director-General in his analysis of the legal implications of a regulation implies a higher degree of moral obligation. *See* note 108 and accompanying text *infra*.

C. *Legal Effects of a Recommendation*

The WHA has the authority "to make recommendations to Members with respect to any matter within the competence of the Organization."¹⁰⁵ According to the Director-General of the WHO, "[r]ecommendations of the Health Assembly are not legally binding on Member States *per se*."¹⁰⁶ The WHO maintains, however, that "recommendations of the Health Assembly carry some moral or political weight, as they constitute the judgement of the collective membership of the Organization."¹⁰⁷ The main difference between a regulation and a recommendation is the extent to which each binds member states.¹⁰⁸ Rather than suggest that the member states adopt the Code of Breastmilk Substitutes in the form of a regulation, the Executive Board of the WHO proposed a draft which identified the proposal as a recommendation under Article 23 of the WHO Constitution.¹⁰⁹ The WHA adopted the Code of Breastmilk Substitutes as a recommendation¹¹⁰ and, therefore, the Code is not a legally binding agreement.¹¹¹

D. *Reasons for Choosing the Recommendation Form*

The adoption of the Code of Breastmilk Substitutes as a recommendation is consistent with the recent trend¹¹² away from the use of treaties and regulations and toward more flexible instruments designed to achieve basically the same goals.¹¹³ Recommendations avoid the "time consuming formal approval procedure"¹¹⁴ of binding instruments. A country's law may require the approval of a national parliament before its representatives can sign a treaty or vote to adopt a

105. CONSTITUTION, *supra* note 38, art. 23.

106. Draft International Code, *supra* note 64, at 4.

107. *Id.*

108. *Compare id.* at 3 with *id.* at 4. The preamble to the draft in regulation form states: "THEREFORE: The Member States have agreed as follows. . . ." *Id.* at 7 (emphasis in original). In contrast, the preamble to the draft in recommendation form states: "THEREFORE: The Member States hereby agree the following articles which are recommended as a basis for action." *Id.* at 16 (emphasis in original).

109. Thirty-Fourth World Health Assembly, Draft International Code of Marketing of Breastmilk Substitutes, Report by the Director-General, WHO Doc. A34/8 (67th Session of the Executive Board, December 10, 1980).

110. Fifteenth Plenary Meeting, *supra* note 29, at 9; Code of Breastmilk Substitutes, *supra* note 8.

111. *See* Draft International Code, *supra* note 64, at 4; Code of Breastmilk Substitutes, *supra* note 8, preamble.

112. 1 D. LEIVE, INTERNATIONAL REGULATORY REGIMES 11 (1976) [hereinafter cited as LEIVE]; ALEXANDROWICZ, *supra* note 103, at 55.

113. LEIVE, *supra* note 112, at 11; ALEXANDROWICZ, *supra* note 103, at 55.

114. LEIVE, *supra* note 112, at 11.

binding instrument such as a regulation.¹¹⁵ Also, states appear to be more willing to accept nonbinding instruments.¹¹⁶

In addition to the problems and obstacles of a formal process, political factors worked to influence the adoption of a non-binding recommendation. In the formula marketing case, Dr. Torbjorn Mork of Norway, a member of the WHA Executive Board, noted that the Executive Board had decided to propose that governments adopt the Code in the form of a recommendation rather than in the more binding form of a WHO regulation in order to permit the Code's adoption without delay by consensus.¹¹⁷ Throughout the preliminary discussions on the draft codes, the United States had clearly maintained that it would not support a binding code.¹¹⁸ Some sources claim that the WHA made the Code voluntary because of a U.S. request and because the United States had promised at one point in the negotiations that the American delegation to the WHA would not oppose the adoption of a voluntary code.¹¹⁹ Despite the objection of the United States to even voluntary guidelines, the WHA adopted the Code as a non-binding advisory instrument.¹²⁰

V. HOW THE CODE OF BREASTMILK SUBSTITUTES MAY BECOME INTERNATIONAL LAW

A. Introduction

While compliance with the Code of Breastmilk Substitutes is completely voluntary at present, the Code provisions may later become legally binding.¹²¹ The general agreement reached within the WHA provides evidence of the political or

115. Meijers, *How is International Law Made? The Stages of Growth of International Law and the Use of its Customary Rules*, 9 NETH. Y.B. INT'L L. 3, 4 (1978) [hereinafter cited as Meijers].

116. *Id.* at 4-5. Nations see codes as less express political actions than treaties, "allowing unostentatious acceptance." *Id.* at 4. LEIVE, *supra* note 112, at 11.

117. N.Y. Times, May 21, 1981, at A10, col. 1.

118. 127 CONG. REC. H2947 (daily ed. June 16, 1981) (remarks of Rep. Pritchard). See note 34 and accompanying text *supra*.

119. 127 CONG. REC. H2947 (daily ed. June 16, 1981) (remarks of Rep. Pritchard). The United States does not oppose all codes but it objects to the provisions of the Code of Breastmilk Substitutes. See Fourteenth Meeting, *supra* note 34, at 9 (statement of Gerald Helman, U.S. ambassador to the WHO). At the time of the behind-the-scenes negotiations concerning the Code, the U.S. delegation may not have known the exact provisions of the Code.

120. Several members of Congress assert that U.S. opposition to the Code will seriously damage U.S. attempts to develop positive relationships with Third World nations. 127 CONG. REC. H2955 (daily ed. June 16, 1981) (remarks of Rep. Schneider). These Congressman feel that developing nations will see the United States as selfish and insensitive to their needs. 127 CONG. REC. E2528 (daily ed. May 21, 1981) (remarks of Rep. Brodhead).

121. See Davidow & Chiles, *supra* note 15, at 255.

moral commitments of member states¹²² which may have an effect on both states and TNCs. Although the Code is not legally enforceable at this time, parties to the instrument may still expect, and rely on, compliance by other parties to the Code.¹²³ The Code itself suggests that individual countries should enact national legislation embodying the Code principles.¹²⁴ National legislation based upon the Code provisions would make these recommendations legally binding on domestic producers as well as foreign producers selling formula within the nation. In addition, if nations engage in state practice in support of the Code provisions accompanied by the requisite *opinio juris*, the Code provisions may evolve into customary international law.¹²⁵

B. Customary International Law

Article 38(1) of the Statute of the International Court of Justice identifies several sources of international law, including international custom.¹²⁶ This Statute provides the "most authoritative statement"¹²⁷ on the sources of international law and expresses "the duty of any tribunal which is called upon to administer international law."¹²⁸ Specifically, Article 38 provides:

The Court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply:

- a. international conventions, whether general or particular, establishing rules expressly recognized by the contesting states;
- b. international custom, as evidence of a general practice accepted as law;
- c. the general principles of law recognized by civilised nations;
- d. . . . the judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.¹²⁹

This Statute sets forth a hierarchy of sources of international law¹³⁰ with treaties

122. Draft International Code, *supra* note 64, at 4. See Davidow & Chiles, *supra* note 15, at 255; Schachter, *The Twilight Existence of Nonbinding International Agreements*, 71 AM. J. INT'L L. 296, 303 (1977) [hereinafter cited as Schachter].

123. Baade, *supra* note 5, at 38; Schachter, *supra* note 122, at 301. For example, a party to a non-binding agreement may be estopped from denying the legality of a course of conduct suggested by the agreement. *Id.*

124. Code of Breastmilk Substitutes, *supra* note 8, art. 11; see notes 104 & 108 and accompanying text *supra*.

125. See *North Sea Continental Shelf (Federal Republic of Germany/Denmark; Federal Republic of Germany/Netherlands)* 1969 I.C.J. 3, 41-45 (Judgment of February 20) where the International Court of Justice outlined the factors necessary for the formation of customary international law.

126. Stat. I.C.J. art. 38(1).

127. M. SHAW, INTERNATIONAL LAW 59 (1977).

128. J. BRIERLY, THE LAW OF NATIONS 56 (6th ed. 1963).

129. Stat. I.C.J. art. 38(1).

130. See generally Akehurst, *The Hierarchy of the Sources of International Law*, 47 BRIT. Y.B. INT'L L. 273 (1974-1975).

and conventions comprising the upper level. Although the Code of Breastmilk Substitutes is neither a treaty¹³¹ nor an international convention, nations may treat the Code as international custom and give it effect as international law.

Article 38(1)(b) describes the creation of customary international law. Nations form customary international law as a result of a state practice which is a "general practice."¹³² State practice can include the physical acts as well as the declarations of individual states.¹³³ The state practice is a "general practice" when the action taken is extensive and virtually uniform, at least among those states whose interests are specifically affected.¹³⁴ In addition, this "general practice" must be "accepted as law,"¹³⁵ i.e. the practice must occur "in such a way as to show a general recognition that a rule of law or legal obligation is involved."¹³⁶ The nations engaging in the state practice must believe that their actions are legally required.¹³⁷ While customary international law is created in this manner, the process is not easily completed, as an examination of the components of customary international law will indicate.

1. Definition of State Practice

Article 38(1)(b) of the Statute of the International Court of Justice establishes that a "general practice" of states is necessary to form customary international law. However, scholars disagree regarding the appropriate definition of state practice. According to the most restrictive view, only physical acts¹³⁸ constitute state action.¹³⁹ At the other extreme, one scholar asserts that almost any official statement is state practice.¹⁴⁰

131. A treaty is an explicit agreement with an immediate binding effect on parties to the agreement. A. D'AMATO, *THE CONCEPT OF CUSTOM IN INTERNATIONAL LAW* 104 (1971) [hereinafter cited as D'AMATO]; see also Draft International Code, *supra* note 64, at 4.

132. Stat. I.C.J. art. 38(1)(b).

133. Akehurst, *supra* note 19, at 10. Akehurst uses an inclusive definition of state practice. For a detailed discussion of several interpretations of state practice, see § V.B.i. *infra*. If the state action stems from a particular instrument, the instrument in question must "be of a fundamentally norm-creating character such as would be regarded as forming the basis of a general rule of law." North Sea Continental Shelf, 1969 I.C.J. at 42.

134. North Sea Continental Shelf, 1969 I.C.J. at 43.

135. Stat. I.C.J. art. 38(1)(b).

136. North Sea Continental Shelf, 1969 I.C.J. at 43.

137. *Id.* at 44.

138. A physical act is what a state does rather than what a state says.

In most cases, a state's action is easily recognized. A state sends up an artificial satellite, tests nuclear weapons, receives ambassadors, levies customs duties, expels an alien, captures a private vessel, sets up a drilling rig in the continental shelf, visits and searches a neutral ship, and similarly engages in thousands of acts through its citizens and agents.

D'AMATO, *supra* note 131, at 88. In contrast, claims and other statements by states are not physical acts and therefore, according to this view, they cannot constitute state practice. *Id.*

139. *Id.*

140. See M. AKEHURST, *A MODERN INTRODUCTION TO INTERNATIONAL LAW* 43-44 (1970).

Professor D'Amato expresses the restrictive view that only physical acts define state practice for the purpose of creating customary international law.¹⁴¹ D'Amato maintains that physical state acts are less likely to conflict with one another than are governmental claims and other official statements.¹⁴² He points out that a state can articulate many contradictory rules but it can only act in one way at one time:

The act is concrete and usually unambiguous. Once the act takes place, the previously articulated rule that is consistent with the act takes on life as a rule of customary law, while the previously articulated rules contrary to it remain in the realm of speculation. The state's act is visible, real, and significant; it crystalizes policy and demonstrates which of the many possible rules of law the acting state has decided to manifest.¹⁴³

Dr. Thirlway holds a more moderate position that statements and claims of nations may constitute state action, but only if nations make statements in the context of a specific dispute or potential dispute.¹⁴⁴ Therefore, "[t]he mere assertion *in abstracto* of the existence of a legal right or legal rule is not an act of State practice."¹⁴⁵ Abstract statements can confirm state practice, but a state must intend that a statement will have an "immediate effect on a legal relationship" to create practice.¹⁴⁶

A third view is that statements and declarations can constitute state action only when the pronouncements come from a source which is competent to make treaties in the name of the state.¹⁴⁷ According to this approach, in determining whether state action exists, one would disregard all national laws and the practices of executive departments which lack the power to make treaties.¹⁴⁸ This view is consistent with the theory that custom constitutes an implied agreement between states and therefore only those organs which are competent to make formal agreements in the name of the state should be able to make implied agreements.¹⁴⁹

In contrast to these views of state practice, Professor Akehurst asserts that "[s]tate practice covers any act or statement by a State from which views can be

141. D'AMATO, *supra* note 131, at 88.

142. *Id.*

143. *Id.*

144. H. THIRLWAY, *INTERNATIONAL CUSTOMARY LAW AND CODIFICATION* 58 (1972) [hereinafter cited as THIRLWAY].

145. *Id.*

146. *Id.*

147. See Akehurst, *supra* note 19, at 8 where this theory is strongly supported by Strupp.

148. *Id.* at 9.

149. *Id.* at 8.

inferred about international law."¹⁵⁰ Under this theory, state practice includes not only physical acts and statements but also

other types of act or statement, such as standing or *ad hoc* instructions by a State to its officials, or criticisms by one State of the conduct of other States, or treaties (including treaties which have not entered into force). It can also include omissions and silence on the part of States.¹⁵¹

Rather than focusing on the source of the potential practice or the existence of an act, Akehurst takes the least restrictive position. He simply asks whether other nations can infer the state's view about customary law from the statement, act or omission.¹⁵² Although legal scholars do not agree on a single definition of state action, the majority appear to favor a less restrictive approach.¹⁵³

Once nations engage in state practice, the frequency, length, prevalence, and consistency of the practice then become significant in determining whether a "general practice" exists. Most writers have expressed the view that while nations can establish state practice within a short period of time,¹⁵⁴ these governments must repeat the action in a constant and uniform manner.¹⁵⁵ As the International Court of Justice has stated:

Although the passage of only a short period of time is not necessarily, or of itself, a bar to the formation of a new rule of customary international law on the basis of what was originally a purely conventional rule, an indispensable requirement would be that within the period in question, short though it might be, State practice, including that of States whose interests are specially affected, should have been both extensive and virtually uniform in the sense of the provision invoked; — and should moreover have occurred in such a way as to show a general recognition that a rule of law or legal obligation is involved.¹⁵⁶

150. *Id.* at 10.

151. *Id.*

152. *Id.* at 53.

153. *See id.* at 2.

154. *Id.* at 15; South West Africa (Ethiopia v. South Africa; Liberia v. South Africa), 1966 I.C.J. 4, 291 (Judgment of July 18) (dissent, Tanaka).

155. Meijers, *supra* note 115, at 13; South West Africa, 1966 I.C.J. at 292 (dissent, Tanaka). Dr. Akehurst suggests that

a rule of customary law is established if it is accepted by the international community, and that the number of states taking part in a practice is a more important criterion of acceptance than the number of acts of which the practice is composed, and a much more important criterion than the duration of the practice.

Akehurst, *supra* note 19, at 16.

156. North Sea Continental Shelf, 1969 I.C.J. at 43.

Therefore, the length, repetition and consistency of the action are important indicators of general consent to the practice by the international community.

The *North Sea Continental Shelf Cases*¹⁵⁷ suggest that the number of states and their respective degree of interest in the controversy are also important factors in determining whether international consensus exists.¹⁵⁸ The Court stated that a "very widespread and representative participation . . . includ[ing] that of States whose interests were specially affected"¹⁵⁹ is required. In an earlier case in which the International Court of Justice interpreted Article 38(1)(b), Judge Tanaka asserted that the consent of all states is not required for the creation of customary law:¹⁶⁰

[T]he Statute does not exclude the possibility of a few dissidents for the purpose of the creation of a customary international law and that the contrary view of a particular State or States would result in the permission of obstruction by veto, which could not have been expected by the legislator who drafted the said Article.¹⁶¹

Judges, however, do not agree on whether unanimity is required¹⁶² or if not, on the minimum number of states required to participate in a practice in order for it to constitute general practice.¹⁶³ Professor Akehurst suggests that "[t]he number of States needed to create a rule of customary law varies according to the amount of practice which conflicts with the rule."¹⁶⁴ A large number of states must engage in the practice only if substantial conflicting practice exists.¹⁶⁵

Professor Meijers, while advocating a similar approach, focuses on the purpose of the regulation.¹⁶⁶ Meijers notes that "[a] state will want to accept the binding force of a rule of law only if the other states which are necessary for the practical and effective application of the rule are prepared to accept the same obligation."¹⁶⁷ Regardless of the criteria used to determine whether a sufficient number of states have participated in a practice, the states who participate in the creation of the rule must be those "whose interests [are] specially affected."¹⁶⁸ The question of how many and which affected states must participate in the rule formation remains unresolved.¹⁶⁹

157. *North Sea Continental Shelf*, 1969 I.C.J. 3.

158. *Id.* at 43.

159. *Id.* at 42.

160. *South West Africa*, 1966 I.C.J. at 291 (dissent, Tanaka).

161. *Id.*

162. See Akehurst, *supra* note 19, at 17, 26.

163. Compare *South West Africa*, 1966 I.C.J. at 291 (dissent, Tanaka) with *North Sea Continental Shelf*, 1969 I.C.J. at 130 (Ammoun).

164. Akehurst, *supra* note 19, at 18.

165. *Id.*

166. Meijers, *supra* note 115, at 7.

167. *Id.*

168. *North Sea Continental Shelf*, 1969 I.C.J. at 43.

169. See Akehurst, *supra* note 19, at 18-19.

2. *Opinio Juris* (Accepted as Law)

In the creation of customary international law, the initial requirements are the existence of sufficient state practice¹⁷⁰ and a rule suitable for evolution into customary international law.¹⁷¹ These factors alone, however, are not enough to create customary international law.¹⁷² Article 38(1)(b) also requires that the "general practice" of the state be "accepted as law" "*opinio juris*"¹⁷³ by that state. The International Court of Justice has traditionally interpreted "accepted as law" to mean:

Not only must the acts concerned amount to settled practice, but they must also be such, or be carried out in such a way, as to be evidence of a belief that this practice is rendered obligatory by the existence of a rule of law requiring it. The need for such a belief, i.e., the existence of a subjective element, is implicit in the very notion of the *opinio juris sive necessitatis*.¹⁷⁴ The States concerned must therefore feel that they are conforming to what amounts to a legal obligation.¹⁷⁵

A radical approach to this traditional requirement is to deny any requirement of *opinio juris*.¹⁷⁶ However, while many cases do not mention *opinio juris*, no case expressly holds that *opinio juris* is unnecessary.¹⁷⁷ Commentators still assert that *opinio juris* is necessary for the creation of customary law and have formulated some variations on the traditional definition of *opinio juris*.¹⁷⁸ Akehurst criticizes the traditional definition of *opinio juris* for its paradoxical nature.¹⁷⁹ The definition "seems to require that States must believe that something is *already* law before it can *become* law."¹⁸⁰ While Akehurst recognizes that the formation of customary international law requires *opinio juris*, he asserts that a statement that

170. North Sea Continental Shelf, 1969 I.C.J. at 43.

171. *Id.* at 41-42.

172. Akehurst, *supra* note 19, at 31.

173. Stat. I.C.J. art. 38(1)(b).

174. "*Opinio juris sive necessitatis*" is translated as "understanding of the law or of necessity." See CASSELL'S LATIN DICTIONARY (5th ed. 1968).

175. North Sea Continental Shelf, 1969 I.C.J. at 44.

176. Akehurst, *supra* note 19, at 32.

177. *Id.*

178. Thirlway asserts that "the requirement of *opinio juris* is equivalent merely to the need for the practice in question to have been accompanied by either a sense of conforming with the law, or the view that the practice was potentially law, as suited to the needs of the international community." THIRLWAY, *supra* note 144, at 53-54. Instead of accepting the traditional definition of *opinio juris* D'Amato substitutes a requirement that the practice be accompanied by articulation. "The articulation of a rule of international law . . . in advance of or concurrently with a positive act (or omission) of a state gives a state notice that its action or decision will have legal implications." D'AMATO, *supra* note 131, at 75. For a discussion of these various definitions, see Akehurst, *supra* note 19, at 34-42.

179. Akehurst, *supra* note 19, at 31-32.

180. *Id.* at 32 (emphasis in original).

the state practice is "permitted, required or forbidden by international law" satisfies the requirement of *opinio juris*.¹⁸¹

3. Codes as Customary International Law

With sufficient state practice and *opinio juris*, the provisions of a code of conduct could become customary international law.¹⁸² However, two common features of codes — their provisions regulating TNCs¹⁸³ and their non-binding form — cause their evolution into customary international law to be more difficult.¹⁸⁴ While a code may have provisions directed at TNCs, and TNCs may, in fact, act in compliance with these provisions, the behavior of TNCs cannot contribute to the formation of customary international law.¹⁸⁵ The evolution into customary international law requires state practice.¹⁸⁶ TNCs are neither "state nor public international organizations."¹⁸⁷ Since TNCs are non-state entities, their actions and pronouncements cannot qualify as state practice or provide the necessary element of *opinio juris*.¹⁸⁸

In addition, nations may approve a code only in a non-binding form; a code may state specifically that it is "voluntary and not legally enforceable"¹⁸⁹ or the code may be non-binding in form.¹⁹⁰ One position is that a non-binding voluntary code shields TNCs from domestic or international enforcement.¹⁹¹ On the other hand, even if nations display state practice in compliance with the code provisions, the voluntary nature of a code would make the requirement of *opinio juris* more difficult.¹⁹² A state would be less likely to believe that its actions were conforming to a legal obligation as is required by *opinio juris*. Nevertheless, Professor Baade continues to assert that despite the voluntary nature of a code, the code provisions may evolve into customary international law¹⁹³ and, therefore, the provisions may apply even to TNCs and nations which have never accepted the code provisions.¹⁹⁴ Two common characteristics of codes which

181. *Id.* at 53.

182. Baade, *supra* note 5, at 15, 22-23.

183. See Code of Breastmilk Substitutes, *supra* note 8; OECD DECLARATION, *supra* note 8.

184. Baade, *supra* note 5, at 16-17.

185. *Id.*

186. See generally Baade, *Individual Responsibility*, in 4 THE FUTURE OF THE INTERNATIONAL LEGAL ORDER: THE STRUCTURE OF THE INTERNATIONAL ENVIRONMENT 290-327 (C. BLACK & R. FALK eds. 1972).

187. Baade, *supra* note 5, at 16.

188. *Id.* at 16-17.

189. See OECD DECLARATION, *supra* note 8, at 970.

190. See Code of Breastmilk Substitutes, *supra* note 8, which the WHA approved in the form of a non-binding recommendation.

191. This position is that since a code is designated as "voluntary and non legally enforceable," the code provisions cannot gain a legal status. See Baade, *supra* note 5, at 30. For a discussion of the shield theory as applied to the OECD Declaration, see *id.*

192. *Id.* at 23.

193. *Id.* at 18.

194. If code provisions evolve into customary international law, they would bind even those nations

contribute to their movement into international law include their statements of official policy and their recommendations of follow-up procedures.¹⁹⁵ These follow-up procedures involve home and/or host countries to insure that the code provisions are more effective. This type of participation by states could represent a form of state practice as states may enact legislation or institute policies in compliance with the code provisions.¹⁹⁶ These actions and their accompanying statements should indicate whether the nation views its actions as legally required.¹⁹⁷ This state practice combined with the requisite *opinio juris* could constitute the formation of customary international law.¹⁹⁸

Several scholars assert that emphasis on the formal legal nature of codes is misplaced.¹⁹⁹ They contend that rather than focusing on whether codes are voluntary or binding, the emphasis should be on recognizing codes as multilateral declarations of policy on matters of international concern.²⁰⁰ Codes are serious, formal pronouncements of policy.²⁰¹ Such multilateral agreements provide evidence of the "international consensus which lies behind the instrument and the concomitant respect that concerned actors would accord it as a legal norm; an agreement need not be binding to be recognized as an authoritative guide to behavior."²⁰² A code's non-legal and non-binding status does not necessarily affect its operation.²⁰³ Parties to a code may still expect and rely on compliance and the instrument may have legal implications.²⁰⁴

C. Case Study of the Code of Breastmilk Substitutes — Its Place in International Law

Despite the fact that the WHA approved the WHO "International Code of Marketing of Breastmilk Substitutes" as a non-binding recommendation, the Code may not remain voluntary for long. The adoption of the Code by an overwhelming majority of the WHA demonstrates a consensus within this group regarding the importance of breastfeeding, and the concomitant need to restrict the marketing of breastmilk substitutes.²⁰⁵ At present, the Code is important

which did not expressly consent to these provisions. A state can avoid being bound by clearly objecting to the formation and application of the code. See Davidow & Chiles, *supra* note 15, at 255.

195. Baade, *supra* note 5, at 19-20.

196. *Id.* at 19-20, 39, 49.

197. See Akehurst, *supra* note 19, at 36-37.

198. See North Sea Continental Shelf, 1969 I.C.J. at 41.

199. See Davidow & Chiles, *supra* note 15, at 255; Coonrod, *supra* note 1, at 297.

200. See Davidow & Chiles, *supra* note 15, at 255; Coonrod, *supra* note 1, at 297.

201. Baade, *supra* note 5, at 19.

202. Coonrod, *supra* note 1, at 297.

203. Falk, *On the Quasi-Legislative Competence of the General Assembly*, 60 AM. J. INT'L L. 782, 783-85 (1966); Schachter, *supra* note 122, at 299-301. See notes 122-23 and accompanying text *supra*.

204. Schachter, *supra* note 122, at 299-301. See notes 122-23 and accompanying text *supra*.

205. That a consensus exists within the WHA on the infant formula issue is a reasonable conclusion, as the Code's central theme is the superiority of breastfeeding. See Code of Breastmilk Substitutes, *supra* note 8, preamble. The WHA approved this Code by a vote of one hundred and eighteen nations to one. Fifteenth Plenary Meeting, *supra* note 33, at 9.

because its principles may have moral and practical force on both states and business enterprises.²⁰⁶ For example, the Code may influence some corporations to develop their own codes restricting marketing practices and may encourage other producers to improve upon existing marketing guidelines.²⁰⁷ In addition, "the understanding and expectation [of the WHA] . . . is that states will modify their practices to conform to the understandings of the agreement."²⁰⁸ Article 11 of the Code specifically suggests that governments take appropriate steps to implement the Code, including the adoption of legislation and regulations.²⁰⁹ If individual nations do adopt the Code provisions, such national legislation would govern formula producers operating in these particular countries.²¹⁰ In this way national legislation would give these originally non-binding provisions the force of law.

More importantly, the Code could be a significant initial step in the creation of customary international law. Sufficient state practice accompanied by *opinio juris* is still necessary for the evolution of the Code provisions into customary international law.²¹¹ Using a broad definition of state practice,²¹² the adoption of the Code by the WHA could be one of the first examples of state practice²¹³ with respect to the Code provisions.

Individual government legislation or regulations adopted in compliance with Article 11 of the Code of Breastmilk Substitutes, as well as future collective endorsements of the Code by the member states of the WHA, could also constitute state action.²¹⁴ In contrast, adherence to or adoption of Code provisions by members of the infant formula industry has no direct significance regarding the

206. See notes 122-23 and accompanying text *supra*. See N.Y. Times, May 21, 1981, at A9, col. 1.

207. "[T]he baby food industry pioneered the notion of marketing codes, although, admittedly, their purpose was to forestall external regulation rather than find guidelines that would effectively protect babies and mothers from inappropriate commercial pressures. As industry's own codes were shown defective in both design and execution, public protest escalated." 1981 Hearings, *supra* note 86, at 96 (statement of Leah Margulies, Co-Director, Interfaith Center on Corporate Responsibility (ICCR)). Now that the WHA has adopted the Code of Breastmilk Substitutes, formula company representatives have become active in proposing their own codes and working with government to propose legislation relating to formula marketing. *Id.* at 97-98. However, industry lobbyists encourage the adoption of legislation that is much weaker than the Code of Breastmilk Substitutes. *Id.*

208. Davidow & Chiles, *supra* note 15, at 255.

209. Code of Breastmilk Substitutes, *supra* note 8, art. 11.

210. See Davidow & Chiles, *supra* note 15, at 256.

211. See § V *infra*.

212. This definition includes "any act or statement by a State from which views can be inferred about international law." Akehurst, *supra* note 19, at 10.

213. See South West Africa, 1966 I.C.J. at 291-92 (dissent, Tanaka). Judge Tanaka stated that "the accumulation of authoritative pronouncements such as resolutions, declarations, decisions . . . can be characterized as evidence of the international custom referred to in Article 38, paragraph 1(b)." *Id.* at 292. Statements made by government officials in support of the Code could also qualify as state practice using Akehurst's definition. See Akehurst, *supra* note 19, at 10.

214. See Akehurst, *supra* note 19, at 10.

formation of customary international law, as private industry is a nonstate actor.²¹⁵

The state action must be repeated, consistent and exhibited by a sufficient number of states in order to constitute customary international law.²¹⁶ Because scholars and judges view the repetition of state action as the central factor in determining general practice,²¹⁷ the frequency and the manner in which various nations exhibit their support of the Code of Breastmilk Substitutes should be significant. If states exhibited this type of general practice with the requisite *opinio juris*, thus making the Code provisions customary international law, the provisions could bind even those states that did not expressly consent to the Code provisions.²¹⁸

D. *Significance of the U.S. Vote*

While the United States was the only nation to object to the WHO Code,²¹⁹ this one vote could have significant effects. Conflicting practice, such as the U.S. vote against the Code and statements by U.S. officials that the United States views the Code as purely voluntary, increases the amount of state practice by other nations that is necessary to create a rule of customary law.²²⁰ The Code could affect the interests of the United States as three major international formula producers²²¹ are U.S. corporations.²²² Without the support of this "specially affected" nation, the evolution of the Code into customary international law may be much more difficult.²²³

Finally, the United States is a major power with worldwide interests, which maintains embassies in many other nations and which has many opportunities to contribute to the development of international rules. Therefore, U.S. actions may receive more publicity than do the actions of smaller states and smaller states may be more likely to imitate the United States. Therefore, the U.S. position against the Code has the potential to affect the actions of other nations.²²⁴ In spite of this, however, Akehurst points out that the occurrence of imitation is uncertain and only "the presence or absence of imitation . . . affects

215. See notes 185-88 and accompanying text *supra*.

216. See *North Sea Continental Shelf*, 1969 I.C.J. at 42-43; see also notes 154-59 and accompanying text *supra*.

217. See note 155 and accompanying text *supra*.

218. Davidow & Chiles, *supra* note 15, at 255. See note 194 and accompanying text *supra*.

219. See Fifteenth Plenary Meeting, *supra* note 33, at 9.

220. Akehurst, *supra* note 19, at 18.

221. The three major American corporations which market formula on an international scale include Mead Johnson, Ross and Wyeth Laboratories. See *N.Y. Times*, May 22, 1981, § IV, at 1, col. 3.

222. For a discussion of the importance of state practice by nations whose interests are "specially affected," see notes 157-59 and accompanying text *supra*.

223. *Id.* See Akehurst, *supra* note 19, at 23.

224. See Akehurst, *supra* note 19, at 23.

the future development of customary law, not the fact that the original actions were taken by a great power."²²⁵ U.S. officials have made several strong statements against the use of a code to govern worldwide marketing;²²⁶ the United States objected during the formation of the Code, and if the United States continues to object to the Code's application, the United States would not be bound by the Code principles or directives.²²⁷ In addition, imitation of this U.S. action by other nations would hamper the Code's evolution into customary international law.²²⁸

E. Analysis

Upon passage, the Code of Breastmilk Substitutes is an expression of the consensus within the WHA on the importance of breastfeeding and the need to restrict formula marketing techniques.²²⁹ The Code is not legally binding on member states²³⁰ and it could remain in this non-binding form. Nevertheless, as an expression of political and moral commitments, the Code may have an effect on states and TNCs.²³¹

The Code provisions could have an even greater impact if they were to become legally binding within the international community. The Code provisions could become customary international law if the requisite events occur. Not only must state practice occur that is consistent, repeated and widespread,²³² but this general practice must be accompanied by *opinio juris*.²³³ "Specially affected"²³⁴ states must participate in the practice. Objections by specially affected states, such as the United States in the present case, heightens the requirements of general practice. The International Court of Justice notes that this process "constitutes indeed one of the recognized methods by which new rules of cus-

225. *Id.*

226. For example, U.S. Secretary of Health and Human Resources Richard Schweiker explained that "[t]he administration honestly does not believe the WHO should be an international Federal Trade Commission." *A U.S. Vote On Baby Formula that Stirred a Storm*, U.S. NEWS & WORLD REP., June 1, 1981, at 60. In voting against the Code at the WHA, U.S. Delegate Gerald Helman took the position that:

the apparent flexibility provided to governments . . . did not . . . overcome the overall effect of prescribing a rigid set of rules applicable to companies, health workers, and health care systems in all parts of the world. The Code also contained provisions that caused serious legal and constitutional problems for his country. Moreover, the United States was seriously concerned about WHO's involvement in commercial codes, and that was the central basis for its inability to support the Code.

Fourteenth Meeting, *supra* note 34, at 9.

227. See note 194 and accompanying text *supra*.

228. See Akehurst, *supra* note 19, at 23.

229. See note 122 and accompanying text *supra*.

230. See notes 110-11 and accompanying text *supra*.

231. See notes 123-25 and accompanying text *supra*.

232. See notes 154-56 and accompanying text *supra*.

233. See § V.B.2 *supra*.

234. *North Sea Continental Shelf*, 1969 I.C.J. at 42.

tomary international law may be formed. At the same time this result is not lightly to be regarded as having been attained."²³⁵

VI. CONCLUSION

While the provisions of the WHO Code have the potential to evolve to the level of customary international law, presently one can only speculate as to whether the Code will establish a precedent of worldwide consensus and concern regarding the important role of breastfeeding and the need to regulate the marketing practices of the producers of breastmilk substitutes. Nevertheless, the Code is not "instant international law." Only future actions taken by nations in accordance with the Code will provide the legal basis necessary to give effect to the Code principles. Such actions by individual nations must take the form of national legislation or regulations similar to the directives in the Code. The adoption of national legislation based on the Code will not only restrict marketing practices within certain countries, but will also provide the evidence of state action required for the creation of customary international law. Domestic enforcement of the Code principles or the Code's evolution into international law will affect TNCs despite the fact that nations approved the Code as a voluntary instrument. The Code provisions are not voluntary for TNCs simply because nations adopted the Code as a voluntary instrument.²³⁶ Of greater importance than the voluntary nature of the Code is the international respect for it as a legal norm. The consensus and respect for its legal nature legitimize the Code's transformation into international law.²³⁷ If and when the transformation occurs, the role of both the WHO, in its regulation of the behavior of TNCs, and of future codes of conduct, in general, will be stronger.

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235. *Id.* at 41.

236. See note 194 and accompanying text *supra*.

237. See notes 200-204 and accompanying text *supra*.