

THE IMPLEMENTATION PROCESS OF THE INTERNATIONAL CODE OF MARKETING OF BREASTMILK SUBSTITUTES

I. INTRODUCTION

The passage of the World Health Organization (WHO) "International Code of Marketing of Breastmilk Substitutes" (Code of Breastmilk Substitutes)¹ in May of 1981 marked a great achievement in the fight for improved infant health, but did not signify a lasting solution to the problem of poor marketing practices of infant formula manufacturers. The implementation of the Code of Breastmilk Substitutes is a long and difficult process because the Code was adopted as a recommendation under article 23 of the WHO Constitution,² rather than as a regulation.³ The practical significance of the Code's status as a recommendation is that the Code alone is not binding on transnational corporations (TNCs).

The second stage in the fight for the proper use of infant formula substitutes, effective implementation of the Code of Breastmilk Substitutes, depends upon "a multidisciplinary effort in policy-making, formulation of strategies, policy implementation, monitoring and feedback."⁴ This article examines the effectiveness of the implementation process of the Code of Breastmilk Substitutes as it has occurred since 1981. The roles of national governments, transnational corporations, and non-governmental organizations are discussed, and the contributions of each of these parties to the process are analyzed. The Code has had visible effects on both in-

1. Thirty-Fourth World Health Assembly, International Code of Marketing of Breastmilk Substitutes, Res. WHA 34.22, Annex W.H.O. Doc. A34/VR15, (Fifteenth Plenary Meeting, May 21, 1981) [hereinafter cited as Code of Breastmilk Substitutes].

2. "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).

3. For a detailed discussion of the reasons for adopting the Code of Breastmilk Substitutes as a recommendation, rather than as a regulation, see Excerpts from the Introductory Statement by the Representative of the Executive Board to the Thirty-Fourth World Health Assembly on the Subject of the Draft International Code of Marketing of Breastmilk Substitutes (May 20, 1981), Doc. SHA34/1981/REC/1, Annex 3. See also Note, *Formulating Customary International Law: An Examination of the WHO International Code of Marketing of Breastmilk Substitutes*, 5 B.C. INTL & COMP. L. REV. 377, 388-91 (1982).

4. Jayasuriya, *Protecting Infants through Legislation in the Third World*, Lanka Guardian, Aug. 15, 1983, at 40.

dustries and nations despite the fact that it has not yet become binding international law.

II. THE CODE OF BREASTMILK SUBSTITUTES AS A LEGAL FORCE UPON NATIONS

To understand why implementation of the Code of Breastmilk Substitutes is such a lengthy and difficult process, it is necessary to understand that the Code is not yet binding customary international law. A code of conduct may become international law if nations comply with the code in a way that fulfills article 38(1) of the Statute of the International Court of Justice.⁵ To fulfill article 38(1), the "states whose interests are specifically affected" by the Code of Breastmilk Substitutes must take "extensive and uniform action . . . [and] must believe that their actions are legally required."⁶ Once a code becomes customary international law, it then has the force of law and "may apply even to TNCs and nations which have never accepted the code provisions."⁷ At the present time, the Code of Breastmilk Substitutes has definitely not reached this status,⁸ although it could still do so in the future.⁹

The individual WHO nations' reactions to the Code of Breastmilk Substitutes are the beginning of the process of creating customary international law. Under article 11.1 of the Code, individual governments are required to "take action to give effect to the principles and aim of [the] Code, as appropriate to their social and legislative framework, including the adoption of national legislation, regulations or other suitable measures."¹⁰ Under article 4.1, governments are responsible for providing objective information and education to both families and health care workers and educators.¹¹ In addition, the member nations are directed to "communicate annually to the Director-General [of the WHO] information on action taken to give effect to the principles and aim of [the] Code."¹² Clearly, under the Code, individual nations must not only act to implement the Code, but also must annually report all action taken to the WHO.

5. STATUTE OF THE COURT OF INTERNATIONAL JUSTICE, art. 38(1)(b) (1945).

6. Note, *supra* note 3, at 395-97.

7. *Id.* at 398 & n.194.

8. See *infra* notes 26-29 and accompanying text.

9. See *supra* notes 5-8 and accompanying text.

10. Code of Breastmilk Substitutes, *supra* note 1, art. 11.1.

11. *Id.* art. 4.1.

12. *Id.* art. 11.6.

It is not practical at this point in time to provide a detailed account of each and every member nation's activities in response to the Code because each nation's situation with respect to the Code is constantly changing.¹³ However, general observations and statistics may help to present an indication of whether the Code is having an effect on national activities and how this national activity will develop in the future.

One of the most interesting, although politically unsurprising, reactions to the Code of Breastmilk Substitutes was that of the United States, the only WHO member nation to vote "no" on the Code. The Reagan administration opposition to the Code was said to be based on legal and constitutional objections,¹⁴ and has been strongly criticized by Code supporters as a bow to the pressure exerted by big business on the administration.¹⁵ Rather than changing other member nations' attitudes about the Code, however, the U.S. vote seemed merely to alter U.S. public opinion toward the Reagan administration in a negative manner¹⁶ and to damage U.S. credibility in the WHO.¹⁷ These reactions are important because they demonstrate that the U.S. vote did not have a negative effect on the implementation process in other countries.¹⁸ Despite the lack of U.S. support for the Code, there are many pro-Code groups that are able to function effectively and, without restraint in the United States, that help to implement the Code in ways other than through national legislation.¹⁹ In addition, although the Code has not been adopted *per se* in the United States, the infant formula controversy surrounding the adoption of the Code of Breastmilk Substitutes has encouraged the Food and Drug Administration to propose a new regulation that would require revision of the labels on infant for-

13. The reason for the constant change is that legislative processes are slow in most countries. If, for example, a country decides to implement the Code, the process may not be completed for several years after that decision is made.

14. Baer & Margulies, *An Intriguing Delivery-An Infant Formula Code is Born*, DEV. F., July-Aug. 1981, at 15, col. 5.

15. *Battle of the Bottle*, ASIaweek, June 19, 1981, at 23.

16. Joseph, *The Anatomy of the Infant Formula Controversy*, 135 AM. J. DIS. CHILD. 889, 891 (1981).

17. *Id.*

18. *Battle of the Bottle*, *supra* note 15. In India, for example, the United States' position encouraged a movement toward the introduction of specific legislation that would embody the Code's goals. *Id.* In October of 1983, India's working party had recommended the Code of Breastmilk Substitutes and the Code was awaiting implementation as national law. IDEAS FORUM, Oct. 25, 1983, at 3, 5, col. 2 & 3. (published by UNICEF's Information Division).

19. See *infra* notes 32-44 and accompanying text.

mula containers.²⁰ The proposal conforms to the spirit of the Code of Breastmilk Substitutes, but does not extend so far as to support the express labeling requirements of the Code.²¹

One of the most revealing signs of the Code's effectiveness thus far is the action which the pro-Code voting nations have taken to implement the Code. Information based on reports supplied to the WHO by governments, and supplemented with information from UNICEF,²² the American Public Health Association's Clearinghouse on Infant Feeding and Maternal Nutrition,²³ and the International Baby Food Action Network,²⁴ has categorized countries into one of twelve²⁵ groups to determine the status of national code implementation.²⁶ Although the state actions taken do not constitute sufficient action to cause the Code to be viewed as customary international law,²⁷ the actions of most states indicate that in time,

20. *Infant Formula Label Proposed*, AM. MED. NEWS, Nov. 1, 1983, at 7. Infant Formula Labeling Requirements, 48 Fed. Reg. 31,880 (1983) (to be codified at 21 C.F.R. §§ 105.65, 107.10).

21. Code of Breastmilk Substitutes, *supra* note 1, art. 9.

22. UNICEF is the United Nations Children's Fund, an organization that is devoted to improving the well-being of children around the world.

23. The American Public Health Association's Clearinghouse on Infant Feeding and Maternal Nutrition is an international center that collects and disseminates research materials on breastfeeding and maternal health.

24. The International Baby Food Action Network (IBFAN) is a coalition of over forty organizations that was formed in 1979 to help further the WHO Code implementation process by exerting consumer pressure on infant food manufacturers.

25. The survey places nations into one of the following categories:

- No action planned
- No action planned, but situation closely watched
- Voluntary code prepared by industry under discussion
- Voluntary code prepared by industry in effect
- A code under discussion incorporating some, not all, of the provisions of the International Code
- International Code being studied by committee, working party; etc.
- International Code recommended for implementation by working party; awaiting implementation
- Voluntary national code or voluntary guidelines, incorporating some, not all, provisions of the International Code in effect
- Legislation, rules, regulations incorporating some, not all, the provisions of the International Code in effect
- International Code in effect as a voluntary measure
- International Code in effect as law
- Government controls distribution/marketing

IDEAS FORUM, *supra* note 18, at 5.

26. *Id.*

27. The creation of customary international law is a difficult and intricate process. For a detailed discussion of the Code of Breastmilk Substitutes in international legal theory,

the Code could become customary international law.²⁸ Although the significance of individual national attempts and statements of intent to implement the Code of Breastmilk Substitutes should not be disregarded, some scholars hold the viewpoint that the emphasis on the legal implications of the Code of Breastmilk Substitutes is actually misplaced.²⁹ Health professionals, as well as international legal theorists, have adhered to this thinking, claiming that the test of the Code's success should not be its effects on the health of infants.³⁰ The Code, itself, offers proof that its drafters did not expect its success to depend solely on the efforts of individual nations.³¹ To analyze whether the implementation process has been successful thus far, we must look further than the actions taken by governments to implement the Code.

III. THE CODE OF BREASTMILK SUBSTITUTES AS A MORAL FORCE

A. THE ROLE OF NONGOVERNMENTAL ORGANIZATIONS IN THE IMPLEMENTATION PROCESS

Article 11.4 of the Code of Breastmilk Substitutes states that "nongovernmental organizations, professional groups, institutions, and individuals concerned should have the responsibility of drawing the attention of manufacturers or distributors to activities which are incompatible with the principles and aims of this Code, so that appropriate action can be taken."³² Nongovernmental organizations (NGOs) have taken it upon themselves to be strong proponents of the implementation process.³³ In a sense, the groups use the Code of Breastmilk Substitutes as a tool that enables them to fulfill their goals; indeed many of them worked to bring the Code of Breastmilk

see Note, *supra* note 3, *passim*. See also Baer & Post, *The International Code of Marketing For Breastmilk Substitutes: Consensus, Compromise and Conflict in the Infant Formula Controversy*, INT'L COMMISSION JURIST, Dec. 1980, at 52, 61.

28. See *supra* notes 5-9 and accompanying text.

29. Note, *supra* note 3, at 399.

30. Dugdale, *Science and WHO Breast Milk Policy*, 2 LANCET 1105 (1982) (letter to editor).

31. Code of Breastmilk Substitutes, *supra* note 1, arts. 11.2, 11.3, 11.4, 11.5.

32. *Id.* art. 11.4.

33. Letter from Judith Philipona of Geneva Infant Feeding Association (GIFA) to Shari Hill (Dec. 2, 1983) [hereinafter cited as Letter]. Some of the active nongovernmental organizations are IBFAN, International Union for Child Welfare, International Planned Parenthood Federation, League of Red Cross Societies, CARE, International Council of Women, World Council of Churches, and the International Catholic Child Bureau.

Substitutes into existence, prior to 1981.³⁴ The motivations of the groups seem to stem from a recognition of "the need for international consumer pressure to force the international infant food industry to halt unethical promotion."³⁵

The International Baby Food Action Network (IBFAN) is dedicated to enforcing the implementation of the Code as its major goal.³⁶ The group is active on many levels, including conducting "surveys of changes in the market situations, analyses of national codes, voluntary agreements, talks and debates on Code interpretation, company campaigns, breast-feeding promotion materials development and preparations of statistical evidence on milk-exports."³⁷ Although IBFAN is one of the major NGOs committed solely to issues concerning infant health³⁸ and has therefore had a very visible effect on implementation, countless other NGOs are dedicated to promoting the implementation process along with their other commitments.³⁹ Other NGOs have organized to try to suppress misleading government advertising, to form clinics to educate women, to train health personnel, to monitor food distribution programs, to actively participate in local committees established to monitor the national situation with regard to the Code,⁴⁰ and to assist mothers in avoiding artificial feeding in relief situations.⁴¹

The actual effects of such activities by NGOs in the total scheme of implementation is impossible to accurately measure. Some Code scholars have suggested, however, that the "long-term value [of the Code] may lie in persuading health workers that they are targets of systematic efforts by the milk and drug industry to win their hearts, minds, and prescribing habits."⁴² If this is so, the activities undertaken by NGOs who provide educational materials to health workers are, therefore, invaluable to the implementation

34. Letter from Mirian Reidy of World Council of Churches-Christian Medical Commission to Shari Hill (Dec. 5, 1983).

35. Statement published by IBFAN describing its activities in relation to the Code of Breastmilk Substitutes (Part of mailing to IBFAN supporters, available from IBFAN) [hereinafter cited as Statement].

36. Letter, *supra* note 33.

37. *Id.*

38. See Statement, *supra* note 35.

39. See *supra* note 33.

40. Letter from CARE, at 1 (Dec. 5, 1983).

41. PANORAMA, Mar.-Apr. 1981 (issued by League of Red Cross Societies to its National Societies).

42. Baer & Margulies, *supra* note 14.

process.⁴³ Perhaps the strongest evidence of the effect which NGOs have had on the implementation process may be seen through an analysis of the changes in practices of infant formula manufacturers.⁴⁴

*B. THE EFFECT OF THE CODE OF BREASTMILK SUBSTITUTES ON INFANT FORMULA MANUFACTURERS: NESTLE AS A CASE STUDY*⁴⁵

Article 5 of the Code of Breastmilk Substitutes includes statements that disallow advertising of products within the Code's scope,⁴⁶ distribution of samples by manufacturers to expectant mothers or their families, point-of-sale advertising, displays, discount coupons or sales at the retail level,⁴⁷ distribution by manufacturers of any gifts that could promote the use of breastmilk substitutes,⁴⁸ and contact between marketing personnel and pregnant women or mothers of young children.⁴⁹ Article 8 of the Code proscribes further the activities of employees of manufacturers and distributors of infant formula,⁵⁰ and article 9 discusses labeling requirements for products sold by these companies.⁵¹ Finally, article 11.3 states that manufacturers and distributors of products within the Code's scope have an independent duty to monitor their own marketing practices under the Code and to insure that their practices conform to the Code.⁵² However, the existence of these Code demands would mean little to the actual implementation process where nations have not yet adopted the Code, without the efforts of protest and activist consumer groups which have fought to cause Nestle to change its marketing practices. Even before enactment of the Code, the Nestle Boycott, described as "a new form of collective bargaining wherein health professionals and consumers and their advocates

43. See *supra* notes 39-41 and accompanying text.

44. See *infra* notes 45-63 and accompanying text.

45. Nestle is an appropriate corporation for a case study because Nestle is the major manufacturer of infant formula in the Third World, and as such had been chosen as the first target by pro-Code activists. After a seven-year boycott of the Nestle Corporation, boycott supporters recently suspended the boycott because Nestle had complied with the WHO Code to their satisfaction. *NEWSDAY*, Jan. 27, 1984, at 13.

46. Code of Breastmilk Substitutes, *supra* note 1, art. 5.2.

47. *Id.* art. 5.3.

48. *Id.* art. 5.4.

49. *Id.* art. 5.5.

50. *Id.* art. 8.

51. *Id.* art. 9.

52. *Id.* art. 11.3.

join to force a change in the policies of multinational corporations"⁵³ had begun.

In March of 1982, Nestle announced its decision to adopt the Code of Breastmilk Substitutes after having previously adopted only certain provisions of the Code.⁵⁴ As part of Nestle's commitment to implementing the Code in its marketing practices, the Nestle Infant Formula Audit Commission (NIFAC) was established in May of 1982 "to examine complaints and allegations about Nestle's marketing practices and to satisfy itself that Nestle is honoring its publicly stated commitments in relation to the applications of the WHO recommendations."⁵⁵

Since the creation of NIFAC in 1982, the Commission has presented quarterly reports describing its activities and Nestle's progress thus far in the implementation process.⁵⁶ NIFAC's activities have included meeting with representatives of anti-Nestle groups to discuss procedures for processing complaints against Nestle, processing complaints submitted in order to ensure that Nestle's policies are being implemented in the field, travelling to Third World nations to spotcheck Nestle practices and submitting reports on these trips, and sponsoring a Conference on Breast-feeding and Infant Nutrition in June of 1983. The quarterly reports describe the results of these activities along with NIFAC's analysis of its own successes. NIFAC intends to continue in its present endeavors to oversee Nestle's implementation of the Code, but it maintains that its efforts cannot succeed without the concomitant actions of governments which must enact strict codes based on the WHO Code and all infant formula manufacturers who must comply with the Code.⁵⁷

Although after discussing NIFAC's activities and self-proclaimed successes, one would be likely to believe that implementation by Nestle has been quite successful, the pro-Code groups such as IBFAN had a very different view of Nestle's alleged successes during the boycott. From the outset, these groups found it difficult

53. Statement by Rev. George McClain of the United Methodist Church, *reprinted in* Statement, *supra* note 35.

54. Nestle Infant Formula Audit Commission (NIFAC), First Quarterly Report, (Oct. 14, 1982).

55. *Id.*

56. *See id.* *See also* NIFAC, Second Quarterly Report (Period ending Dec. 31, 1982); NIFAC, Third Quarterly Report (Period ending Mar. 31, 1983); NIFAC Fourth Quarterly Report (Period ending June 30, 1983); NIFAC, Quarterly Report No. 5 (Period ending Sept. 30, 1983).

57. *See supra* note 56.

to believe that a "commission created, mandated and funded by [Nestle] could really act as a fully independent monitor of Nestle's infant formula marketing behavior."⁵⁸ One group claimed that NIFAC had taken an inordinate amount of time to implement the complaint process, leading to that group's decision to delay filing more violations with NIFAC.⁵⁹ Finally, these groups claimed that NIFAC had "naively allowed itself to be used by Nestle's public relations machinery."⁶⁰ Although criticism of Nestle and NIFAC had been quite strong during the boycott, recently INFACT⁶¹ suspended the seven year boycott because Nestle had finally satisfied their demands.⁶² Regardless of whether the boycott has caused Nestle to implement the Code or whether NIFAC's actions have provided the major impetus,⁶³ clearly Nestle has made the necessary changes to comply with the Code.

IV. PROSPECTS FOR THE CODE OF BREASTMILK SUBSTITUTES' EFFECTIVE IMPLEMENTATION IN THE FUTURE

The Code of Breastmilk Substitutes' effectiveness in actually improving infant health has been called into question by many proponents of breastfeeding. Some experts have held that the Code is lacking certain fundamental attributes,⁶⁴ without which implementation can occur, but *effective* implementation may not occur. One argument, which calls into question the entire strategy of the Code of Breastmilk Substitutes, is that the Code does not have a clause insisting that governments monitor its effects on the health and growth of infants and children.⁶⁵ The legal implications of the Code on governments is irrelevant under this theory, as compared to the Code's practical effects as a consciousness-raising statement of

58. Hallman, *Nestle Audit Commission Stalled*, INFACT Canada Newsletter (Fall/Winter 1983-84).

59. *Id.*

60. *Id.*

61. Infant Formula Action Committee.

62. After announcing the suspension, boycott supporters said they plan to monitor Nestle for a six month period before determining whether they should end the boycott completely. N.Y. Times, Jan. 27, 1984, at A1, col. 5.

63. The work of both groups seems to have contributed to the implementation of the Code by Nestle. In NIFAC's First Quarterly Report, for example, the Commission states that "changes that have been made by Nestle," in its Implementation Instructions, were made "in response to suggestions and recommendations of [NIFAC] and other interested groups and individuals." *Id.*

64. Steady, *Infant Feeding in Developing Countries: Combating the Multi-nationals Imperative*, 27 J. TROPICAL PEDS. 215, 219 (1981).

65. Dugdale, *supra* note 30, at 1105.

policy. Finally, some pediatricians have argued that there is no sound, scientific data that supports the claim that advertising has actually had an effect on the decline of breastfeeding.⁶⁶ This view, however, seems to have been largely discounted by most experts in the field of breastfeeding and infant health.⁶⁷ In general, the medical profession seems to have reached a consensus that the Code of Breastmilk Substitutes should be implemented even if it is only a partial solution to a world health problem.⁶⁸ Indeed, it must be recalled that the WHO has, in fact, adhered to the theory that the Code of Breastmilk Substitutes is only a partial solution, and has therefore called the Code a minimum requirement.⁶⁹

Once it is recognized that the Code is meant to function as one step along the road to world-wide infant health, the success of the Code's future implementation as such may be predicted. Statements by both boycott sponsoring groups and Nestle indicate that neither will stop their implementation activities until they have satisfied the Code's demands.⁷⁰ In terms of the implementation of national codes, most governments are just beginning to promote the Code of Breastmilk Substitutes in their countries, and although the process is slow, it shows no signs of stopping before the participating nations have achieved their goals.⁷¹

V. CONCLUSION

The implementation process of the Code of Breastmilk Substitutes has been the result of efforts by governments, manufacturers and nongovernmental organizations. Although these efforts have not yet resulted in the Code becoming binding international law, the Code may become customary law at some future point. Furthermore, despite the fact that the Code is not a binding legal force, it has already had a major effect on many nations' policies and on industry. If, therefore, the Code's successfulness is measured by its actual effects as a policy influencer, rather than a forceful rule of law, then the WHO Code implementation process has been quite a successful one.

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66. May, *The Infant Formula Controversy: A Notorious Threat to Reason in Matters of Health*, 68 PEDS. 428, 429 (1981).

67. See Baer & Margulies, *supra* note 14.

68. See *supra* note 66, at 432-33.

69. Code of Breastmilk Substitutes, *supra* note 1.

70. "Once the Nestle Boycott is settled, we will move on to the U.S. companies, one by one with equally effective strategies." Statement, *supra* note 35.

71. See *supra* notes 22-28 and accompanying text.