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## THE INFANT FORMULA CONTROVERSY

### INTRODUCTION

The running controversy over infant formula promotion and sales in the Third World moves into a new phase this month as the World Health Assembly meets in Geneva to consider the adoption of a code regulating the marketing of breast milk substitutes.

The proposed International Code of Marketing for Breastmilk Substitutes has drawn criticism from industry and government. Both groups have expressed concern that the Code would lead to U.N.-imposed marketing and promotion constraints in other areas as well as foreshadow the adoption of the Code as policy rather than mere recommendation.

Also at issue are questions concerning the effectiveness of the proposed Code in reducing infant malnutrition in the Third World. Critics contend the Code fails to consider other facets of the malnutrition dilemma such as maternal starvation, inability to breast-feed, need to work and decision not to breast-feed.

The purpose of this paper is to review the controversy surrounding infant formula in the developing world and examine the issues involving the proposed International Code of Marketing for Breastmilk Substitutes currently under consideration in the World Health Assembly meeting in Geneva.

### BACKGROUND

Until the beginning of the present century, breast-feeding was the principal source of nutrition for newborn children and remained the primary method of feeding during the child's infancy. In the early part of the 1900s, however, the inability of some mothers to nurse successfully prompted the research and develop-

ment of breast milk substitutes which could adequately replace mother's milk while still supplying the required nutrients for the growing infant.

The popularity of formula feeding grew steadily in the United States, hitting a peak during the 1950s when it was estimated that as many as 75 percent of all mothers were substituting formula for breast-feeding for at least part of the infant's first year of life.

As the consumption of infant formula slowly declined in the 1960s, the formula industry began to concentrate on Third World countries, where demand for breast milk substitutes had sharply increased.

In response to the growing concern over infant malnutrition in the developing nations of the world, the international health community initiated a series of meetings in the early 1970s under the direction of the Pan American Health Organization, UNICEF, and the Protein Advisory Group (PAG), a United Nations agency charged with overseeing and evaluating the nutritional requirements and successes in developing nations. Meeting in Paris in 1972, the PAG approved a document -- Statement 23 -- which affirmed the superiority of breast-feeding whenever possible, while recognizing the need for alternative infant foods when breast-feeding proves impossible for whatever reason.<sup>1</sup>

The PAG pointed to the need for collective action on the part of sovereign governments, United Nations organizations, the various private and public relief groups, members of the health care community, and the infant formula industry, advocating a comprehensive approach to reducing infant malnutrition through a variety of programs at all levels.

Specifically, PAG called on governments and agencies to recognize the urgency of the infant malnutrition problem and to place the development and planning of food sources on a high priority. At the same time, it maintained that it "is clearly important to avoid any action which would accelerate the trend away from breastfeeding."<sup>2</sup>

PAG assigned the role of promoting breast-feeding to the health care profession, while charging governments with the responsibility of ensuring that nutritionally adequate substitute foods be available in the event breast-feeding was not possible.

In 1974, the World Health Assembly initiated a series of studies in nine countries representing a variety of different "geographical, climatic and developmental conditions." The study

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<sup>1</sup> Protein Advisory Group Statement No. 23, Paris, 1972.

<sup>2</sup> Ibid., at 1-2.

found that the decision to breast-feed was related most significantly to whether the mother lived and functioned in a rural or urban community. The overall exposure of mothers to breast milk substitutes was "extensive," but the direct effect of advertising and promotional practices on patterns of breast-feeding was not determined.

Beginning in 1978, the World Health Assembly took up the question of regulating the promotion of breast milk substitutes in developing nations. In October 1979, the Joint W.H.O./UNICEF Meeting on Infant and Young Child Feeding presented a statement of policy which emphasized "that marketing substitutes and weaning foods should be designed not to discourage breastfeeding."<sup>3</sup> The Meeting recommended a ban on:

1. all promotion of breast milk substitutes, supplements and feeding bottles directly to the general public;
2. the distribution of all free samples; and
3. any promotional devices which suggested the superiority of any product over natural mother's milk.<sup>4</sup>

The text was followed in May 1980 by the draft International Code of Marketing of Breastmilk Substitutes which was approved by the W.H.O. Executive Council on January 28, 1981, and forwarded to the World Health Assembly for consideration this month in Switzerland.

Responding to increasing concern over infant formula and its possible adverse effects on nutrition in the Third World, manufacturers of breast milk substitutes met in Zurich in 1975 to organize the International Council of Infant Food Industries (ICIFI). The ICIFI set forth a "Code of Ethics and Professional Standards" which suggested levels of performance regarding advertising, product information, promotion and instructive services for breast milk substitutes. In paragraphs 2, 3 and 4, the Code affirms the superiority of breast-feeding whenever possible and details the importance of informing mothers on the use of infant formula and the necessity of following proper sanitation procedures in its preparation.

Since that time, the industry has continued its emphasis on self-regulation both through the International Council of Infant Food Industries and independent corporate effort.

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<sup>3</sup> World Health Organization, Joint W.H.O./UNICEF Meeting on Infant and Young Child Feeding: Statement, Recommendations, and List of Participants (1979), art. 8.

<sup>4</sup> Ibid., art. 28, 29.

The popular movement opposed to marketing infant formula in developing nations began in earnest in August of 1973 with the publication of an article entitled "The Baby Food Tragedy," which appeared in a British publication called the New Internationalist. The article, which was actually an interview with Dr. R. G. Hendrickse and Dr. David Morley (tropical medicine experts), charged that Western corporations had in part contributed to the problem of infant malnutrition through overly zealous marketing techniques, but that other factors were more to blame.

Shortly thereafter, War on Want, a British charity organization, published a special report entitled "The Baby Killer" authored by journalist Mike Muller. The Muller report synthesized the various charges of promotional malfeasance levied against the formula industry and was rather direct in its accusations, insisting that "Third World babies are dying because their mothers bottle feed them with Western style infant milk...."<sup>5</sup> It further charged that multinational corporations are promoting artificial substitutes which are a prime cause of needless death and disease.

Muller's piece was translated in German and published by a Swiss activist organization, the Third World Working Group, under the title of "Nestle Kills Babies."

One year later, in the spring of 1975, independent film maker Peter Kreig went to Kenya to produce what later became one of the most compelling attacks on the use of infant formula and its promotion in the less developed Third World.

Though the Kreig film has, itself, been attacked by those who participated in it as distorted and deliberately misleading, the Third World Institute in Minneapolis along with other activist groups like the National Council of Churches, began to circulate the piece nationwide. More recent works, including CBS Reports' production of "Into the Mouths of Babes" and the Packard Manse Media's "Guess Who Is Coming to Breakfast," have added fuel to the anti-formula coalition.

On July 4, 1977, the Third World Institute of the Newman Center and the Minnesota Infant Formula Action Coalition simultaneously formed INFAC (Infant Formula Action Coalition) and initiated a nationwide boycott of all Nestle's U.S. products. The boycott was quickly endorsed by a number of social activists, including Ralph Nader, Cesar Chavez, Dr. Benjamin Spock, Drs. Derrick Jellife and Michael Latham. Additionally, the boycott has drawn support from the National Education Association, the National Council of Churches, and strongly leftist groups such as Mother Jones Magazine, Berkeley Citizens Action, and Earthwork.

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<sup>5</sup> Mike Muller, "The Baby Killer" (London: War on Want, 1974), p. 2.

There has been some response from the governments of developing nations. Papua New Guinea, the Philippines, Jamaica and Venezuela have adopted various codes directed at the marketing of infant formula, while other nations are currently considering such a move.

The United States Congress acted positively on legislation promoting the quality of infant formula produced, while refusing to consider several other proposals which would have placed restrictions on the marketing of infant formula domestically and abroad.

#### BREAST MILK IS BEST/THE ROLE OF INFANT FORMULA

The preamble of the Draft International Code of Marketing of Breastmilk Substitutes (ICMBS) states that "...breastfeeding is an unequalled way of providing ideal food for the healthy growth and development of infants." Equally important, the Code recognizes that infant formula has a significant role to play in providing adequate nutrition among children denied breast-feeding:

when mothers do not breastfeed...there is legitimate market for infant formula and for suitable ingredients from which to prepare it; that all these products should accordingly be made accessible to those who need them through commercial or non-commercial distribution systems.

The W.H.O. recognizes, therefore, the need for breast milk substitutes and the critically important role that these products play in stemming the problem of infant malnutrition in the developing world. However, the Code itself is constructed contrary to this stated premise, and in fact penalizes the mother who cannot or does not wish to breast-feed her infant.

The decision to breast-feed depends on several conditions. First, the mother must be sufficiently nourished and free of disease to provide breast milk of adequate quantity and quality for her nursing infant. Secondly, the mother must be free to breast-feed and have access to conditions which allow for successful breast-feeding, independent of constraints placed on mothers forced to work in factories or away from home and children. Thirdly, the mother herself must choose to breast feed her children.

If any of the above conditions are not met, the mother will most likely turn to a breast milk substitute for partial or complete feeding of her children. If infant formulas are not available, then she will be forced to use substitute foods such as cereal gruels made of water and maize, rice or millet flours, crackers, sugar-water or mashed fruits. The nutritional quality of these native foods is low and their nature and consistency make it difficult for children to digest, thereby robbing the child of nutrients vital to proper growth and development.

In these instances, the introduction of infant formula is crucial and fills the nutritional needs of the child whose mother cannot or chooses not to breast-feed. The clearly anti-formula bias contained in the Code may have a correspondingly negative impact on infant nutrition by discouraging the most effective and medically sound alternative to breast milk, rather than upgrading infant health as it claims to.

#### MARKETING OF INFANT FORMULA

The proposed Code rests on the incorrect assumption that marketing practices employed in the promotion of infant formula are the primary cause in the decline of breast-feeding in the developing world, leading eventually to infant morbidity and mortality.

There is, however, little empirical evidence to suggest that changes in traditional patterns of breast-feeding in the Third World have occurred as a direct result of marketing techniques.

Dr. R. G. Hendriske, interviewed in an early article written against the use of infant formula, maintains there are a number of factors which influence the decision to breast-feed, most notably "need to work" and "insufficient milk" on the part of the mother. He added, "it would be a mistake if we believed that the drift away from breast-feeding is entirely due to the seduction of advertising."<sup>6</sup>

W.H.O.'s own study on breast-feeding, reporting information based on interviews with 23,000 mothers, failed to show any causative relationship between commercial activity and breast-feeding practices.<sup>7</sup>

Even so, the Code seeks to regulate only marketing practices and fails to address the more significant causes of the decline in breast-feeding mentioned above. Equally dangerous, the Code eliminates those services provided by the industry designed to aid the mother in preparing and administering the formula to her children.

The use of "mothercraft nurses" or similar personnel is not permitted by the code (see art. 6.4). Preparation and use of infant formula is to be demonstrated by hospital or government health workers only, unnecessarily overtaxing already understaffed hospitals and health clinics and reducing the availability of

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<sup>6</sup> "The Baby Food Tragedy," Interview with Dr. R. G. Hendrikse and Dr. David Morley, *New Internationalist*, August 1973, p. 12.

<sup>7</sup> W.H.O. Collaborative Study on Breastfeeding: Methods and Main Results of the First Phase of the Study (Preliminary Report), W.H.O., MCH, 1979.

information necessary in the proper application of breast milk substitutes.

With the improper mixing and use of infant formulas cited as a major concern among critics of the formula industry, this section of the Code increases the opportunity for error and corresponding infant malnutrition.

Clearly, there is little scientific evidence to justify the notion that marketing practices of industry have been the primary cause of infant death in the Third World. The Code dangerously asserts that infant formula is to blame for premature death in babies, thereby directing attention away from the real killers of children: disease, unsanitary living conditions, impure water and lack of nutritious diet supplements.

#### POLITICAL QUESTIONS AND RAMIFICATIONS

Not only will the proposed Code on breast milk substitutes have a profound impact on the international infant population, but it will also have a pervasive spillover effect in other, non-formula areas. The instituting of a code regulating the marketing and internal business practices of private industry by an international organization would set a dangerous precedence in the arena of world business regulation, particularly in light of similar moves in UNESCO and at the Law of the Sea Convention.

Even though it is currently presented in recommendation form only, Article 11 calls on the ratifying states to take action on the Code "including the adoption of national legislation, regulations or other suitable measures" (Article 11.1). The W.H.O. may also upgrade the current draft code from recommendation to policy by a future vote of the World Assembly. It is important to recognize that the action taken in Geneva this month may lay the groundwork for legislative action in the future which may prove contrary to the free market system.

Second, the Code is to be implemented in all nations who are currently members of the W.H.O. and participate in the Assembly. The draft text would be technically binding on all states whether they voted for it or not and in all regions of the globe regardless of need or existing national law. The effect on consumers by the marketing of infant formula is greatly different in Senegal as opposed to the United States or Great Britain, and the legal restrictions should be tailored accordingly. The proposed text is clearly designed for those regions of the world with a less commercially-sophisticated audience and would be of little value in most Western nations.

Finally, it is important to recognize that several provisions of the proposed Code are fundamentally contrary to U.S. law as it relates to commercial activities in the United States and abroad. The arbitrary prohibition of advertising and product information

dissemination would make its implementation impossible here and in other Western nations with similar free market systems. Secretary of Health and Human Services Richard Schweiker reinforced this view when he declared that the Code could not be "enforced in the United States because it 'runs contrary to the Constitution on the First Amendment' and would violate antitrust laws."<sup>8</sup>

#### INDUSTRY SELF-REGULATION

In 1975, representatives of the infant formula industry met in Zurich to organize the International Council of Infant Food Industries (ICIFI). The Council then prepared a "Code of Ethics and Professional Standards" which:

1. affirmed the preference for breastfeeding when possible (par. 2, 3, 4);
2. calls for "explicitly worded instructions" to safeguard against improper use and preparation of infant formula (par. 5);
3. emphasizes the need for potable water before infant formula is introduced (par. 6);
4. govern the conduct and use of personnel and "mothercraft nurses" and similar personnel (par. 7-12).

In addition to the ICIFI code, several manufacturers have implemented policies to promote breast-feeding and minimize the improper use of breast milk substitutes. Bristol-Meyers, for example, requires that its product labels state that breast milk is the best food for infants and should be used whenever possible. Additionally, the company forbids direct advertising to consumers through the media in developing countries and has hired an outside auditing firm to insure compliance. Bristol-Meyers and Nestle's have both discontinued the use of "mothercraft nurses" and milk-craft personnel.

Though Abbott Laboratories has continued to use "mothercraft nurses," the term of their employment is strictly regulated. Like Bristol-Meyers, they forbid the use of media advertising and restrict formula promotion to medical professionals, providing samples only to health care personnel and at their request. Product labels stress the importance of breast-feeding and instructions have been simplified and pictographs added.

In like manner, Wyeth International has added pictographs to their labels, which declare in bold type that breast-feeding is

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<sup>8</sup> "Rules on Infant Formula Called Unconstitutional," The Washington Post, May 13, 1981, p. A8.



the most preferred method for feeding infants. Wyeth does not distribute samples directly to consumers nor does it use mass media advertising to promote its products. The company encourages health care professionals to evaluate critically the financial constraints placed on each mother before recommending the use of breast milk substitutes.

The industry recognizes the importance of regulating the use, distribution and promotion of infant breast milk substitutes and has demonstrated the success of self-regulation. Volunteer regulation initiated by the private sector is vastly superior in both the long and short run to an international agreement inflexible to location, custom or existing national law, and one which arbitrarily would remove a major portion of the information services available to mothers of the Third World.

## CONCLUSION

There is no doubt that breast-feeding is the most preferred method of infant nutrition. Given a healthy mother, it provides most of the necessary nutrients in a vehicle best suited for the child. Any decision not to breast-feed by mothers capable of nursing their children should be made after carefully weighing all other alternatives.

If a mother then decides to employ a breast milk substitute, either by choice or by necessity, infant formula is vastly superior to native substitute foods and should be readily available.

The proposed International Code of Marketing of Breastmilk Substitutes severely restricts the access and information options available to Third World mothers. The inflexible and often anti-formula nature of the Code distorts the question of breast milk substitute use in such a manner as to be potentially dangerous for the child whose mother cannot or does not want to breast-feed.

There have been abuses and distortions on both sides of the infant formula dilemma in the past. Industry has already demonstrated the ability and desire to impose regulation on itself in line with those dictated by the Code. The implementation of the proposed draft is unnecessary, potentially disastrous and politically dangerous, for it would set a precedent for subsequent regulation of industry in other areas as well.

The problem of infant malnutrition is real and compelling. The draft text currently under consideration in Geneva, however, fails to address the central issues of starvation in developing countries and will act only as an impediment to reducing the suffering of those infants who might otherwise benefit from access to infant formula.

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