
Formula labeling violations to the WHO Code : A quantitative and qualitative analysis

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Background: The WHO Code on Marketing of Breastmilk Substitutes is intended to be adopted as a minimum requirement by all governments and aims to protect infant health by preventing inappropriate marketing of breastmilk substitutes. Labels need to have correct and clear dispositions since they frequently are the only source of vital information for consumers regarding the content of the product and its uses.

Objective: The purpose of this study was to determine violations to the provisions of the International Code Article 9 regarding infant formula labeling existing in Puerto Rico.

Methods: A quantitative and qualitative evaluation of 34 labels of infant formula was done. Instrument 4-A of the IBFAN Monitoring Project (IMPIII) and the Standard IBFAN Monitoring (SIM) was utilized. This instrument included 14 criteria that identified violations to the International Code of Breastmilk Substitutes on labeling. Descriptive analysis was used for all variables. The 34 labels evaluated represent 77.3% of infant

formula labels of the four companies which market them in the island.

Results: All the labels (100%) that were evaluated were found to violate the Code in one or more of its dispositions. Most striking violations include: a statement that breastfeeding is best is lacking in 73.5%, as well as a statement that the product should be used only on the advice of a health worker. None of the labels are written in Spanish, the local language. Text which may idealize the use of infant formula or discourage breastfeeding is present in 97.1% of the samples, and the same percentage has a photo or picture idealizing the use of infant formula.

Conclusions: It is vital to produce legislation that implants the WHO Code in Puerto Rico in order to regulate indiscriminate marketing practices and their subsequent ill effects on children's health and breastfeeding practices

Key words: Formula, Labels, Breastfeeding, WHO Code, Marketing.

The advantages of human milk and breastfeeding and the risks associated with artificial baby milk feeding have been recognized by national and international health organizations (1,2,3). Artificial infant feeding (formula feeding) has been associated with significant lower scores for cognitive development (4), increased risks of urinary tract infections (5); bronchial asthma (6,7); diarrhea, vomiting and medical visits (8); obesity (9, 10); Crohn's disease and ulcerative colitis (11); allergic disease (12, 13); some childhood malignancies (14, 15); otitis media (16); and diabetes mellitus (17), among others.

The marketing practices of the formula companies are oriented towards maintaining among health care providers and the general public the erroneous belief that feeding of artificial baby milk (ABM) is equivalent to breastfeeding (18). Artificial milk does not have the biological complexity and specificity that human milk has and cannot provide infants and children with all the health, nutritional, immunologic, developmental and economic benefits that human milk offers them (2, 19).

The International Code was adopted by the World Health Assembly on May 21, 1981 (20). It is intended to be adopted as a minimum requirement by all governments and aims to protect infant health by preventing inappropriate marketing of breastmilk substitutes. Its Preamble explains that "the marketing of breastmilk substitutes requires special treatment, which makes usual marketing practices unsuitable for these products". In the last 20 years the Code has been endorsed by the World Health Assembly on many occasions and other Resolutions with the same legal status as the Code have been adopted to clarify certain articles and attempt to keep up with changing

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marketing practices (21, 22). A summary of the Code and all its subsequent Resolutions are presented in Table I.

Table 1. Summary of the The International Code and Subsequent World Health Assembly Resolutions

1.	Scope – the Code covers the marketing of all breastmilk substitutes including infant formula, follow-up milks and complementary foods marketed for use before the baby is six months old. Also covers feeding bottles and teats. (Article 2)
2.	The provision of clear information (Articles 4.2, 7.2).
3.	No promotion to the public (Article 5).
4.	No gift to mothers or health workers (Article 5.4, 7.3, WHA 49.15 [1996]).
5.	No promotion to health care facilities (Articles 6.2, 6.3, 4.3)
6.	No promotion to health workers (Articles 7.2, 7.4).
7.	No free samples or supplies (Articles 5.2, 7.4, WHA 39.28 [1986], WHA 45.34 [1992], WHA 47.5 [1994])
8.	No promotion of complementary foods before they are needed (Code preamble; WHA 39.28 [1986], WHA 45.34 [1992], WHA 47.5 [1994], WHA 47.5 [1996]).
9.	Adequate labels: clear information, no promotion, no baby pictures (Articles 9.1, 9.2).
10.	Companies must comply with the International Code (WHA 49.15 [1996], Article 11.3).
11.	Promote and support as optimal exclusive breastfeeding for six months and to provide safe and appropriate complementary foods, with continued breastfeeding for up to two years of age or beyond. (WHA 54.2 [2001]).

The International Code has received many international endorsements, among them are the Innocenti Declaration adopted by the World Summit for Children in 1990 (23, 24) and more recently by the HHS Blueprint for Action on Breastfeeding (25) and the United States Breastfeeding Committee (26). This latter organization is comprised of governmental, educational and not-for-profit organizations which promote and protect breastfeeding in the United States. The organization, endorsed by the Health Resources and Services Administration, developed the strategic plan for breastfeeding in the US which “encourages the implementation of the International Code of Marketing of Breastmilk Substitutes” (26).

The International Baby Food Action Network (IBFAN) was founded at the WHO/UNICEF Meeting on Infant and Young Child Feeding, in Geneva, in October 1979. IBFAN takes action in monitoring the marketing practices of the baby food industry around the world and in sharing and disseminating the information gathered (18). The International Code Documentation Center (ICDC) was created in 1986 by IBFAN, with the task of keeping track of Code compliance by governments and companies (21). Since its foundation, IBFAN has conducted several International Monitoring Projects for the evaluation of Code compliance. The monitoring of the Code does not ban artificial infant food marketing, rather, it assures appropriate marketing. Companies may manufacture and

distribute these products and make health professionals aware of them by providing scientific and factual information. However, the monitoring of the Code sees that the ban for promotion that the Code requires is observed. Promotion is synonymous of advertising and advertising is about persuasion, that often leads to unhealthy choices (27).

Labels need to have correct and clear dispositions since they frequently are the only source of vital information for consumers regarding the content of the product and its uses (21). The purpose of this study was to determine the violations to the provisions of the International Code Article 9 regarding infant formula labeling in Puerto Rico.

Methods

A quantitative and qualitative evaluation of 34 labels of infant formula was done using a non experimental cross-sectional descriptive design. Instrument 4-A of the IBFAN Monitoring Project (IMPIII) and the Standard IBFAN Monitoring (SIM) was utilized. This instrument included 14 criteria that identified violations to the International Code of Breastmilk Substitutes for labeling. To the 14 criteria included in the instrument (see Table II) another one was added to evaluate if the Spanish translation of the labels was present in the reverse of the label. The labels were from infant formula sold in 3 drug stores, 2 supermarkets

Table 2. Labeling Violations of the Code by Criteria

Criteria	n	%
Do not include the words “Important Notice” or their equivalent.	32	94.1
Do not state that breastfeeding is best	25	73.5
There is no warning about the health hazards if not prepared properly.	0	0.0
Do not include a statement that the product should be used only on the advice of a health worker.	31	91.2
Do not include clear and easy to follow instructions for appropriate preparation.	0	0.0
Do not include easy legible expiration date.	0	0.0
It is not written in the local language (Spanish).	34	100.0
Do not include storage instructions.	0	0.0
Do not include batch number	3	8.8
Do not include the composition and ingredients analysis of the product.	0	0.0
Contain terms as “humanized”, “maternalized” or similar terms	25	73.5
Has text which may idealize the use of infant formula or discourage breastfeeding.	33	97.1
Has a photo, a picture or any representation of an infant	2	5.9
Has a photo or a picture idealizing the use of infant formula.	33	97.1

and 2 megastores in the metropolitan area of San Juan. The sample included infant formulas of the four companies that market them in the island: Wyeth, Mead-Johnson, Abbot/Ross and Nestlé, representing 77.3% of the infant formula labels identified as markets by these companies. Descriptive analysis was calculated for all variables. The 34 labels evaluated represent 12 trademarks. The labels were divided by composition type as: 10 regular with iron, six regular low iron, seven from soy and 11 special types (lactofree, hypoallergenic, etc). A division by form was also done resulting in eleven ready-to-feed, eleven concentrated liquid and twelve powder form.

Results

All the labels (100%) evaluated violate the Code in one or more of its provisions (See Table II). Thirty-two (94.1%) do not include the words "Important Notice" or their equivalent, explaining the superiority of human milk over formula (artificial milk). Twenty-five (73.5%) do not even state that breastfeeding is best. Although two brands (Little Ones® by Wyeth) include the words "Important Notice" on the label, the underlying message does not stress that mothers should breastfeed and the consumer is not warned as to what the infant is being deprived of if not breastfed.

Thirty-one (91.2%) do not state that the product should be used only on the advice of a health worker. A carbohydrate-free soy formula made by Ross states that it should be used only under the supervision of a physician. Two formula preparations made by Wyeth under the trade name Little Ones® state that professional advice should be followed on all matters of infant feeding. Some of the remaining studied labels only refer to professional advice on the matter of preparation of the formula and do not clearly state that the use of the product should be only under the direction and supervision of a health professional. All studied labels include clear instructions on preparation as well as a statement on the expiration date.

Thirty-four (100%) are not written in the appropriate language, that spoken by the Puerto Rican people (Spanish). This is a particularly dangerous omission since English is fully understood by only around 10% of the Puerto Rican population. Although 28 brands (82.35%) have instructions in Spanish on the reverse side of the label, reaching these instructions requires removing the label and they are printed in a light gray or blue tint, making reading and comprehension difficult and cumbersome. Moreover, Article 9.2 of the WHO Code states that these instructions be written directly on the container or on a label which cannot be readily separated from it (20).

All studied labels include storage instructions, as well as the composition and ingredients analysis of the product. Three (8.8%) do not include a batch number.

Twenty-five (73.5%) contain terms such as "humanized" or "maternalized". Mead Johnson's Enfamil® claims their product comes closer to breast milk than any other formula. Little Ones® by Wyeth proclaims that it is formulated to be close to mother's milk. Not to be outsmarted, Nestlé/Carnation's Good Start® states that it starts with 100% whey protein, the primary type of protein of breast milk, obviously not specifying that their whey is cow's whey. Similac® by Ross proudly claims that it is improved! (in bright red letters) and is now closer than ever to mother's milk. In beautiful baby-blue lettering it assures parents that even the baby's stools will be softer and similar to those of breastfed infants.

Thirty-three (97.1%) have texts which may discourage breastfeeding and idealize the use of infant formula. Ross uses the physician's image and prestige by stating that its Isomil® formula is the first choice of doctors for common feeding problems. Nestlé/Carnation® claims that its "comfort proteins" in Good Start® helps bring out the very best in babies. Mead Johnson's Enfamil AR® (added rice) is marketed as a formula specially designed for babies who spit up frequently or whose doctor recommends a thickened formula. Ross advises potential buyers of its Similac® with iron formula that the improvements in its protein and fat content make it closer than ever to breast milk and that its recently added nucleotides are compounds naturally present in breast milk. In the label of its *Alimentum®* formula it states (in bold lettering) that breast milk is best for babies except where special medical conditions exist. Once the customer's attention is caught it goes on to proclaim the virtues of *Alimentum®* for infants and children with food allergies, colics due to protein sensitivity or problems digesting protein or absorbing fat.

The WHO Code specifies that neither the container nor the label should bear pictures of infants nor should they have other pictures which may idealize the use of infant formula. Two (5.9%) of the studied labels have a photo or other representation of an infant, while thirty-three (97.1%) of them have photos or pictures idealizing the use of infant formula. The Little Ones® brand made by Wyeth has a drawing of a smiling baby in its label. In most other brands, the use of baby faces has disappeared and has been replaced with beautiful animals and cartoon characters. Abbott-Ross utilizes a brown and lovely teddy bear. Mead Johnson uses the Peter Rabbit character made famous in Beatrix Potter's writings. In Puerto Rico and in the United States, where there are no restrictions on promotion, the baby rabbit is being given a milk bottle. In countries with legal regulations, such as Mexico and Colombia, the bottle

is omitted (18). Nestlé uses a mother duck and her duckling enraptured with love, a mother and a baby butterfly, as well as pink heart representations which break up into the “comfort proteins” and go into the milk bottle, symbolizing the love which is transmitted through the formula.

Discussion

Aggressive marketing strategies of artificial milk manufacturers, in open violation of the WHO Code, constitute a significant threat to the health of mothers and children. The feeding of our children with artificial milk (formula) is presently considered as equivalent to breastfeeding by a large majority of the lay public and, unfortunately, by health professionals and by their professional organizations (18, 28). At this very moment, the international organizations which protect and promote breastfeeding are protesting the American Academy of Pediatrics (AAP) decision to allow Ross Pharmaceuticals distribute the Academy’s booklet on breastfeeding with Ross’ logo attached. The confusion and ethical insensitivity has reached such levels. The promoters of breastfeeding have even allowed ourselves to be placed on the defensive and many times we insist on the “benefits of breastfeeding”, rather than basing our work on warning the public and the health professionals on the dangers and risks attached to artificial feeding. With this prevailing scenario, the manufacturers of artificial milks have exploited the false paradigm of “free choice” for mothers, as if we were talking of equivalent options (18, 28). As we struggle for higher rates of exclusive breastfeeding in the first six months, and for higher rates of prolonged breastfeeding beyond the first year, the application of the WHO Code becomes a necessary and very useful tool. Our colleagues who have fought the tobacco companies for so many years have proven that it can be done. The “smoking trail” left behind shows us the way. The promoters of unrestricted advertising will raise, again and again, the specter of free speech and free enterprise. They will attack, as they have done in the past, the promoters of breastfeeding as fanatics who prefer to hurt the economy and our democratic way of life in order to attain our goals. Nothing farther from the truth. Regulation of commercial “speech” is fundamentally different from noncommercial speech (29, 30). Government has the right, and exercises it continuously, to verify the truth behind claims in commercial ads and to forbid those which are false.

The truth is that formula manufacturers utilize the prestige of health professionals and health facilities as tools for their marketing strategies. It is not an accident that the studied labels claim the favor and support of doctors for their products. In exchange, they pour hundreds

of thousands of dollars into the health care facilities in order to channel their products through them. There must be no doubt in our minds that private profit must not prevail against public health. Big industry must not be allowed to hurt our children and their mothers for a profit. The WHO Code does not forbid the manufacture and sale of artificial milks. It pursues rational, evidence-based advertising of these products for those situations when they are necessary. Obviously, these cases are the minority and not the majority. Most mothers should breastfeed according to the international recommendations since most do not meet any contraindications to breastfeeding.

Legislation is necessary at all levels in order for the Code to become a reality (31). A bill presently being studied in the Puerto Rico legislature purports to provide legal status to labeling regulations for artificial milks and baby foods (32), another prohibits the distribution of free samples, gift coupons etc (33), and a third one (34) forbids the use of public money to provide incentives for artificial feeding. Another bill (35) will prohibit indiscriminate use of artificial milks in hospitals in the island, unless there is a valid medical indication for doing so. Another bill strives to incorporate the WHO Code in its entirety (36). The wheels of the formula manufacturers are already turning in efforts to abort these bills, and they are using the same arguments presented in other jurisdictions. Doom will fall on the Puerto Rico economy if these bills are passed, according to these spokespersons for the industry. Notwithstanding these threats, 17 countries all over the world have incorporated the WHO Code in their legal systems, and 49 others include some aspects of the Code in their laws (21).

Another reason why adopting the WHO Code is necessary is the Baby Friendly Hospital Initiative (BFHI). Puerto Rico is far behind the international community in this regard, with no Baby Friendly Hospitals and only two hospitals presently holding certificates of intention. With over 16,000 Baby Friendly hospitals worldwide, the United States only has 32 Baby Friendly hospitals (28). The American Hospital Association recommended that members not embrace the BFHI program because it might contribute to unfair marketing competition among hospitals, represent an unwelcome intrusion, and is a potential added expense (28). The hand of the formula manufacturers is again evident. The reason why there are so few Baby Friendly hospitals in the USA, and none in Puerto Rico, is that these hospitals must comply with an institutional philosophy of not accepting donations from formula manufacturers which promote artificial feeding (37). Formula manufacturers’ donations to hospitals constitute big money for these institutions.

Health professionals must increase their awareness of

the importance of these economic and social issues which have a significant impact on public health. We are ethically bound to honor our commitment to health and must not be influenced by the financial interests of any company. Our objective should be the wellbeing and health of the community we serve, and we must refuse to be the pawns of the artificial milk industry. Our active involvement in legislative actions in favor of the WHO Code, and in gaining for our hospitals the Baby Friendly credential, will place our professional prestige on the side of our patients and our communities. Our inaction, on the other hand, will be used by industry for their commercial interests at the expense of the health of our people.

Resumen

Trasfondo: El Código de Comercialización de Sucedáneos de la Leche Materna de la OMS intenta que se adopte como un requerimiento mínimo de todos los gobiernos para proteger la salud del infante y prevenir la comercialización inadecuada de los sucedáneos de la leche materna. Las etiquetas necesitan tener unas disposiciones claras y correctas ya que frecuentemente éstas son la única fuente de información vital para los consumidores acerca del contenido y uso del producto. El propósito de este estudio fue determinar las violaciones a las disposiciones del Artículo 9 del Código Internacional con relación al etiquetado de fórmula para infantes en Puerto Rico. **Método:** Se realizó una evaluación cuantitativa y cualitativa de 34 etiquetas de fórmula para infantes. Se utilizó el instrumento 4-A del Proyecto de Monitoreo IBFAN (IMPIII) y del Monitoreo Estándar de IBFAN (SIM). Este instrumento incluye 14 criterios que identifican violaciones del Código Internacional de Sucedáneos de la Leche Materna en etiquetado. Se usaron análisis descriptivos para todas las variables. Las 34 etiquetas evaluadas representan el 77.3% del etiquetado de fórmula para infantes de las cuatro compañías que las mercadean en la isla. **Resultados:** Todas las etiquetas (100%) evaluadas violan el Código en una o más de sus disposiciones. Las violaciones más llamativas incluyen: la carencia de una declaración de que la lactancia es lo mejor en el 73.5%, así como una declaración de que el producto sólo debe usarse bajo el consejo de un trabajador de la salud. Ninguna de las etiquetas estaba escrita en español, la lengua local. Textos que pueden idealizar el uso de la fórmula para infantes o desalentar la lactancia están presentes en el 97.1% de las muestras, y el mismo porcentaje tiene fotos o dibujos idealizando el uso de la fórmula para infantes. **Conclusión:** Es vital producir legislación que implemente el Código OMS en Puerto Rico

para regular estas prácticas indiscriminadas de comercialización y sus subsecuentes efectos dañinos en la salud de los niños y las prácticas de la lactancia.

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