

Dangerous liaisons: The health worker-industry relationship

If breastfeeding, with all its benefits, is to be established as a majority activity, we paediatricians must learn to recognise the elaborate web woven around us by formula manufacturers, which currently ensures our goodwill and support for a product that we may acknowledge, but would mostly not wish to actively promote.

- Wright C.M., Waterston A.J.R., "Relationships between paediatricians and infant formula milk companies", Archives of Disease in Childhood, 91: 383-385, 2006.

Article 7. Health Workers

- 7.1 Health workers should encourage and protect breastfeeding; and those who are concerned in particular with maternal and infant nutrition should make themselves familiar with their responsibilities under this Code, including the information specified in Article 4.2.
- 7.2 Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code should be restricted to scientific and factual matters, and such information should not imply or create a belief that bottle feeding is equivalent or superior to breastfeeding. It should also include the information specified in Article 4.2.
- 7.3 No financial or material inducements to promote products within the scope of this Code should be offered by manufacturers or distributors to health workers or members of their families nor should these be accepted by health workers or members of their families.
- 7.4 Samples of infant formula or other products within the scope of this Code, or of equipment or utensils for their preparation or use, should not be provided to health workers except when necessary for the purpose of professional evaluation or research, at the institutional level. Health workers should not give samples of infant formula to pregnant women, mothers of infants and young children, or members of their families.
- 7.5 Manufacturers and distributors of products within the scope of this Code should disclose to the institution to which a recipient health worker is affiliated any contribution made to him or on his behalf for fellowships, study tours, research grants, attendance at professional conferences, or the like. Similar disclosures should be made by the recipient.

The following resolutions clarify Article 7, in particular on the issue of sponsorship and conflicts of interest.

WHA resolution 47.5 [1994]

Member States are urged to ensure that all health personnel concerned are trained in appropriate infant and young child feeding practices, including the application of the principles laid down in the joint WHO/UNICEF statement on breastfeeding and the role of maternity services.

WHA resolution 49.15 [1996]

Member States are urged to ensure that the financial support for professionals working in infant and young child health does not create conflicts of interest, especially with regard to the WHO/UNICEF Baby Friendly Hospital Initiative.

WHA resolution 58.32 [2005]

Member States are urged to ensure that financial support and other incentives for programmes and health professionals working in infant and young child health do not create conflicts of interest.

WHA resolution 61.20 [2008]

Member States are urged to strengthen implementation of the International Code of Marketing of Breastmilk Substitutes and subsequent relevant WHA resolutions by scaling up efforts to monitor and enforce national measures in order to protect breastfeeding while keeping in mind the WHA resolutions to avoid conflicts of interest.

Minimising the impact of commercial promotion

Article 7.1 makes health workers responsible for the encouragement and protection of breastfeeding. Many health workers, however, inadvertently assist manufacturers and distributors in their marketing in ways which undermine breastfeeding. The situation is compounded by the low level of awareness amongst health workers regarding the real risks of artificial feeding. While the Baby Friendly Hospital Initiative³⁰ has made major inroads in educating health workers, there are still many doctors, nurses and other health workers who believe that artificial feeding, mostly administered by feeding bottle, is a good alternative to breastfeeding. In the long run, this should be addressed by improving the pre-service curriculum and training of health workers to include breastfeeding and lactation management, in line with WHA resolution 47.5 [1994]. In the meantime, Code provisions and resolutions must be introduced into the work policies of all health care settings to ensure that misleading information and promotion is not allowed to distort health workers' perceptions.

Manufacturers and distributors sometimes offer educational materials (videos, brochures and posters) for health workers to promote breastfeeding. Nothing in Article 7.1 requires companies to do this.³¹ Companies benefit from having such breastfeeding materials to create dependency and build trust with mothers. At the same time, they subtly undermine good practice with misleading information and instill familiarity with the company name and products. Indeed, WHA resolutions urge Member States to prevent such conflicts of interest. (See pages 24 and 25)

Profiting from failure of breastfeeding

Infant formula manufacturers have a duty to their shareholders to maximise sales of their products, which by definition means minimising exposure of infants to breastmilk. Hence while publicly stating their commitment to breastfeeding, ... infant formula milk companies are in fact profiting from the failure of breastfeeding.

Wright C.M., Waterston A.J.R., "Relationships between paediatricians and infant formula milk companies", *Archives of Disease in Childhood*, 91: 383-385, 2006.

Article 7.2 allows manufacturers and distributors to provide information materials to health professionals regarding products covered under the scope of the Code. This type of product information is only for health professionals, not for the wider class of health workers and should be scrutinised carefully. Anything that is not restricted to matters that are factual and scientific, and anything that implies or creates a belief that artificial feeding is equivalent or superior to breastfeeding, should be rejected.³²

Myths of small gifts

One way for manufacturers and distributors to forge links with health workers is by offering them personal benefits and gifts, a practice forbidden by Article 7.3. The financial and material inducements referred to under Article 7.3 can take many forms. Gifts, regardless of value, create brand awareness and corporate goodwill. They act as inducements for health workers to recommend the company's products. Despite the clear provisions of Article 7.3, some manufacturers and distributors allow their marketing personnel to offer low-cost items of professional utility or "culturally appropriate" gifts to health workers.³³

There is a widely accepted assumption among health workers that small gifts do not significantly influence professional behaviour, but research findings using a variety of methods have called the validity of this assumption into question.³⁴

30 See pages 32–33 for a description of the Baby Friendly Hospital Initiative (BFHI).

31 Paragraph 44 of the "Global Strategy on Infant and Young Child Feeding" confines the role of companies to ensuring quality of their products and compliance with the Code and resolutions.

32 See analysis of company materials in the part on *Manipulating information* on page 14. See also discussion in the part on *Information to health professionals* on page 15.

33 Nestlé Instructions for Implementation of the WHO International Code of Marketing of Breastmilk Substitutes (updated July 2004).

34 Brennan T.A. et al, "Health industry practices that create conflicts of interest", *Journal of American Medical Association*, 295:429-433, 2006.

Social science research demonstrates that the impulse to reciprocate for even small gifts is a driving force behind people's behaviour. Individuals receiving gifts are often unable to remain objective; they reweigh information and choices in light of the gift or the gratitude they feel for it. Even when gifts are offered with no explicit "strings attached" there is still an implicit expectation of some kind of reciprocity. Since even gifts of minimal value carry influence, health workers should subscribe to a "no gift" ethos and extend the same principle to family members in line with Article 7.3.

Me ? No ! Others ? Yes !

While most doctors consider themselves immune to manipulation by drug representatives and their gifts, they consider that such activities will influence other doctors.

J.W. Foppe van Mil., "Influences of prescribing," Pharm World Sci, 28:1-2, 2006

Samples for professional evaluation or research

Some manufacturers and distributors interpret Article 7.4 to mean that they are able to provide samples to individual health workers when they want to introduce a new product, a new formulation of an existing product or to introduce a range of products to newly qualified health professionals.³⁵ This is a ruse for promotion which cannot be supported by the plain wording of Article 7.4. These samples are usually provided in bulk and passed on to mothers as intended by manufacturers and distributors. The distribution of samples to pregnant women, mothers or members of their families are specifically forbidden by Article 7.4. There is only one exception to the ban on samples: professional evaluation or research at the institutional level. In most health care settings, this would require protocols and approval by ethics committees. Health workers should bear in mind that the very notion of using free samples to conduct professional evaluation and research gives rise to ethical concerns. The use of free samples may induce babies into being artificially fed or to cease breastfeeding causing potential harm to both mothers and babies. In order to avoid this ethical problem, any professional evaluation or research involving infants should require mothers' written consent after they have been properly counselled on the risks of artificial feeding. Ideally, products used in professional evaluation and research should be purchased, not acquired as free samples. This is because company-supported research is known to produce results favourable to company products and when they are not favourable, companies restrict the dissemination of the research results.³⁶

Problems with sponsorship and disclosures

The most effective and insidious way in which manufacturers and distributors forge links with health workers is by providing them with contributions for their professional development such as fellowships, study tours, research grants, attendance at professional conferences, etc. Manufacturers and distributors use sponsorship as a marketing strategy to create the image that they are responsible corporate citizens and to link their name to health professionals and prestigious organisations. Article 7.5 allows these types of sponsorship even though it can create conflicts of interest. The only safeguard provided by Article 7.5 is the need for manufacturers and distributors and recipients to disclose the contribution to the institution to which a recipient is affiliated with. The assumption that disclosure is sufficient to prevent health workers entering into conflict of interest situations is unfounded for the following reasons:

- Health workers differ in what they understand and consider to be a conflict of interest, which makes the disclosure of conflicts incomplete.
- Declarations of conflict of interest are usually unverified, casting doubts on accuracy.
- Disclosure may be used to "sanitise" a problematic situation, suggesting that no ill effects will follow from the disclosed relationship.³⁷

Article 7.5 is a weakness in the Code as financial or other support by manufacturers and distributors goes a long way towards providing goodwill and wielding influence over health workers. Companies spend considerable sums, mostly from their marketing budgets, on sponsorship with the intention of obtaining a proportionate return for the money invested, calling into question the professionalism and the integrity of the beneficiaries of their largesse. For this reason, it is important to remember the later resolutions which address this problem (see page 25).

³⁵ supra footnote 33.

³⁶ Brennan T.A. et al, "Health industry practices that create conflicts of interest", Journal of American Medical Association, 295:429-433, 2006.

³⁷ ibid.

Responding to conflicts of interest

'Conflict of interest' means a conflict between the private interest and the official responsibilities of a person in a position of trust.³⁸ Health professionals have specialised knowledge and hold the trust of their patients. As patients are in no position to check whether health professionals are acting solely for their benefit or have been influenced by some personal interest, a duty to avoid conflicts of interest is implied. A conflict of interest exists even if no unethical or improper act results from it.³⁹

Conflicts of interest do not only apply to professionals. In the context of infant and young child feeding, a conflict of interest arises every time anyone (including a non-professional health worker or health educator) whose duty is to promote breastfeeding accepts gifts from manufacturers and distributors. The term 'conflict of interest' also covers any situation in which an individual or an organisation (whether private or public) is in a position to exploit a professional or official capacity in some way for their personal or organisational benefit.

A non-exhaustive list of actions that would give rise to conflicts of interest situations is:⁴⁰

- acceptance of gifts, even of relatively small items, including meals;
- acceptance of payment for attendance at lectures and conferences, including online activities;
- acceptance of fellowship for continuing medical education;
- acceptance of fees for time while attending meetings;
- acceptance of funding for travel to meetings or fellowships to attend meetings;
- acceptance of samples;
- acceptance of grants for research projects;
- acceptance of payment for consulting relationships; and
- the provision of ghost-writing services.

“Sponsorship by its nature creates a conflict of interest. Whether it takes the form of gift items, meals, or help with conference expenses, it creates a sense of obligation and a need to reciprocate in some way. The “gift relationship” thus influences our attitude to the company and its products and leads to an unconscious unwillingness to think or speak ill of them.”

“Even if individuals are uninfluenced by sponsorship and subsequently act wholly responsibly in relation to breast and formula feeding, by accepting sponsorship or speaking at an infant formula milk company meeting they still lend credibility to the company by the visible association of their name and position with that company.”

Wright C.M., Waterston A.J.R., “Relationships between paediatricians and infant formula milk companies”, Archives of Disease in Childhood, 91: 383-385, 2006

There are three WHA resolutions on infant and young child nutrition which caution against conflicts of interest, namely WHA resolution 49.15 [1996]; WHA resolution 58.32 [2005] and WHA resolution 61.20 [2008]. The 1996 resolution calls for caution in accepting financial support for health professionals working in infant and young child health which may create conflicts of interest. The need to avoid conflicts of interest is repeated in 2005 and expanded to cover programmes. The word “programme” is not explained but using its ordinary dictionary meaning, would cover a planned series of events or ongoing services. In the context of infant and young child nutrition, these can include support for research, community out-reach activities and multiple, ongoing and inter-dependent projects implemented within schools and colleges, medical or health education. The need to avoid conflicts of interest was reiterated in the 2008 resolution within the context of Code implementation and scaling up of efforts to monitor and reinforce national measures to protect breastfeeding. Article 7.5 of the Code has to be read in the light of these three resolutions.

38 Merriam-Webster online dictionary, 2005.

39 Paraphrased from http://en.wikipedia.org/wiki/Conflict_of_interest (accessed on 27 Nov 2008).

40 Adapted from Brennan T.A. et al, “Health industry practices that create conflicts of interest”, Journal of American Medical Association, 295:429-433, 2006.

Drawing the line between the unacceptable from the permissible

The best way to deal with conflicts of interest is to avoid them completely. However, unless national laws which implement the Code include a specific ban on sponsorship and other interactions with industry, it will not always be possible to avoid every conflict-of-interest situation. Moreover, not all conflicts of interest are the same. Some may be very serious and should be prohibited at all costs. Others may be minor and could be permitted with appropriate management.

Questions for assessing the seriousness of a conflict of interest include:⁴¹

- What is the probability that professional judgment will be influenced by financial interest and ties?
- What kinds of risks are posed?
- How serious might the consequences be?

Serious consequences include not just avoidable harm to infants and young children, or to society, but also the insidious damage associated with the loss of public confidence. To draw the line between the unacceptable and the permissible, there must be an evaluation of the value of an activity to society. Some conflicts of interest may stem from an action or relationship that is considered socially desirable. Looking at the value of an activity to society should not be interpreted as an invitation to disregard the problem of conflicts of interest. There may be alternatives which may create fewer or less serious conflicts of interest and one should investigate how best to mitigate predictable ill effects from unavoidable conflicts of interest. Tables 1 and 2 below may help to decide whether or not a conflict of interest situation is unacceptable or permissible.

Table 1* Which types of businesses should be avoided	
Definitely	Any manufacturer and distributor whose main product is breastmilk substitutes, bottles or teats.
Arguably	Any manufacturer and distributor who markets other clinical products using a name clearly identified with breastmilk substitutes and feeding bottles and teats.
Not usually	Any company that sells, among other products, infant formulas, e.g. a supermarket might generally be an acceptable sponsor, but not if this was linked to their promotion of breastmilk substitutes, feeding bottles and teats.

Table 2* What sort of sponsorship should be avoided	
Within an organisation or association	Reason to be avoided
The use of leaflets or posters displaying name and logo of manufacturer and distributor	Promotes company to public in trusted environment
Development of publications, brochures etc. on infant and young child feeding	Link of company name to organisation enhances the credibility of company products
Support from manufacturers and distributors for teaching sessions or meetings	Publicity will associate organisation with the company
Support for staff salaries, equipment, or research	Organisation will be indebted to the company, tending to stifle expressions of doubt about their products or practices
Support for programmes	Conveys impression that company is health-giving even if products may cause harm to children's health
As an individual	Reason to be avoided
Accepting gifts of stationery, pens, clinical equipment	You promote the company to your patients by using them
Speaking at meetings sponsored by companies	Publicity will be used to promote the company and link your name to it
Support for attending a conference or course	You will feel indebted to the company and be inclined to expect such support in future
<small>*Adapted from Wright C.M., Waterston A.J.R., "Relationships between paediatricians and infant formula milk companies", Archives of Disease in Childhood, 91: 383-385, 2006</small>	

It should be noted that the International Baby Food Action Network (IBFAN) is against sponsorship of any sort while a few professional associations have guidelines which seek to prevent conflicts of interest.⁴²

41 Richter, J. "Conflicts of Interest and Young Child Feeding", IBFAN-GIFA, 2005.

42 The International Paediatric Association (IPA), for example, drew up a set of guidelines in 2005 to govern its relationship with industry. IPA states in the guidelines that it fully supports the Code and resolutions. The guidelines also determine that donations will not be accepted from organisations or industries directly engaged in negative practises including violations of the International Code of Marketing of Breastmilk Substitutes. In Britain, the UNICEF UK Baby Friendly Initiative prohibits the acceptance of funding from companies which manufacture food or drinks for infants and young children. See also footnote 6.

Taking a stand against sponsorship of events

Individual health workers are increasingly faced with the question of whether to participate in industry sponsored events such as seminars, exhibitions and conferences.

In considering whether to attend any such event, it helps to go through the following checklist:⁴³

- Have the event's organisers been told why sponsorship of the event is objectionable?
- Have suggestions been provided for alternative sources to fund the event?
- Is the sponsorship in any way directly "benefiting" the participant? (meals, gifts etc.)
- Will health workers compromise their ability to be a critical voice for breastfeeding protection?

If the decision has been made to participate in the event, health workers should consider **whether**:

- Participation is tantamount to endorsing company practices?
- There could be transference of their good image onto the company and/or the event itself?
- Participation might be used against them in the future?
- Participation would send out mixed messages about their expressed principles?
- The meeting is likely to provide information, contacts, opportunities for learning and interaction with key actors not available elsewhere or in other ways?
- Any difference would be made through their technical/strategic presentations?
- Any interventions could be made to raise awareness of the sponsorship and conflicts of interest?
- If going as speakers, whether there will be an opportunity to publicly express discontent about the sponsorship in a noticeable manner e.g. in a keynote speech or on a panel?
- Speeches/abstracts will be used/published in company materials or in conference announcements or reports, which also contain advertisements for breastmilk substitutes or feeding bottles and teats?
- The sponsoring company is subject to any NGO campaign or boycott for abuses regarding labour, environment or human rights either in the country where the event is taking place or elsewhere in the world?

If the final decision is not to attend the event, the ethical reasons behind the decision should be made known to the organisers.

If the decision is made to attend, there should be an explanation of that decision to the institution the health worker is affiliated to, for accountability and consistency.

Professional associations have to act responsibly on behalf of members. The points which individual health workers must consider apply equally to associations, so the office bearers have a primary duty to question offers of sponsorship. Pressure to accept may be high. Where sponsorship is offered for events which professional associations are themselves organising, alternatives should include the option to scale down the luxury of the event like using college or hospital auditoriums instead of five-star hotels.

Conflicts of interest principles are aimed at minimising conditions that would cause reasonable persons (patients, colleagues and citizens) to believe that professional judgement has been influenced and loyalties have been divided, whether or not they have been. Applied in the context of infant and young child feeding, health workers and professional associations whose duties under the Code are to promote breastfeeding should steer away from any interaction with companies whose practices might be detrimental to infant and young child health.

⁴³ Modified from "Guidance for IBFAN groups and members on participation in events sponsored fully or partially by companies with commercial interest in infant and young child feeding", IBFAN-GIFA, 2006.

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