

## Position Statement

### Guidelines for the Funding of Paediatric Research by Formula Companies

#### Summary

1. Paediatricians promote breastfeeding for all healthy infants. Paediatricians recognise that some mothers are unable to breastfeed, and that some infants are unable to tolerate breastmilk, and that therefore formulae are important for the health and wellbeing of some children.
2. Paediatricians recognise the possible conflict of interest created by accepting funds for paediatric and/or nutritional research from formula companies. Therefore, applications for alternative funding from bodies who peer-review projects, such as the NH&MRC, are encouraged for projects for which funding by a formula company is considered.
3. If funding from a formula company is accepted, it is imperative that:
  - study design and data collection are controlled by the investigator
  - the investigator has total control of data presentation and publication
  - funding is clearly acknowledged in all presentations
  - the investigator's department and institution are aware of the funding company.
4. Researchers need to be made aware that association with formula companies may result in:
  - exclusion as a speaker from some meetings, seminars and conferences
  - exclusion from the Editorial Board of some journals
  - rejection of papers submitted for publication by some journals
  - perception by some of reduced scientific credibility.
5. Women considering breastfeeding, establishing breastfeeding or successfully breastfeeding, should not be approached by those investigating formula, except for enrolment as a reference group.

Researchers should avoid providing inducements to formula-feed, such as providing formula free of charge to healthy infants when the formula is commercially available.

6. The Paediatrics & Child Health Division endorses the *Ethical Guidelines in the Relationship Between Physicians and the Pharmaceutical Industry* published by The Royal Australasian College of Physicians in 1994.

#### Background

Members of the Paediatrics & Child Health Division who seek funding for nutritional research have requested guidelines concerning the appropriateness of accepting funds for paediatric research from formula companies. This document aims to develop guidelines which protect the promotion of breastfeeding and limit collaboration compromising professional integrity and scientific rigour. It is hoped that the guidelines will be helpful to both researchers and industry. For example, guidelines could be useful when researchers are

asked to sign contracts. Similarly, guidelines may limit companies withdrawing support because of uncertainty about what is acceptable practice. Guidelines from the Paediatrics & Child Health Division might also provide a valuable model for countries in Asia and the Pacific where formula manufacturers are currently working hard to persuade health professionals to recommend their products.

Funding of paediatric research by manufacturers of infant formula is a complex and controversial topic. Antagonism is based on the health problems associated with the inappropriate promotion of formula and the detrimental effect it has on global health. Formula companies have a history of actively promoting their product in competition with breastfeeding to the detriment of infant health. The International Baby Food Action Network surveyed the marketing practices of the formula companies world wide in 1994 and reported non-compliance with the World Health Organization (WHO) requirements by most companies. In Australia, companies are signatories to a voluntary agreement on the Marketing in Australia of Infant Formula. The agreement is monitored and interpreted by an independent panel: the Advisory Panel on the Marketing in Australia of Infant Formula <sup>1</sup>. The first report in 1994 documented 36 breaches of the agreement, the 1995 report documented four breaches involving one company and the 1996 report, nine breaches involving three companies. Similarly, in other countries, many formula companies regularly break WHO Code <sup>2</sup>.

There is convincing evidence that protection, promotion and support of breastfeeding is an important and cost-effective public health strategy. As child advocates, we need to ensure infant nutrition is optimal, and for an infant whose mother has decided not to breastfeed, alternative milk must be of optimal quality. Paediatricians also rely on formula companies to develop products for infants with specific medical problems such as malabsorption or metabolic disease. Research into the short and long-term effects of infant nutrition is essential, funding is difficult to obtain, especially for long-term clinical studies, and manufacturers of formula are in a position to contribute to such funding.

Concerns have been raised that accepting sponsorship from formula manufacturers creates a conflict of interest and that acceptance by health professionals is endorsement by association and gives industry credibility. Jelliffe suggested that “the medical and nursing profession can sometimes be very naive in their interactions with commercial companies so that mixtures of ‘manipulation by assistance’ and ‘endorsement by association’ are very frequently and successfully used promotional methods, usually unperceived, minimised, or tolerated by the physicians, nurses and nutritionists concerned” <sup>3</sup>. The Nursing Mothers’ Association of Australia (NMAA) believes that formula company sponsorship of paediatric research exists only to further the commercial interests of the formula company which may not be compatible with promoting optimal health world-wide.

The WHO International Code on the Marketing of Breastmilk Substitutes (WHO Code) received endorsement from the World Health Assembly in 1981 <sup>4</sup>. The WHO aims to protect the well-being of all infants through the protection and promotion of breastfeeding, and the appropriate use and marketing of breastmilk substitutes, bottles and teats when these are necessary. The Code does not address research funding except in Article 7.5: “Manufacturers and distributors ... should disclose to the Institution with which a recipient health worker is affiliated, any contribution made to him or on his behalf for fellowships, study tours, research grants, attendances at professional conferences or the like. Similar disclosures should be made by the recipient”. The interpretation is that, before acceptance of a grant, the health

worker should be aware of the potential for conflict of interest and discuss possible implications with his/her employers and/or professional associations.

In May 1996, the WHO's governing body, the World Health Assembly, passed a resolution urging health institutions, professionals and ministries in all member states to prevent the baby food industry from providing financial or other support for health workers (WHA Resolution 49.15)<sup>5</sup>.

In this document, the arguments for and against funding are directed to paediatric research. However, discussion could be expanded to include the acceptance of formula company funds for seminars, visiting speakers, scholarships and prizes, and allowing formula companies to mount trade exhibitions at scientific meetings and to advertise their formula in scientific journals. The Paediatrics & Child Health Division Travelling Fellowship is currently funded by a formula company. Advertising of formula is commonplace in the *Journal of Paediatrics & Child Health*.

The Indian Academy of Pediatrics, the Indian Medical Association and the Pakistan Pediatric Association will not accept funding from formula companies. Such examples from resource-poor countries put pressure on health professionals and researchers in developed countries who continue to accept funding from the companies. The Royal College of Paediatrics and Child Health (formerly the British Paediatric Association) is under pressure to cease receiving funds from formula manufacturers. Journals such as *Acta Paediatrica Scandinavica* and *Journal of Tropical Paediatrics* no longer accept advertisements from formula companies. At some Australian universities, paediatric prizes funded by formula companies have been revoked. Concern has been expressed that industry attempts to buy allegiance of health workers with special awards and gifts.

The discussion needs to be kept in the context of industry funding of pharmaceutical trials. In some countries, such as Canada and France, guidelines prevent doctors accepting gifts, including free or subsidised conference travel, from formula or pharmaceutical companies. The Royal Australasian College of Physicians has established *Ethical Guidelines in the Relationship Between Physicians and the Pharmaceutical Industry*. The Paediatrics & Child Health Division has developed the following guidelines specifically concerning formula companies because formulae have been blamed for increased infant mortality and morbidity in developing countries and formula-feeding directly competes with breastfeeding.

### **Methods**

The Nutrition Committee was asked to develop guidelines for the funding of paediatric research by formula companies. Members of the Nutrition Committee, researchers in infant nutrition and national and international organisations concerned with the promotion of breastfeeding were contacted (see list on last page).

### **Results**

Suggestions varied from the complete banning of formula sponsorship of research to treating formula companies the same as the pharmaceutical industry. There was almost general agreement that the infant formula industry is a legitimate industry making a needed product and therefore prohibiting any interaction with researchers was inappropriate but that guidelines are needed to protect efforts to promote breastfeeding.

Suggestions included the following:

- Research funding from formula companies should only be allowed under strict Paediatrics & Child Health Division guidelines.
- All funding from industry must be acknowledged in presentations and publications: The researcher must have the initial and final say on experimental design, control of all data and analysis and control of publication including content, journal selection and timing of submission. Authorship should be restricted to investigators with no industrial affiliation. Complete editorial control is essential when funding is accepted. Funding should be accountable with no cash, travel or gift incentives. No special payments should be made to investigators, hospital or associate clinicians. All funds should be administered by the institutional home of the chief investigator.
- The Paediatrics & Child Health Division should:
  - Write a strong statement that informs all vested interest groups (industry or its critics) that a scientific or professional body will listen to any concerns expressed and develop reasonable approaches to research problems;
  - Ban (or at least restrict and monitor) all sponsorship by any commercial interests (formula, drug, agricultural) wherever there is any conflict of interests;
  - Promote the WHO code with the new NH&MRC Guidelines and APMAIF interpretations.
  - Endorse funding guidelines which include:
    - untied or arms-length funding to the research institute, not the researcher or the project;
    - involvement of independent critics (on a basis of confidentiality) at both formulation and analysis stages of the research;
    - public acknowledgment of the sources (and perhaps even terms) of funding in all publications and presentations;
    - the unfettered right to publish results regardless of outcomes, and to comment publicly if outcomes are being misrepresented or distorted.
- Ongoing profession-based analysis of research being generated is necessary to assess the impact of industry inputs, not only on what is done but also on omissions in research, i.e. areas never funded but needed.
- Guidelines are essential for formula companies. Companies have withdrawn funding from organisations because they were unsure of what was considered acceptable practice due to lack of clear guidelines.
- Research to improve formula was generally seen as necessary as there are reasons why mothers cannot breastfeed (e.g. breast abnormalities, maternal drug therapy, adopted infants) and some mothers, despite best intentions, cannot produce enough milk. There are also medical conditions for which formula is an essential part of the management. These mothers and their children need a safe alternative. However, companies should be “at arm’s length” from the investigators. Means to facilitate this include a nutritional trust fund controlled by a third party and a register of all formula-funded studies.

- Manufacturers and importers of formula should not use any facility of the health care system for promoting infant formula. They should not offer any financial or material inducement to health care professionals to promote formulae. Inducements should not be accepted by health care professionals. Sponsorship of conferences, seminars or publications should be declared. The sponsor should not market their products or interfere with the promotion of breastfeeding at the meeting. The sponsor should not exert any influence over the choice of speakers or the content of presentations. Research funding should be declared by researchers who must be aware that any conclusions may be viewed with suspicion by some readers.
- Research sponsored by a formula company may become a vehicle for the promotion of the formula and the concept of artificial feeding. It is inappropriate for professional associations in the field of human health to accept from formula companies funding for the running of conferences, airfares of speakers or delegates, sponsorship of sessions, meals or secretariat assistance with organisation. Trade displays are acceptable. Gifts or financial incentives for health workers are ways of ensuring formula market share. Regular education during in-service training to increase awareness of these ethical matters would benefit health professionals.
- No accreditation points with reference to breastfeeding or infant nutrition should be awarded for formula-funded speakers. An alternative view is that most abstracts are reviewed by a scientific program committee and if there is a suggestion of influence from industry, the committee could/should decide not to select the abstract for presentation.

## References

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4. World Health Organization. International Code of Marketing Breastmilk Substitutes. Geneva, Switzerland, 1981.
5. World Health Assembly. Resolution on Infants and Young Children. Nutrition. (WHA 49, 15), 25 May 1996.

## Comments received from:

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