

SPONSORSHIPS AND GIFTS FROM INFANT FORMULA COMPANIES TO
HEALTH PROFESSIONALS: ETHICAL AND LEGAL ISSUES

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Declaration

I, Malebina Botsane, declare that this research report, entitled: "Sponsorships and gifts from infant formula companies to health professionals: Ethical issues" is my own unaided work. It is being submitted for the Degree: Masters in Bioethics and Health Law at the University of the Witwatersrand, Johannesburg. It has not been previously submitted for any other degree.



(Signature)

2/12/2016

(Date)

Dedication

Thank you Lord for your grace.

In loving memory of my father Moseli Botsane.

Gratitude to my beloved mother Mahlapenyana Botsane.

Abstract

In South Africa, poor infant feeding practices, particularly the lack of breastfeeding and the unsafe use of infant formula, are some of the contributory factors of ill-health amongst infants. In order to limit the use of infant formula, the World Health Organization (WHO) recommends that countries put in place measures that restrict the marketing and promotion of infant formula by adopting the International Code of Marketing of Breast Milk Substitutes (BMS). In 2012, South Africa adopted the International Code of Marketing of Breast Milk Substitutes (BMS) by promulgating the following: The Regulations Relating to Foodstuffs for Infants and Young Children (R991).

This research paper is based on normative research that uses pertinent ethical and legal arguments that support or critique some aspects of the regulations (R991) in South Africa. Various concepts and principles are used to support or refute the claims made. Some of the concepts and principles used include: *Undue inducements, conflict of interests, professionalism, beneficence, non-maleficence, autonomy and justice.*

The researcher argues that unrestricted sponsorships and offering of gifts to health professionals as part of marketing by infant formula companies raises certain, serious ethical concerns. The basis of these concerns is that such practices could result in negative consequences for infants who, by their very nature, are vulnerable and who should be protected from practices that could compromise their health. Gifts and sponsorships, as part of a marketing strategy from infant formula companies to these health professionals, may have the potential to distort the accuracy of the information given to pregnant women, mothers/caregivers regarding infant feeding.

To prevent infants from being harmed in this way, health professionals are expected to uphold the fundamental ethical principles of beneficence, non-maleficence, justice and autonomy when dealing with mothers or the caregivers of infants.

Unfortunately, the regulations alone are not adequate to ensure that mothers/caregivers practise appropriate feeding methods. Other interventions, such as the educating of mothers, the strengthening and supporting of health policies that promote optimal infant and young child feeding practices, need to be emphasized. It

is important that a mother/caregiver get factual and accurate information regarding infant feeding; that said, it is still the mother/caregiver's choice whether or not to breastfeed the infant.

Proper training and advocacy is needed in both the public and private sector to strengthen the effectiveness of the regulations. Continuous monitoring, enforcing of the regulations and corrective measures are all necessary to ensure that the regulations are complied with.

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List of Abbreviations

BMS	Breast milk Substitutes
CPD	Continuing Professional Development
CRC	Convention on the Rights of the Child
CSR	Corporate Social Responsibility
DG	Director General
EBP	Evidence-Based Practice
EU	European Union
HPCSA	Health Professional Council of South Africa
IBFAN	International Baby Food Action Network
NDoH	National Department of Health
NGO	Non-governmental Organizations
RSA	Republic of South Africa
SANC	South African Nursing Council
UAE	United Arab Emirates
UK	United Kingdom
UNICEF	United Nations Children's fund
WHO	World Health Organization

CHAPTER 1

INTRODUCTION TO THE RESEARCH

1.1 Background and statement of the research problem

Every year, approximately seven million children under five years of age die mainly as a result of preventable causes. These preventable causes include poor feeding practices.¹ One of the contributing factors of ill health amongst infants is the fact that mothers/caregivers do not breastfeed, but use infant formula instead. ^{1,2} In developing countries, infant formula is associated with increased risk of infectious disease and it has been found that, in developed countries, formula-fed babies are five times more likely to be hospitalized compared with those who are fully breastfed. ³ Infant formula is a manufactured food intended and marketed for feeding infants less than 12 months of age.⁴ It is these infants who are at their most vulnerable, simply because of their age.

Aggressive marketing and the promotion of infant formula to the public can contribute to infant ill health and, ultimately, the death of already vulnerable infants, especially in developing countries where there is a lack of access to clean and safe water. Given the risks associated with infant formula, allowing health professionals to market and promote infant formula is a matter of some concern.

Health professionals are expected to contribute towards society's wellbeing as part of their ethical duty; indeed, doing this is part of their professional obligation and is why they have a certain standing in the community.⁵ This means that, to return to our subject (infant wellbeing), they have a significant role to play in improving infant health.

Regrettably, gifts and sponsorships from infant formula companies have the potential to influence health professionals' conduct and their capacity to make moral decisions in matters pertaining to infant feeding; this can have negative consequences on the wellbeing of the society they are obliged to serve.

Health professionals have a moral obligation towards their clients' wellbeing and, in virtue of their professionalism; they should be putting their clients' interests' first.⁶ A moral obligation is a duty that arises out of considerations of right or wrong, and one that is based on ethical considerations.⁷ The ethical imperative and conscientious duty of all health professionals ought to be such that harming their clients in any way is simply unthinkable.

Infant feeding advice given to mothers/caregivers should be influenced by best evidence-based practices and not by companies that manufacture infant formula. Evidence-Based Practice (EBP) means integrating scientific evidence, clinical expertise and individual patient needs.⁸ EBP has shown that breastmilk is superior to infant formula and has health benefits not found in infant formula.^{1,2} This is why breastmilk, and not infant formula, should be promoted.

Some of the benefits of breastmilk are as follows: it contains the antibodies that protect the infant from possible infections; it contains all the nutrients needed to satisfy the infant's needs for the first 6 months of life, and; it involves no financial outlay.^{1, 2, 3} Given this last point, it contributes towards infants and young children's food security, particularly those who come from poor households. The advice given to mothers/caregivers should therefore be based on these facts and not influenced by the relationship that health professionals have with companies that manufacture infant formula.

Of course, this is not to deny the fact that there are infants who require infant formula for a variety of reasons. These reasons include: infants with certain medical conditions where breastmilk is contraindicated; infants from mothers who have certain medical conditions where breastfeeding is contraindicated; infants who have been orphaned; and infants whose mothers have made an informed choice not to breastfeed.^{2,9}

Given all this, it is important that health professionals provide mothers/caregivers of infants who require infant formula with the necessary information to ensure that the risks of using infant formula are minimized. The government needs to ensure that proper policies and guidelines are in place to guide health professionals in assisting mothers/caregivers on how to feed their infants.

As part of reducing infant mortality caused by poor infant feeding practices, in December 2012, the government of the Republic of South Africa (RSA) promulgated a set of regulations relating to foodstuffs for infants and young children (*R991*) under the “Foodstuffs, Cosmetics and Disinfectants Act” (Act 54 of 1972).¹⁰ Regulation 7 of the regulations (*R991*) prohibits the marketing and promotion of infant formula. Sub-regulation 7 (2) of the regulations prohibits companies from using health professionals to market their products.

These regulations limit the marketing and prohibit the promotion of infant formula in order to minimize the use of infant formula. Marketing is defined by the regulations as “promoting, distributing, selling or advertising a designated product, and includes product public relations and information services, including the use of professional service representatives, or any person acting on behalf of a manufacturer or distributor”.¹⁰ The regulations define promotion (promote) as “to employ any method scheme or design, of encouraging or enticing a person or group of persons, in whatever form, to purchase or use a designated product. This includes but is not limited to advertising, the giving of samples, special sales, free supplies, donations, sponsorships, gifts, whether related or unrelated to purchases of designated products, free utensils, or other articles, prizes,

carrier bags with pack-shots or product logos, prizes or special displays at retail outlets, discount coupons, premiums, loss-leaders, tie-in-sales, rebates and other giveaways”.

The regulations specifically prohibit promotional practices such as the offering of rebates, benefits in kind, kickbacks, special displays to increase sales and the public advertising of infant formula. Sub-regulation 7 (2)(h)(i)(j) states that sponsorships by infant formula companies (whether it be research grants, congresses or meetings) to health professionals who work with pregnant women, mothers of infants and young children can only be approved by the Director-General (DG) in the Department of Health or his/her proxy.

Sub-regulation 7 (3) states that no person shall sell, promote or advertise any foods meant for infants and young children (those less than three years of age), through health personnel or health establishments. This means that companies cannot expect health professionals or health facilities to sell promote or advertise their products (the only health establishments allowed to sell designated products are pharmacies, but such establishments may not promote or advertise these products). Sub-regulation 7(3) (a) prohibits any “provision or offer, direct or indirect, of any *gift* in cash or in kind, contribution, or benefit to health care personnel whether intended for such workers’ personal use or not”

Under section 15 of the Foodstuffs, Cosmetics and Disinfectants Act, 54 of 1972, 2007 amendment, the Minister of Health has the authority to prescribe, prohibit and regulate the use or employment of a substance or any appliance, container, object, process or method related to the designated product.¹¹ The Minister can also restrict the sale of certain products.

The Minister is therefore guided by the Act to control the marketing of infant formula in anticipation of restricting its sales.

The regulations prohibit the promotion of infant formula to health professionals and only allow scientific information regarding a product to be given to health professionals. However, the regulations do not explicitly define and differentiate between what constitutes promotional or educational information. This lack of a clear definition means that it is too easy for companies to contravene the regulations.

Nor are the regulations clear in terms of how companies that manufacture both infant foodstuffs and medical products should conduct themselves as far as offering sponsorships to health professionals is concerned. Aspen, which is a pharmaceutical company that manufactures both infant formula and medical supplies, used to have various initiatives aimed at certain health department programmes or health professionals (who did not necessarily work with infants).¹² At present, there is no provision for such companies in terms of what they may or may not do in their dealings with health professionals in general (not just only those who work specifically with infants).

The aim of the regulations is to ensure adequate, safe and appropriate nutrition for infants. Given the risks of ill health associated with infant formula, it is fair and just to regulate the marketing of infant formula. However, the challenge is how to ensure that health professionals continue to receive and provide adequate scientific information that is free from commercial influence. In this regard, the restriction of sponsorships affects health professionals who work with pregnant women, mothers, infants and young children. Such health professionals include paediatricians, dieticians, midwives and paediatric nurses (in both the private and public sector).

Although the regulations prohibit companies from offering any individual gifts, this particular research will focus on gifts to health professionals.

The term 'health professionals' in this particular research only relates to health professionals who work with pregnant women, mothers, infants and young children. In other words, this research project concerns those health professionals listed above: paediatricians, dieticians, midwives and paediatric nurses in both the private and public sector.

Study objectives

- To critically examine the section of "Regulations Relating to Foodstuffs for Infants and Young Children (R991)" regarding the sponsorships and prohibition of gifts to health professionals who work with pregnant women and mothers/caregivers of infants and young children.
- To identify some of the pertinent ethical and legal areas which the regulations address in terms of restriction of sponsorships and prohibition of gifts to health professionals who work with pregnant women and mothers/caregivers of infants and young children.
- To critically evaluate the ethical implications of the regulation regarding sponsorships and prohibition of gifts to health professionals who work with pregnant women and mothers/caregivers of infants and young children.

1.2 Statement of the problem

There is a paucity of literature, especially here in South Africa, on the ethical and legal issues that might arise regarding relationships between health professionals and infant formula manufacturers.

Health professionals working with pregnant women and mothers/caregivers of infants and young children are sometimes the recipients of gifts and sponsorships without realizing the true intentions of the infant formula companies that offer such gifts and sponsorships.

This research will attempt to tease out, from an ethical and legal perspective the questions that arise from these gifts and sponsorships.

1.3 Research rationale

The researcher is a dietician by profession and has seen instances where infant formula companies gave gifts and sponsorships to health professionals who work with infants (e.g. dieticians, midwives and paediatricians). The concern or rationale of this research, therefore, is to convince other health professionals about some of the ethical pitfalls they must watch for when dealing with infant formula companies.

The research will contribute towards justifying the reasons behind the implementation of the “Regulations Relating to Foodstuffs for Infant and Young Children (R991)”, particularly the regulating of the sponsorship of research, conference, fellowships and the prohibition of offering gifts (by infant formula companies) to health professionals who work with pregnant women, mothers of infants and young children.

1.4 Outcomes

To contribute towards compiling an ethics mediated policy document on sponsorships and gifts from infant formula companies which will be targeted at health professionals such as dieticians, midwives, paediatric nurses, and paediatricians.

The researcher intends on publishing the results in a journal; the results will also be presented at various seminars and conferences.

1.5 Methodology

This is a normative research using pertinent ethical and legal arguments which support or critique certain aspects of the regulations in South Africa (SA). Normative research investigates possible questions that arise when one determines what would be

considered a moral action.¹³ Normative research also examines standards for the rightness and wrongness of actions in light of factors such as consequences, harm and consent.¹⁴ Three of the most common normative theories include virtue ethics, consequentialism and deontology. Virtue ethics emphasises the character of the person as a critical addition to knowledge about principles, rules, and duties, as well as the consequences of their actions.¹⁵ Deontology bases morality on duty and obligations, and views actions to be right or wrong regardless of the consequences that could result from the action.¹⁶ Whereas the notion of consequentialism considers an act to be right purely based on its consequences.¹⁶

For the purpose of this research, the theories of consequentialism and deontology will be briefly discussed. The consequentialism theory will be used to determine whether unregulated sponsorships and gifts from infant formula companies to health professional are ethically acceptable. Deontology theory will be applied to determine whether it is wrong or right to promote infant formula.

Other concepts and principles are used in the research to support or refute the claims made. Some of the concepts and principles used include: *Undue inducements, conflict of interests, professionalism, beneficence, non-maleficence, autonomy and justice.*

1.5.1 Argument

The researcher argues that unrestricted sponsorships and offering of gifts to health professionals by infant formula companies raise ethical concerns that could result in negative consequences for infants; infants are, by their very nature, vulnerable and should be protected from practices that could compromise their health.

The researcher argues that allowing infant formula companies to promote their products by sponsoring and giving gifts freely to health professionals has the potential to result in biased information being given out to mothers/caregivers. Biased information regarding the use of infant formula can result in poor infant health and could also contribute towards increased infant and child mortality.

CHAPTER 2

REGULATIONS ON MARKETING OF INFANT FORMULA: GLOBAL AND NATIONAL VIEW

In this chapter, the researcher will discuss laws and regulations relating to the marketing of infant formula in South Africa and other countries. The researcher will also discuss the history of the promotion and marketing of infant formula.

2.1 Conventions and the Code regarding the marketing of infant formula

The World Health Organization (WHO) recommends that countries put measures in place that restrict the marketing and promotion of Breast-milk Substitutes (BMS). ²The WHO states that countries should do this by adopting the WHO Code of Marketing of Breast-milk Substitutes.¹⁷ (The WHO Code of Marketing of BMS will be referred to as the “Code” throughout the rest of the research paper.) BMS is any food marketed as a partial or total replacement of breastmilk; as such, it includes infant formula and other foods given to infants before the age of six months (e.g. Cereal, juice, tea, etc.).

Over and above the adoption of the Code, the WHO also recommends that countries develop country specific laws and regulations that ensure safe, appropriate and adequate nutrition through the prohibition of harmful marketing practices.^{17,18}

In 1981, the World Health Assembly’s recommendations regarding the marketing of infant formula were that infant formula companies conduct their business in a much more ethically acceptable manner by, firstly, refraining from any marketing or promotion of infant formula to the public and mothers.¹⁹ Secondly, companies were required to indicate the superiority of breastfeeding over infant formula and were required to state the risks of using formula on the packaging and labelling of their infant formulas. Thirdly, health

facilities were not to be used to display products or posters about infant formula or distribute any material emanating from infant formula companies.¹⁷

The Innocenti Declaration, adopted in 1990 by a group of high-level policy-makers from 32 countries and several United Nations agencies, was also a major impetus in the implementation of the Code.²⁰ The number of countries that had partially or fully adopted the Code has since grown from 9 in 1990 to 76 by 2005.^{19,20,21}

The regulations relating to the marketing of infant formula vary from country to country. Although certain countries have some legislation in place, some have taken no action at all as far as the aggressive marketing of infant formula is concerned. According to the 2011 WHO status report on *Country implementation of the International Code of Marketing of Breast-milk Substitutes*, a small number of governments have regulations in place to address issues relating to food, including the safety and quality of infant formula.²¹

The report indicated that 35% of all countries fully prohibit the advertising of BMS; 31% completely prohibit the distribution of free samples or low cost supplies to health services; and 32% completely prohibit the giving of gifts by manufacturers to health professionals. However, only 42% require that companies state the superiority of breastfeeding on BMS labels, and only 23% have monitoring systems in place.²¹

Although only a small number of countries have adopted the Code, this does not mean that the regulating of the marketing of infant formula is unnecessary, given the repercussions that could occur and the harm that has occurred, historically, owing to the aggressive marketing of infant formula.²¹

European Union (EU) countries such as Italy, France and the United Kingdom (UK) have included certain aspects of the Code in their legislation which address the labelling and

advertising of infant formula.²² In certain EU countries, the regulations relating to the advertising of infant formula only affect “starter infant formula”; this is formula which is meant for infants of between the ages of 0-6 months and not follow-on infant formula, which is meant for infants of 6-12 months.²²

The EU regulations on the advertising of infant formula restrict the type of information to be published by companies (only scientific publications are allowed) and prescribe that no publication should state infant formula as being equivalent or superior to breastmilk. Any promotional device to increase sales such as samples, special displays, discount coupons, special sales and tie-in sales is prohibited. Manufacturers and distributors are prohibited from offering any promotional free or low-cost product samples or any gifts, whether directly or indirectly, through a healthcare system or a health professional. Donations of informational or any educational equipment should only be made if the company has written approval from the relevant national authorities ²².

Interestingly enough, the United States of America (USA) is one of the countries that has taken no action against the marketing of infant formula²¹ although it has one of the lowest exclusive breastfeeding rates, its infant mortality rate is low compared with that of South Africa.

In 2008 the *Shanghai daily* reported that approximately 30 000 infants fell ill in China as a result of melamine that was deliberately added to the infant formula; with six infants dying due to that infant formula.²³

China is one of the countries that has one of the strictest regulations, particularly regulations relating to the safety of infant formula.²⁴ These regulations came into place after the 2008 contamination of infant formula incident that claimed the lives of infants²⁵.

Recently only a few violations of the code affecting health professionals have been reported in certain countries. These countries include: Italy, South Africa, Gabon and Botswana. Developed countries such as Italy have had their fair share of paediatricians who have contravened legislation regarding gifts and sponsorships. In November 2014 it was reported that twelve paediatricians were placed under house arrest for accepting “extravagant gifts and costly holidays” from infant formula companies in exchange for these professionals promoting the companies’ products over breastmilk.²⁶

In South Africa it was reported that Nestlé had planned an event; “Scientific luncheon” to launch a new baby formula with the event targeting nurses and dieticians. This incident was reported to the local IBFAN office. Nestlé cancelled the lunch, apologised and released a statement that they will carry out a full investigation and assessment and also stated that such incidents will not happen again in future.^{27,28}

In other developing countries such as Gabon, some infant food companies have gone so far as to criticize breastfeeding and to distribute articles to health professionals that state “Rather a well prepared bottle than a cranky breast”.²⁹

In February 2016, The Botswana Gazette, reported that Nestle’ violated Part 3 Section 8 of the regulation by hosting an unlawful meeting for doctors in Botswana. The meeting was meant to “increase awareness” on breastfeeding and their products”. The article also reported that the event possibly went against the regulation that stated “direct or indirect method of introducing a designated product or encouraging the buying or use of a designated product’, is prohibited by the regulation.^{30,31}

Developing countries, where infant mortality is high and where a lack of resources also poses a threat to infant health, need to have stricter regulations relating to the marketing of infant formula, given that the consequences of aggressive marketing are potentially particularly harmful to infants born in these countries.

Ghana is one of the developing countries that has been successful in ensuring that national legislation regarding the marketing of infant formula is effective; it has done this by the establishment of clear strategies. In Ghana, officials responsible for enforcing the provisions of national legislation are expected to have a thorough knowledge of infant feeding, child survival issues and know precisely how the Code relates to these issues. Ghana has also instituted an independent monitoring body that can submit its findings and recommendations to a specific government enforcement agency.³²

By 2005, Botswana already had regulations in place that explicitly barred any practices that allow for a relationship to develop between infant formula companies and health professionals. Botswana's regulations prohibit health professionals from accepting, from infant formula companies, gifts, financial support, fellowships, study tours and sponsorships to attend conferences.³⁰ Like South Africa, Botswana allows for research activities provided that the researchers concerned have written approval from the health research authority. Unlike South Africa, Botswana has strategies in place on how to monitor the regulations; Botswana has trained health professionals who monitor the implementation of the Code and legislation relating to the marketing of infant formula. The monitoring reports are submitted to the National Food Control Board of Botswana. All health professionals in Botswana are required to keep records of violations within their premises; these records should be submitted to specific monitors and authorized officers.^{30, 33.}

Based on the National Department of Health (NDoH) assessments on the knowledge of the Code and regulations amongst South African health professionals, it is clear that most health professionals are not aware or do not understand the Code or the regulations.³⁴ This situation obviously raises the question: how can health professionals abide by and promote the Code and regulations if they do not understand either?

If health professionals fail to uphold the regulations in a country such as South Africa, where government sponsorships for research, education, conferences and meetings are not easily obtainable, it is likely that these same health professionals will seek sponsorships from infant formula companies.

The significance of sponsorships offered by infant formula companies in South Africa, and the impact of restriction of such sponsorships on various health associations and the health profession is not well documented. The government needs to work together with its partners to ensure that the restriction of sponsorships from infant formula companies does not hinder any progress relating to improved infant health. In short, the government needs to offer more in the way of research funding, and funding for conferences and the training of health professionals.

Although having appropriate legislation in place is a good start, this is not sufficient on its own; legislation needs to be accompanied by effective training, information and monitoring systems so that scientific knowledge rather than commercial interests influences and guides the conduct of health professionals.

2.2 The marketing of infant formula in South Africa

Historically, in South Africa, infant formula was mainly manufactured by pharmaceutical companies, and pharmaceutical companies have always spent large amounts of money on marketing. In the USA, for instance, it has been estimated that pharmaceutical company expenditures for promotional activities were \$57.5 billion in 2004, including \$20.4 billion for detailing (sales visits) by pharmaceutical company representatives, \$15.9 billion for product samples, and \$2 billion for meetings with health professionals.³⁵

Prior to the regulations in 2012 and the Code in 1981, companies used to freely advertise and promote infant formula through various media such as newspapers, magazines, the internet, billboards and through health professionals. (By offering them promotional materials such as pens, calendars, diaries. In some instances, gifts such as free lunches,

travel allowance and sponsorships of conferences and research have also been offered).^{2,28}

Over the years this relationship between health professionals and the pharmaceutical industry has raised serious concerns about companies using health professionals to promote their products and, certainly at times, compromise their clients' wellbeing clients.³⁶ It is worth remembering that companies use health professionals to market their products because health professionals are respected and trusted by society - a mother is likely to accept a recommendation from a health professional regarding the feeding of her infant.³⁷

The marketing of infant formula has been criticized because it convinced mothers to change to formula and stop breastfeeding; this decision sometimes resulted in the death of the infant.³⁸ The three causes of ill health as a result of switching to formula included the following: One, infants were at risk of infections because, compared with breastmilk, formula lacked essential antibodies; Two, some mothers were uninformed on how to prepare formula safely; and three, some mothers could not afford the price of formula and saved money by "over-diluting" the formula so that it would last longer – needless to say, this resulted in infant malnutrition and, often, death.^{2,39}

A number of concerns have been raised about marketing tactics of companies that manufacture infant formula; these companies sometimes promote infant formula by distributing samples and giving out biased information to mothers about infant formula.^{2,19}

The aggressive marketing of infant formula, historically, contributed to the decline in breastfeeding rates in developing countries and thus contributed to infant morbidity and mortality.⁴⁰ This in itself is an indication that allowing infant formula companies to freely market their products can have extremely serious and detrimental consequences. Also, of course, the aggressive marketing and giving out of biased information about infant

formula to pregnant women and mothers/caregivers, particularly those who in the lower income groups, and those who simply do not have the resources and the knowledge of how to safely and adequately prepare formula puts infants at possible risk of harm from both infection and malnutrition.

This is not to downplay the fact that companies have a significant role to play in the advancement of paediatric medicine and improved infant healthcare generally. Indeed, health professionals need to keep up with medical advancements, and they need to equip themselves with current and properly researched information. Although these companies have always been at the forefront of research that involves infant feeding, there seems to be uneasy disjuncture between profit making (which is well and good), and the need for some of these companies to further increase their profits by enticing unwary health professionals with inappropriate inducements. The need for profit cannot be justified in any way if it has the potential to harm infants, the most vulnerable members of our society.

2.3 Monitoring of the Code and the regulations

The WHO recommends that governments not only adopt the Code, but also put in place effective measures that will monitor its implementation.²¹ The effective monitoring of various infant feeding policies and interventions, including monitoring the implementation of the regulations, is obviously necessary. Also, of course, monitoring needs to be conducted in an independent and transparent manner that is free from commercial influence. The government needs to work with independent entities and various bodies such as Non-Governmental Organizations (NGOs), academics and professional bodies, such as the Health Professional Council of South Africa (HPCSA), and the South African Nursing Council (SANC). These entities, in turn, need to be empowered to investigate violations and be in a position to impose legal sanctions on those who break the law.

In the researcher's experience within the Gauteng province, one of the reasons that some health professionals do not implement the regulations is due to poor training and sensitization of health professionals in both the public and private sector. Training health personnel about the regulations is a challenge, since most health staff members (particularly those working in the public sector) are unable to attend trainings for logistical reasons (i.e. staff shortages, the cost and inconvenience of travel/transport to conferences and seminars).^{41,42,43} A thorough knowledge and understanding of the regulations on the part of health professionals would make implementing the regulations easier. This, in turn, would mean that any systematic violations and aggressive commercial marketing would be minimized.

At present in South Africa there are, unfortunately, no oversight committees and monitoring bodies designated to monitor the implementation of the regulations. The only facilities that are assessed or monitored for "Code compliance" or adherence to the regulations are those that offer maternity services, particularly those facilities that want to be accredited as being Mother-Baby Friendly. Mother-Baby Friendly facilities are health facilities that actively promote and support breastfeeding and abide by the standards set by the WHO.² According to UNICEF, South Africa has more than 170 facilities which MBFI accredited.⁴⁴

The current tool (see Appendix A) used to assess and monitor the Code does not allow for adequate monitoring as far as gifts and sponsorships being offered to health professionals is concerned. The question asked regarding gifts and sponsorships specifically asks: *"Do staff members understand why it is important not to give any free or promotional materials from formula companies to mothers"*.⁴⁵

The shortcoming of this tool is that it focuses on the health professionals' understanding of the Code and not adherence to the Code.

Another shortcoming is that the tool only emphasizes promotional gifts being given to mothers and pregnant women and not the gifts and sponsorships that are targeted at health professionals. Currently it seems like there is no measure or tool that can be used to assess or report the actual conduct of health professionals regarding gifts and sponsorships.

The prescribed channels for reporting complaints concerning the regulations could certainly be improved. The regulations only state that all complaints should be reported to the Director-General in the Department of Health.⁹ It would certainly be more effective if each province had its own means of dealing with complaints, rather than having to report each one to the Director-General. Alternatively, South Africa needs to have an independent body, as is the case in Botswana.³³

The role of the law is pivotal in addressing public health issues regarding food and malnutrition. When it comes to infant feeding, several countries have not only adopted the Code, but have strongly advocated for laws such as maternity leave protection, the provision of safe breastfeeding environments for women in the workplace, and the removal of barriers that hinder breastfeeding in public. South Africa needs to make more stringent those labour laws that are meant to ensure that mothers/caregivers are able to give infants the best start in life by breastfeeding their infants.

Continuous research on infant formula is needed to ensure that the non-breastfed infants get the best nutrition. Further research is also needed to improve the safety of infant formula to ensure that formula fed infants are protected from possible harm.

2.4 Protecting the vulnerable infant

2.4.1 Convention on the Rights of the Child

The United Nations Convention on the Rights of the Child (CRC) is an international human rights treaty that is meant to protect the rights of every child. The CRC treaty stems from the Universal Declaration of Human Rights, which was adopted in 1948.⁴⁷

*“Human rights are those rights which are essential to live as human beings – basic standards without which people cannot survive and develop in dignity. Human rights are inherent to the human person, inalienable and universal” UNICEF 2014.*⁴⁸

According to Article 6 of the CRC, children have the right to life, survival and to develop healthily, and governments have a duty to ensure that children’s rights are protected.⁴⁹ As part of protecting the child’s right to live, the CRC recommends that state parties have appropriate measures that specifically address the following: a) *Reduce infant and child mortality; (b) To combat disease and malnutrition, together with the framework of primary health care, through the provision of adequate nutritious foods and clean, safe, drinking-water, taking into consideration the dangers and risks of environmental pollution; (c) To ensure that the citizens of this country, particularly parents and children, are well informed, have access to education and are supported in the use of basic knowledge of child health and nutrition, the advantages of breastfeeding, hygiene and environmental sanitation and the prevention of accidents.*⁵⁰

The CRC also declares that *“State Parties, in harmony with the national state of affairs and within their means, shall take suitable measures to help parents and those responsible for the child to ensure the rights of the child are upheld and shall in case of need provide material assistance and support programmes, particularly with regard to nutrition, clothing and housing”.*⁵¹

The regulations are one way of enabling mothers/caregivers of infants to protect the right of the child to life, survival and development.

By prohibiting companies from marketing to the public, particularly through health professionals, the rights of the child to live and develop healthily are protected, simply because the harm that could arise from the use of infant formula is minimized. As previously defined, the theory of consequentialism would view any act that is likely to cause harm as being unethical. In chapter one the researcher stated how aggressive marketing and promotion can result in negative consequences for infants. Health professionals have a role in protecting the rights of infants and need to always ensure that their conduct does not compromise the health of infants in anyway.

In the researcher's opinion, health professional can protect children's right by doing the following:

- Ensuring that any information they give regarding infant feeding is factual and non-biased
- Refusing gifts from companies
- Ensuring that companies do not market to the public
- Serving as whistleblowers regarding any unethical conduct on the part of companies.

In order to uphold the rights of the child, the CRC also recommends that state parties undertake all legislative and administrative measures that ensure the child's protection and care, both of which are needed for the child's wellbeing. The rights and duties of the child's parents, legal guardians or other persons legally responsible for the child also need to be taken into account. The regulations do not prohibit the use of infant formula by parents and caregivers and thus take into account mothers/caregivers' rights and duties as far as their choice of how to feed the infant is concerned. It is, however, crucial that the decision the mother makes regarding infant feeding be not influenced by potentially harmful marketing tactics, and this includes the tactic of companies using health professionals to market their products.

2.4.2 The RSA legal obligation in protecting the infant

2.4.2.1 The Constitution

The Constitution of the Republic of South Africa 1996 is the highest law in the country, the Constitution sets out how the country will be constituted and run. The Constitution sets out the rights and responsibilities of its citizens. It also guides institutions that support and safeguard the democracy of the country.⁵²

The Bill of Rights, chapter 2 of the Constitution, is the cornerstone of South Africa's democracy. The Bill of Rights enshrines the rights of all people in our country and affirms the democratic values of human dignity, equality and freedom. The state is required to respect, protect and fulfil the rights contained in the Bill of Rights.⁵³ Note that the rights contained in the Bill of Rights are subjected to certain limitations.⁵⁴

Section 10 of the Bill of Rights states that "Everyone has inherent dignity and the right to have their dignity respected and protected".⁵⁵ The CRC, like the Constitution, also states that everyone should be treated with dignity.^{47, 49, 55} To be treated with dignity means that one should be treated with respect.⁵ In this context, *respect* means taking one's needs, ideas, feelings and beliefs in to consideration. Health professionals will therefore be infringing on the infant's right to dignity if they overlook the infant's needs and allow companies to use them, the health professionals, to promote their products at the expense of vulnerable infants. Mothers and caregivers' ideas, feelings and wishes regarding how they want to feed their own infants also need to be respected and taken into consideration since they, too, have the constitutional right to be treated with dignity.

The Bill of Rights, under section 28 (1c), states that each child has the right to basic nutrition, shelter, basic health-care services, and social services.⁵⁶ In South Africa, the challenge of household food security is a major one, which is just one of the reasons why, in order to ensure that every infant's right to basic nutrition is protected, breastfeeding

ought to be protected, since this form of feeding alone can ensure that most infants have food security. This is an important point – historically, as we have said already, the aggressive marketing of infant formula resulted in some mothers resorting to infant formula even though they could not afford it.⁴⁰ The constitutional rights of both the mother/caregiver and the infant need to be protected. The best interest of the child should always be paramount in all situations.⁵⁷

2.4.2.2 Children's Act

The Children's Act, 38 of 2005, is meant to give effect to certain rights as contained in the Constitution.^{52, 57} The principles set out in the Children's Act include the care and protection of children and the definition of parental responsibilities and rights.

The CRC, the Bill of rights and the Children's Act state the child's best interests as being paramount in all decisions regarding the child.^{49,50,58} In the Children's Act, the "best interests of the child" concept often relates to what would be best for a child as far as custody judgements are concerned. However, the concept can also be used to determine how any decision involving the child can affect the child and which decision would be best in a specific situation. Some of the factors to consider when applying the "the best interests of the child" include.⁵⁸

- a) The nature of the personal relationship between the child and the parents, or any specific parent or caregiver or person relevant in those specific circumstances
- b) The attitude of the parents, or any specific parents, towards- the child; and the exercise of parental responsibilities and rights in respect of the child
- c) The capacity of the parents, or any specific parent, or of any other care-giver or person, to provide for the needs of the child, including emotional and intellectual needs
- d) The child's- age, maturity and stage of development, gender, background any other relevant characteristics of the child

- e) The child's physical and emotional security and his or her intellectual, emotional, social and cultural development

The CRC explains "best interests of the child" as doing what is best for the child, and suggests that when adults (parents/guardians/policy and lawmakers) make decisions they should think how these decisions will affect children.^{50,54}

Best interests' determinations are carried out when the matters involving the child are expected to have significant implications on the child's present and future life.⁵⁹ The best interest concept is mostly used by health professionals and ethics consultants in cases where parents refuse to provide consent for a child's medical care. There seems to be a common view that suggests the harm threshold should determine the acceptability of overruling parental desires.⁶⁰

According to Kopelman, the best interest concept involves choosing "the option that maximizes the person's overall good and minimizes the person's overall risks of harm."⁶¹ Health professionals have an ethical and legal duty to advocate for the best interests of the child when parental decisions are potentially dangerous to the child's health and well-being.⁵

To return to our subject: it is certainly not in the best interests of children to allow companies to use health professionals to market infant formula. Promoting breastfeeding can certainly be considered an action that supports the best interests of a significant number of infants. Promoting breastfeeding does not necessarily mean that infants who require infant formula should be ignored. It is as important to ensure that safe and appropriate use of infant formula is supported.

Information that should be given to mother/caregivers regarding the feeding of infants needs to such that it ensures that the infant's best interests are considered. The CRC, the Constitution and the Children's Act are set out to ensure that children are protected from possible harm. Given that infants are at an age that the makes them vulnerable and susceptible to various illnesses, this requires the state to be even more wary of possible risks to the infant's health and have strong measures in place to ensure that infants are protected.

CHAPTER 3

SPONSORSHIPS AND GIFT OFFERINGS BY INFANT FORMULA COMPANIES: SOME CONCERNS

This chapter focuses on the ethical issues regarding gifts and sponsorships by companies to health professionals; these gifts and sponsorships are usually part of a company's marketing strategy. Indeed, promotional gifts that carry the company's name, logo or slogan are often used to market and promote a particular product. In the context of this research, a gift is defined as "an item offered voluntarily without compensation in return as to show kindness toward someone, honor an occasion or as gesture of assistance which includes but not limited to free samples of a designated product, meals, refreshments, stationery or any item of whatever value".¹⁰ Sponsorships have become a common form of marketing, since they allow companies to gain access to prospective clients by sponsoring events/organizations that attract a certain target market. For the purpose of this research the relationship between infant formula companies and health professionals will be broadly categorized under the following headings (all of which relate to ethics): undue inducements, conflict of interests, professionalism, beneficence, non-maleficence and justice.

3.1 Perverse incentives and undue inducement

In 1981, the World Health Assembly (the decision-making body of the WHO) made a number of resolutions that called for member states to ensure that financial support and other incentives for programmes and health professionals do not create conflicts of interest.⁶² A conflict of interest can arise when industry uses sponsorships and other incentives to influence the conduct of health professionals.⁶³ Although, in 1981, South Africa was not part of the World Health Assembly, the country realizes the need to regulate such gifts and sponsorships.^{2,10,64}

A perverse incentive is an incentive that determines someone's action in order that he or she receives the incentive and, as such, usually results in harmful consequences.⁶⁵ Although the HPCSA uses the term "perverse incentives", the term "undue inducement" is commonly used in the literature. Emmanuel et al define undue inducements as "any offer of a desirable good in such excess that it compromises and leads to serious risks that threaten fundamental interests".⁶⁶ It needs to be said that the health professional's fundamental interest is the infant's wellbeing while the primary interest, as far as infant formula companies are concerned, is profit. As part of their marketing strategy to improve profits, companies that manufacture infant formula used to freely offer gifts, free lunches and travel allowances to health professionals and this, of course, raises the issue of a conflict of interests.^{2, 28, 63, 64}

Some health professionals believe that receiving gifts from companies does not influence their decisions when it comes to patient care; however, research has shown that receiving gifts from companies does, in fact, influence the behaviour of health professionals.⁶⁷

A study by Chren and Landefeld indicated that physicians who met with company representatives and those who received incentives to speak at symposia organized by a company were likely to recommend or use the products from that particular company. Researchers who get funding from industry are more likely to use or recommend a particular product and, at times, have shown bias in preferring a product from the company who funds their research.⁶⁸

Studies have found that certain company sponsored researches and publications reported distorted information in order to favour the companies concerned; selective reporting or the actual withholding of unfavourable results has also been reported.⁶⁹ Given the probability of a company influencing the behaviour of health professionals (in terms of product choice), it would be much better if companies did not offer health

professionals any gifts at all – whether the gift be something as minor as a lunch or something more substantial, such as a travel allowance.

In the past, infant formula companies have contributed significantly in the funding of conferences, fellowships, and Continuing Professional Development (CPD) activities for nutrition (specifically).⁷⁰ For the companies concerned, such occasions also gave them an opportunity to advertise their products at both a scientific and commercial level. Of course, it is crucial that health professionals are familiar with the scientific information regarding the products offered by infant formula companies. However, there seems to be a thin line between scientific information and promotional material, promotional material which, historically, was often given out freely at these events.

In terms of research sponsorships, the regulations only allow research sponsorships if these have been approved by the Director-General in the Department of Health. Research sponsorships from companies could contribute positively towards infant health and health education. For instance if it was not for research, Acidified formula which can be used in cases where the risk of infections are high would not have been developed.⁷¹ One needs to keep in mind that as much as exclusive breastfeeding is the best for most infants; the reality is, currently in South Africa only 8% of infants are exclusively breastfed during the first six months of life.⁶⁴ For the rare cases where breastfeeding is not possible further research is needed to ensure that those infants receive improved and optimal nutrition. Companies that produce infant formula also need to conduct research on their products to improve on them and this indeed requires collaboration with health professionals.

The process of approving research sponsored by infant formula companies is not stated or explained in the regulations. As part of approving research, various ethic committees

also consider who sponsors the research and determine whether any ethical issues could arise from this sponsorship. This raises the question of whether it is necessary to have the approval of both the Director-General and research ethics committees for research sponsored by infant formula companies. In general, most research ethics committees have the ability to determine whether or not sponsored research is ethical; there is therefore no real need to have approval from both bodies (the Director-General and ethics committees).

3.1.1 The HPCSA's view of perverse incentives

In terms of sponsorships/financial contributions, the NDoH⁷² document regarding the interpretations of the regulations recommends that both companies and health professionals familiarize themselves with the HPCSA guidelines regarding *Over-servicing, perverse incentives and related matters*.⁷³ The HPCSA booklet 5 on *Over-servicing, perverse incentives and related matters* clearly states that no incentive or any form of inducement should threaten the independence or commitment of the health professional to their ethical rules and policies; the booklet also states that health professionals should refrain from doing anything that is not aligned to the clinical needs of their clients.⁷³ The HPCSA's standing on financial contributions from companies ensures that the public is protected and that the health profession is not compromised. In order to regulate the funding of CPD activities, including the travelling and lodging of health professionals, the HPCSA states that companies should act in a fair and transparent manner and refrain from incurring any exuberant costs; the HPCSA also states that all funded events should focus on education and not on entertainment and/or hospitality.

The HPCSA can penalize any person, corporate body or other legal entity in terms of the Corruption Act, 94 of 1992 ⁷⁴ should the actions or omissions of such person, body or other legal entity be in breach of the provisions of that Act. Under Section 1 (1) (a) (ii) of the Act, it is considered a criminal offence when “*anyone corruptly gives or offers or*

agrees to give any benefit of whatever nature which is not legally due to any person upon whom any authority has been conferred or who has been charged with any duty by virtue of any employment or the holding of any office or any relationship of agency or any law, or to anyone else”.

As far as dealing with offences is concerned, the regulations state that the penalties as stipulated in the Act will apply. Contravening of the Act, as stated in Section 18 of the Act, carries certain penalties. These penalties can be a fine of R400 to R2000, or imprisonment for 6 months to up to 24 months, depending on the number of offences.

It is the researcher's opinion that the penalties carried by this offence are ridiculously low, given the possible harm that could arise from the offence. Also, the fines carried by the offences compared with the amount of money most health professionals earn and the amount of profit companies make are simply absurd.

Incentives are not the only gain that health professionals are likely to receive from their relationship with infant formula companies; professional recognition is one of the most common non-financial gains within the health profession. Being listed as a health professional of one of the top medical centres may carry critical acclaim amongst peers and society at large. Also, the recognition of research activities in the form of awards granted and articles published is significant in terms of a health professional's career and prestige.⁷⁵

Given the above, it is therefore important that policies on the conflict of interests are established and that all health professionals are aware of these policies.

3.2 Conflict of interests

A conflict of interests occurs when judgement concerning the professional's primary interests (e.g. a client's wellbeing) is unduly influenced by secondary interests such as financial gain (i.e. gifts, free lunches and travel allowance).⁷⁶ To put it another way: a conflict of interests occurs when an individual or entity is in a professional or official position which they can exploit for their own gain.

Undue inducements can result in a conflict of interests, particularly in cases where a health professional allows incentives and sponsorships to determine his or her conduct. According to the United States of America Committee on Conflict of Interest in Medical Research, Education, and Practice, the problem is not solely related to the incidences in which primary interests are inevitably compromised, but also involves a set of circumstances or relationships that could result, or increase the risk, of primary interests being neglected due to the pursuit of secondary interests. This means that a conflict of interests exists regardless of whether the particular individual is actually influenced by the secondary interest.⁷⁷

Generally speaking, most health professionals and medical researchers know and understand their professional role in ensuring that these primary interests are not compromised by any other interests. Health professionals and researchers normally exercise judgement and discretion in their work; these people are expected to conduct themselves and make judgement in a manner that is consistent with primary interests – in this case, we are talking about the infant's wellbeing.

A conflict of interests seems to be more of a concern when it comes to research funded by companies. In countries where public funding for education, training and research is lacking, offers from infant food companies to health professionals for sponsorships is obviously more attractive. Indeed, to ensure that health professionals are not heavily reliant on commercial sponsorships is just one of the reasons why the South African

government and various health professional bodies need to ensure that adequate funding is available for education, training and research.

In the past, researchers have been reported to have withheld information regarding competing interests regarding sponsorships from pharmaceutical companies.⁷⁸ Although withholding such information does not necessarily equate to bias in research results, it does raise concerns, given the history of research funded by companies. There is clearly a need to have measures in place that address the problem of conflicting interests.

Note that the aim of policies on conflicts of interest within the field of medical research is to guard the integrity of professionals and to preserve public trust and not necessarily to remediate bias and mistrust.⁷⁸

Conflict of interest is likely to arise as a result of a professional's collaboration with industry.⁷⁹ It is recommended that researchers determine ethical issues related to conflict of interests at each stage of the research process, and openly make such issues part of educational programmes for discussion by investigators, sponsors and, of course, the public.⁸⁰ Some have criticized the paternalistic approach taken by South Africa's NDoH in dealing with infant formula challenges in that the NDoH censors companies.⁸¹ The current recommendations on infant feeding do not allow health professionals to give mothers/caregivers information on formula routinely, but do allow such information to be given to mothers/caregivers if there is a medical reason for doing so or if and when the mother herself enquires about infant formula.⁹ Although infant formula cannot be marketed, it is still available for the mothers to purchase.

The National Infant and Young Child Feeding Policy (2013) makes provision for educating and supporting mothers who have made an informed decision to formula feed their infants IYCF policy.⁹ This decision often depends on the information and the support from the health professional.⁶⁴

Health professionals can offer advice to mothers/caregivers on infant feeding; however, the decision on what to feed solely depends on the mother/caregiver.

3.3 Professionalism

A profession is an occupation that is built on a comprehensive body of knowledge and skills. Members of a profession are governed by a code of ethics and affirm a commitment to competence, integrity, altruism and the promotion of the public wellbeing within their scope.⁶ Professionalism requires health professionals to maintain high moral standards, to have a strong loyalty to the welfare of others, to possess specialized academic training, and be able to cope with a high level of autonomy.⁸² Professionalism is at the centre of medicine's social contract; the notion of a social contract within the medical fraternity is the view that a health professional's moral obligation depends on the "contract" or agreement between him or her and the community he or she serves.⁸³

It has been suggested that society has allowed the health profession to be autonomous in practice, to have a monopoly over the use of its knowledge base, to enjoy self-regulation and to be able to gain both financially and non-financially from its practice of medicine.⁸⁴ It is therefore necessary for the health professions to be given guidance to ensure that they conduct themselves in a manner that does not exploit the public. Health professionals need to earn respect from society and for them to remain trustworthy they should conduct themselves in a manner that is deemed acceptable by the community they serve.

Given the privileges that they enjoy as being a member of the health profession, health professionals are expected to put their patients before themselves, ensure they remain competent by continuing to acquire the relevant skills and knowledge, act morally and with integrity, and be dedicated in serving society.⁸⁵ If society does not trust health professionals this could result in even stricter government regulations in terms of gifts and

sponsorships from infant formula companies. Stricter regulations could put health professionals at a disadvantage in terms of seeking and receiving sponsorships.

The type of information given during antenatal care is influential, and often both the health professional's knowledge and attitude towards various feeding options influences the mother's choice regarding infant feeding.⁶⁴ When health professionals allow companies that manufacture infant formula to influence their conduct at the expense of the community they serve, it is likely that the community will lose trust in them, and the profession itself will ultimately be compromised. Health professionals are therefore required to adopt principles that will help them conduct themselves ethically.

The HPCSA, and other regulatory bodies, exists to promote the health of the South African population, to establish values and standards of professional education and training, and to ensure good standards of professional practice. In the researcher's opinion, health professionals should be guided by four ethical principles when dealing with infants and infant formula companies. These principles include beneficence, non-maleficence, autonomy and justice.

3.4 The concept of beneficence and non-maleficence

Beneficence is about maximizing good, whereas non-maleficence is about minimizing harm. Actions that contribute towards the welfare of others, including their health, are commonly referred to as acts of beneficence. According to Beauchamp and Childress⁸⁶ the concept of beneficence includes three elements: firstly, one should prevent harm; secondly, one should remove harm; and lastly one should do or promote good.

Beneficence involves positive acts that can either prevent or remove harm or promote good, while non-maleficence requires the non-infliction of harm.

According to consequentialism (*defined earlier*) it is unethical to carry out an act that has the potential to cause harm to others. Based on consequentialism, it can be said that,

promotion of infant formula is unethical as it could result in infants' health being compromised.

The theory of deontology would support breastfeeding (as breastfeeding is good) over infant formula. Deontology suggests that is the duty of health professionals to support and promote breastfeeding. Although the duty of infant health is primarily the duty of the health professional, all moral agents understand the need to take preemptive measures to avoid any form of unethical marketing and promotion of infant formula, particularly marketing and promotion tactics that are specifically aimed at health professionals

Exceptional beneficence requires one to act beyond the call of duty and to do more than is required.⁸⁷To return to our focus: dealing with vulnerable groups such as infants requires health professionals and companies to go beyond and above the call of duty, particularly in a country such as South Africa, where infant mortality is still unacceptably high. Health professionals need to be proactive in ensuring that policies, guidelines and regulations are in place that addresses those issues that could result in infants being harmed. Indeed, acting for the benefit of others is not only part of their professionalism, but is an intrinsic duty on the part of those called upon to be true moral agents of society.

The actions of beneficence can sometimes be outweighed by concerns of autonomy⁸⁶ in other words, what the health professional knows to be good will not necessarily apply to each and every mother/caregiver. Also, and related to this, is the fact that respect for persons means that all people have the right to exercise their autonomy⁸² and this requires health professionals to respect the mother/caregiver's desire.

3.5 Autonomy

The “concept of autonomy” is a notion that recognizes patients as main decision makers.⁸⁸ In various democratic countries the notion that patients should make their own choice regarding their own health and well-being is becoming increasingly common.⁸⁹

People find it fundamentally valuable to plan their own lives and live as they wish. To practice autonomy⁹⁰, however, one needs to have the necessary information and also capacity to carry out the decision.⁹¹ Kant who was one of the first philosophers to address autonomy had the view that; an agent cannot act morally unless they were free to choose what is right.⁹² The fact that health professionals are not allowed to market infant formula does not mean that the mother/caregiver’s right of autonomy should be denied; indeed, it is essential to equip with information to make their own, informed decision. The information given by health professionals can enable mothers/caregivers to make the decisions that would be best for their infants.

There is a view that patients’ autonomy can be restricted if there is a threat of very severe harm to patients’ wellbeing.⁸⁶ Another view is that there should be no limits to autonomy except in cases where patients’ autonomy can result in harming others.⁹³ In cases where the mother/caregiver’s decisions poses harm to the infant the child’s best interests can override the mother/caregiver’s right to autonomy. Paternalism is a notion that suggests health professionals make decisions based on what they view to be best for the patient rather than allowing patients to make their own decisions.⁸² It has been stated that paternalism can be justified where the patient concerned lacks the capacity (or not competent) to look after their own interests.^{94,95} A competent patient is a person that has the capacity to act on his/her behalf.⁹⁴ Infants can be considered as not being “competent patients” due to their age and development. In most cases parents/ caregivers are the ones who have the capacity to decide on their behalf.

In South Africa there is no law that forces mothers to breastfeed their infants and thus this allows mothers to choose how to feed their infants. One country that has made it compulsory for mothers to breastfeed is the United Arab Emirates. Mothers in UAE are required by law to breastfeed their infants until two years of age and those who are unable to breastfeed wet nurses are provided to them.⁹⁶

In the researchers' view it is important for health professionals to provide mothers with facts regarding breastfeeding and risks associated with infant formula; however the mother/caregiver's attitudes and views should be respected.

3.6 Justice and fairness

Justice refers to treating an individual or people with fairness, equitably and with appropriate treatment.⁹⁷ One acts justly towards another individual when that individual has been given what is due or owed to them; this means that the other can legitimately claim what is owing to him or her.⁸⁶ Injustice occurs when a wrongful act is committed or there is an omission that denies people resources or protections to which they have the right. There are four types of justice: distributive, comparative, procedural and retributive justice.⁹⁸ For the purposes of this paper, however, the researcher will focus on distributive justice.

Distributive justice refers to the just distribution of benefits and burdens in society.^{82,82,86} To have benefits and burdens fairly distributed within society can be an overwhelming task, particularly in a country such as South Africa, where there is an issue of inequality, including inequality in terms of access to healthcare.

Fairness is the ability to make decisions that are not necessarily general, but those that are peculiar to a certain case, and fairness means that one's own feelings and interests do not influence such decision.^{82,86,99} Justice is about treating individuals based on what

is due to them. When considering how benefits and burdens should be distributed among a group of people, justice and fairness are likely to come up.

The fairness principle suggests that all those who are equal should be treated equally and those who are not equal due to appropriate differences should be treated in a manner that is fair and proportional.⁸⁶ The health profession has an advantage over the general public when it comes to knowledge relating to health. It would not be fair to use that knowledge in a manner that could disadvantage infants.

Although, in South Africa, a significant number of people live in poverty there are those who earn a decent living, who have access to safe water and sanitation, who have electricity and who are less likely to suffer harmful consequences as a result of feeding their infants infant formula (compared with those in low-income groups). This is why public health policies and any marketing and promotional messages regarding infant feeding need to be conveyed in a manner that ensures that the poor are not disadvantaged. That said, to ensure fairness, these policies need to be geared towards protecting the poor simply because, in any society, this is the group of people who are vulnerable.

Any company that claims to be fair would operate its business in a manner that ensures that its quest for profit does not result in influencing health professionals to promote infant formula over breastmilk. Even in cases where poverty is not an issue, justice and fairness regarding the promotion of infant formula over breastmilk still needs to prevail, since most infants are more likely to benefit from breastmilk than infant formula.

As much as health professionals have a moral obligation towards infants, companies are also expected to conduct their business in a fair and responsible manner. Business is not merely about products/services, jobs and a profit, but also about being part of a community it operates within. Pursuing profits and economic process does not imply that

companies should ignore community norms, values, and integrity. Infant mortality is a serious concern in South Africa¹⁰⁰, and companies operating in South Africa should conduct their business in a manner that ensures that infant health is not compromised by irresponsible marketing.

Health professionals should be in the forefront of ensuring that justice prevails within healthcare services by, firstly, ensuring improved healthcare access to every citizen, particularly infants, secondly, by preventing further deterioration of infant health and, lastly, having measures in place that would deal with existing infant health legislation.

Improved access to healthcare will not necessarily result in healthy infants if those who work in health facilities allow companies to influence the type of care and information they offer to mothers/caregivers.

The HPCSA and SANC^{101,102} expect all health professionals to act fairly and equitably, particularly where there is competing interests among parties, groups and individuals.

In any situation that could be perceived or experienced as unequal, health professionals need to strive for justice and advocate for the vulnerable; furthermore, they should be able to justify their conduct. A health professional's duty should be driven by what is deemed morally acceptable and not what they could personally gain as a result of their conduct. Companies can still contribute positively to the health profession through regulated sponsorships; they certainly do not have to offer gifts.

CHAPTER 4:

CORPORATE SOCIAL RESPONSIBILITY AND ADVERTISING

This chapter focuses on Corporate Social Responsibility (CSR) and advertising on the part of infant formula companies. In this chapter, the relationship between bioethics and business ethics will also be explored.

First of all, we need to remember that the production and marketing of infant formula and complementary food is a highly profitable business; this is the reason why these products are promoted so enthusiastically, particularly in emerging economies.

In certain parts of Asia, the market for commercial baby food grew to US\$14.7 billion in 2011 and this swift growth is projected to continue: in places such as China and Eastern Europe, the infant formula market is growing rapidly. Furthermore, the development of this market is associated with the economic growth of those countries and one of the consequences of this economic growth is an increase in the number of working women.¹⁰³

As far as ethics are concerned, business ethics has become a significant part of most businesses: business ethics consists of set of principles, values and standards that determine what constitutes acceptable conduct within an organization.^{104,105} It involves properly thought out business policies and practices about controversial issues such as corporate governance, bribery, discrimination, fiduciary responsibilities and CSR.

The acceptability of behaviour in business is determined by customers, competitors, government regulators, interest groups, and the public, as well as each individual's personal moral principles and values.¹⁰⁶ Given this, offering gifts can be viewed as no more than a pleasant gesture and offering sponsorships may well be regarded as an initiative that specifically addresses the important subject of infant health. However, the fact remains that the offering of gifts or sponsorships in order to influence an individual is

wrong, whether or not the motive behind the action will determine whether the act is ethical or not. The true motive behind gifts and sponsorships offered by companies (in our case, infant formula companies) is impossible to determine and thus it is necessary to have measures in place that severely restrict the influence of commerce on health professionals.

4.1 Corporate Social Responsibility

Corporate Social Responsibility (CSR) refers to companies' continuing commitment to conduct business in a manner that contributes towards the wellbeing of the communities in which they operate.¹⁰⁷ Over the past years, socially responsible investing which encompasses ethical values, taking care of the environment, improving social conditions and good governance have all become a significant part of several business organizations,^{106,107,108} including infant formula companies such as Nestlé and Aspen.^{12,109} The notion of CSR is based on the view that companies have duties to society that lie beyond their economic functions and legal obligations.¹¹⁰

Today companies are much more open to the concept of CSR, since CSR demonstrates their commitment to societal concerns and to fairness and ethics.^{111,112}

Ethics and CSR are interconnected in three ways: a) company policies and practices that make certain that companies operate their businesses in an accountable and ethical manner; b) external initiatives that contribute towards the wellbeing of communities in which a company operates (e.g. philanthropy and employees volunteering to do certain charity work); and c) the impact these initiatives have on society.¹⁰⁸

The major infant formula companies that operate in South Africa include Nestlé and Aspen and both these companies have policies that explicitly state that they operate their

businesses ethically and both have initiatives that benefit various communities in South Africa. ^{12,109}

Nestlé

Nestlé state that it discourages improper favours between their employees and other parties, including the inappropriate offering of symbolic gifts and meals.

Some of the community initiatives that they conduct include the food security programme; this programme involves women working towards improving the nutritional status of their communities through various food, nutrition and agriculture projects.

Other projects include the water project, the aim of which is to reduce the incidence of water-borne diseases in communities.¹⁰⁹

Aspen

Aspen states that its vision includes delivering value to their stakeholders; these stakeholders include shareholders, customers, and employees, suppliers, regulating authorities, government, communities, trade unions, business partners and bankers ¹².

Aspen also states that it believes in the importance of carrying out its business in a manner that is sustainable, which takes in to account the future, and the fact that the company is accountable to its stakeholders. As a way of practising good cooperate citizenship, Aspen states the company takes into consideration ethics, human capital, transformation, human rights, health and safety, corporate social responsibility, and the environment.

Aspen has an initiative that is aimed at addressing vital community healthcare projects within the country; these projects include the acceleration of access to primary healthcare and educational facilities, and giving added weight to South Africa's national campaigns against HIV/AIDS, TB and other non-communicable diseases.

Although CSR is a concept that has the potential to contribute towards society's wellbeing, not every organization values or sees the need for it. Based on the policies and certain practices on the part of both Nestlé and Aspen, it would appear that these companies are not merely interested in profits, but are also concerned about the wellbeing of South Africa's communities. That said, and even though some companies contribute towards the good of society, it still remains the government's responsibility to ensure the overall wellbeing of a country's various communities.

To return to the subject of this dissertation – infant formula – companies need to make a profit from selling infant formula; this is precisely why it is necessary to have regulations in place to ensure that companies operate in a manner that does not result in the harming of infants in their pursuit of profit. Also, given that companies are not legally bound to practice CSR and to contribute towards society's wellbeing, such regulations are needed to ensure that infants' mothers and caregivers are protected from potential harmful marketing and the irresponsible promotion of infant formula.

Consumers expect companies to operate in an ethical manner; in fact, consumers' purchasing decisions are often influenced by a company's practice of ethics. In fact, poor corporate ethics can cause consumers to boycott the company, as was the case of the Nestlé boycott in the 1970s.⁴⁰

4.2 Advertising

Advertising allows consumers to obtain information, and thus make informed choices. Consumers (in this case, mothers/ caregivers) who decide not to breastfeed or those who, for some reason, cannot breastfeed can get access to reliable and accurate information about infant formula through responsible advertising. It needs to be remarked that advertising has been accused of various things, from the purveying of harmful products, to outright deception and manipulation.¹¹³ In the case of infant formula, deceitful and manipulative

advertising can jeopardize the health of the infants under the care of mothers/caregivers (particularly if the mother/caregiver is illiterate).

Drumwright and Murphy's study reported that advertising agency personnel were not sensitive to ethics in advertising.¹¹⁴ Some agency personnel have argued that the deception used in advertising is not an issue since most consumers have the intelligence to filter out commercial information^{115,116} The case of infant formula, if companies were to freely advertise and offer misleading information about feeding (i.e. putting health claims on their packaging), by no means all mothers in South Africa will be able to discriminate between health claims made for commercial purposes, and that such health claims by no means guarantee that their infants will be healthier. Again, this is why it is necessary to have laws in place that protect consumers from possible harm as a result of misleading advertising.

The purpose of promotion and marketing is to increase sales and, according to Piety, there are four "marketing failures" that carry possible negative consequences: (a) the spreading and acceptance of false ideas; (b) the suppression of truthful information; (c) the failure to produce truthful information; and (possibly) (d) limitations on choice, and the deliberate channeling of people's exercise of preferences within those limitations.^{117,118}

Historically, certain infant formula companies were never forthcoming about the risks associated with their products.⁴⁰ It was only when the Code and the regulations were introduced that companies started making a point of stating that "breastmilk is best", even though this was, in fact, common knowledge.^{2,10, 19,64,119}

The Advertising Standards Authority of South Africa (ASA) under Appendix E-Advertising of breastmilk substitutes, baby feeding bottles and teats prohibits the promotion of breastmilk substitutes.¹¹⁹

The provisions by ASASA regarding advertising of BMS include:

- Prohibition of advertising the use or advantages of BMS.
- Prohibition of point-of-sales, distribution of samples or any other promotional method meant to induce sales.

A study by Radebe which was conducted between November 2012 and March 2014 identified 30 violations from that 117 baby products.¹²⁰ Some of these violations included promotion of food and drinks to infants younger than six months. The study also found that a small percentage (4.7%) of magazines targeted at pregnant women violated the code.

Although this particular study reported violations, there seems to be no documented complaints regarding any violations relating to marketing of infant formula, after the year 2012. While the violations seem to be few, it does raise an issue of whether those few violations can be effectively dealt with if they are not reported to ASA.

Advertising has been criticized as an intensifier of certain societal problems.^{40,116,117} That said, responsible advertising can help to address certain social problems. In this case, advertising that makes a point of explaining how to use infant formula safely, that states the options available in the market, and that states the risks associated with the use of infant formula can help in to address infant ill-health. However, we need to remember that the low rates of breastfeeding and infant ill-health due to the lack of breastfeeding in South Africa is already a problem⁶⁴ a problem that could be made worse by the public advertising of infant formula. The main reason for advertising is to improve sales and to allow companies to advertise would defeat the objective of trying to promote breastfeeding.

Mothers/caregivers who have opted to use infant formula have the freedom to do so without being influenced by advertising or promotion tactics from any company.

Information regarding infant feeding, particularly the use of infant formula, needs to come from a source that does not have obligations or ties to a company that manufactures infant formula. Health professionals who are trained and knowledgeable about infant feeding, and not influenced by their relationship with infant formula companies, remain the best people to give advice on infant feeding. This is because informed health professionals who are not influenced by commercial concerns are likely to impart information that is based on best practice.

Consumers (mothers/caregivers) need to be protected from any form of irresponsible advertising; this is particularly true of less literate consumers who might well not be able to differentiate between promotional and factual information.

4.3 The Consumer Protection Act

Given that, in the past, South Africa's laws have been such that they resulted in high levels of poverty, illiteracy and other forms of social and economic inequalities, since 1994, governments have believed it necessary to establish and apply innovative means that ensure that all consumers are protected from any form of exploitation. Hence the passing, in 2008, of the Consumer Protection Act, the purpose of which is as follows.¹¹⁸

- "Fulfill the rights of historically disadvantaged persons and disadvantaged persons and to promote their full participation as consumers"
- "Protect the interests of all consumers; ensure accessible, transparent and efficient redress for consumers who are subjected to abuse or exploitation in the marketplace, and
- "To give effect to internationally recognized customer rights by establishing the Consumer Protection Act no. 68 of 2008"¹¹⁸

The purpose of the Act, as stated in Chapter 1, Part B, Section 3(1),¹²¹ is to promote and ensure the progression of social and economic welfare of consumers in South Africa.

The Act is meant to ensure that a legal framework exists that contributes towards achieving and maintaining a consumer market that is fair, accessible, efficient, sustainable and responsible for the benefit of consumers in general (66/CPA). The Act also aims to reduce and ameliorate any disadvantages experienced in accessing any supply of goods or services by consumers.¹²¹

The Act is also meant to protect consumers from (a) unconscionable, unfair, unreasonable, unjust or otherwise improper trade practices; and (b) deceptive, misleading, unfair or fraudulent conduct. It is also directed to *improving* consumer awareness and information and encouraging responsible and informed consumer choice and behaviour.¹²¹

As far as the marketing of infant formula is concerned, unfair and unreasonable conduct has occurred when companies have used health professionals to offer discount packages that included infant formula for mothers.¹²² The fact remains that such conduct failed to take into consideration the fact that infants' health might be compromised as a result of mothers' failure to breastfeed and the fact that many mothers simply lacked the resources and knowledge required to prepare infant formula safely.^{122, 123}

Chapter 2: Part D, Section 22(2) of the Consumer Protection Act requires producers to provide consumers with information about their product in a manner that is easy to understand; this chapter of the Act specifically focuses on consumers who might have average literacy skills and minimal experience as consumers.¹²⁴ Part E, Section 29(a) (b), which is about the consumer's right to fair and responsible marketing from companies requires producers, distributors, retailers, importers or service providers to refrain from marketing any product in a misleading, fraudulent or deceptive manner.¹²⁵ Although Section 16(1) (b) of the Constitution states that everyone has the "freedom to receive or impart information or ideas", information given by marketers to the public should not be misleading or deceptive.¹²⁶ The fact that the Constitution allows for freedom to receive

and impart information or ideas implies that mothers can freely receive information on infant formula and that companies can freely give out information on infant formula.

It is crucial for mothers/caregivers to have adequate and accurate information regarding the use of infant formula so that the risks associated with infant formula are reduced. False and misleading marketing carries possible negative consequences for public health and welfare. Misleading statements from infant formula companies thus raise challenges. Given this, the criticism that the regulations are infringing on the mother's right to receive information is, in the researcher's opinion, without basis. Firstly, although infant formula cannot be promoted it is still available for mothers to purchase. Secondly, the Infant and Young Child Feeding Policy⁹ make provision for educating and supporting mothers who have made an informed decision to formula feed.

Consumers need to have accurate information regarding the quality and other characteristics of the products offered for sale. In the researcher's view cases where information given out to consumers is not completely accurate and factual, the government ought to intervene.

The current challenge, as far as the counselling of mothers regarding formula feeding is concerned, is that the national infant feeding training for health professionals does not cover all the infant formula products available on the market.⁶⁴ This means that the health sectors, and those who work in this sector, have to rely on the education given by infant formula companies.

Needless to say, allowing companies to train health professionals makes it possible for some health professionals becoming a "marketing platform" for these companies. At present in South Africa, there are no set guidelines which states how best to ensure that companies who share scientific information with health professionals avoid using this as a form of commercial marketing.

Although there is a legal framework that consumers can use to seek redress after a violation of their rights, this is invariably reactive. Preemptive measures such as avoiding conflict of interest, and upholding professionalism, minimize the risk of possible harm to consumers. The regulations relating to foodstuffs for infants and young children are particularly relevant in this regard.

CHAPTER 5

CONCLUSION AND RECOMMENDATIONS

Infants are vulnerable because of their age and development. The fact that they cannot speak for themselves makes them vulnerable as well. There is a need to protect them from possible harm that could arise as a result of how they are fed. Breastfeeding and particularly exclusive breastfeeding for the first six months is beneficial to the health of most infants. Promotion of continued breastfeeding for two years and beyond⁹ contributes to the infants and young children optimal nutritional status. For infants born in poor communities, continued breastfeeding contributes towards household food security significantly. Lack of breastfeeding and/or the use of infant formula can negatively affect the health of infants. The risks of using infant formula are evidently higher in poorer communities.

Arguably, the parent's right to autonomy ought to be respected when deciding whether to breastfeed or formula feed their infants. However, in cases where the feeding choice by parents may result in possible harm to the infant; health professionals may have to counsel and advise the parents about the importance of breastfeeding. Health professionals are expected to put the interests of the infant first in all situations. In certain situations (*where the child's health is compromised*) it is acceptable for health professional to override the parents' right to autonomy for the sake of the infant's wellbeing. In South Africa, infant mortality is still fairly high (34 per 1000)¹⁰⁰ and lack of breastfeeding and the improper use of infant formula are some of contributory factors to infant morbidity and mortality.⁹ One of the reasons for adopting the Code ⁹, ⁶⁴and promulgating the regulations (R991) is to improve infant health, and this includes minimizing the marketing and promotion of infant formula.

Since the adoption of the Code (by various countries), there seems to have been less infant formula disasters. One can thus conclude that the Code has been somewhat

successful in reducing the risks associated with the marketing infant formula and the use of it.

Even though South Africa has regulations in place, there are shortfalls in their implementation. The main challenges here include the need to train health professionals in the regulations and the need to comprehensively monitor the regulations. It is difficult to determine the success of the regulations in South Africa as there seems to be no means of monitoring and evaluating its implementation.

An independent monitoring body needs to be established to which all findings can be submitted and recommendations given accordingly. Implementation of the regulations needs to be monitored in all health facilities, and not just those that offer maternity services.

The tool used to monitor adherence to the Code/regulations needs to be more comprehensive; this tool should not only concentrate on the offering of gifts and sponsorships to mothers/ pregnant women, but also the offering of gifts and sponsorships to health professionals.

Continuous research on the development of suitable BMS is crucial in order to meet the nutritional needs of infants who require other foods other than breastmilk. Infant formula companies have had a significant role in the development of safer and appropriate BMS (*i.e. the development of acidified formula which has lower risks of causing infections*). Companies are the ones who know their products best and therefore should continue to offer health professionals scientific information regarding the use of their products.

Wager suggests that there should be a proper dialogue between industry and health professionals prior to any updating of guidelines or regulations relating to conflict of interests.¹²⁷ In my opinion this may improve the adherence to the regulations.

The fact that the regulations are promulgated is a good start as far as ensuring the protection of infant wellbeing is concerned. However, these regulations alone are not adequate in ensuring that mothers/caregivers practise appropriate feeding methods. Other interventions, such as the educating of mothers, supporting existing health policies and making such policies more stringent need to be emphasized.

The government agencies that regulate the marketing of BMS need to have the capacity to deal with any misconduct on the part of companies. More research is needed, in South Africa, to determine whether the regulations have contributed positively towards an increase in breastfeeding rates and improved infant health.

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BABY-FRIENDLY HOSPITAL INITIATIVE

Revised Updated and Expanded for Integrated Care

SECTION 4 HOSPITAL SELF-APPRAISAL AND MONITORING

2009

Original BFHI Course developed 1992



Compliance with the International Code of Marketing of Breast-milk Substitutes

Code.1 Does the healthcare facility refuse free or low-cost supplies of breast-milk substitutes, purchasing them for the wholesale price or more	Yes	No
Code.2 Is all promotion for breast-milk substitutes, bottles, teats, or pacifiers absent from the facility, with no materials displayed or distributed to pregnant women or mothers?		
Code.3 Are employees of manufacturers or distributors of breast-milk substitutes, bottles, teats, or pacifiers prohibited from any contact with pregnant women or mothers?		
Code.4 Does the hospital refuse free gifts, non-scientific literature, materials or equipment, money or support for in-service education or events from manufacturers or distributors of products within the scope of the Code?		
Code.5 Does the hospital keep infant formula cans and pre-prepared bottles of formula out of view unless in use?		
Code 6 Does the hospital refrain from giving pregnant women, mothers and their families any marketing materials, samples or gift packs that include breast-milk substitutes, bottles/teats, pacifiers or other equipment or coupons		
Code.7 Do staff members understand why it is important not to give any free samples or promotional materials from formula companies to mothers?		

The Global Criteria for Code Compliance are on the following page.

Appendix B

Human Research Ethics Committee (Medical)

Research Office Secretariat: Senate House Room SH 10005, 10th floor. Tel +27 (0)11-717-1252
Medical School Secretariat: P V Tobias Building Room 304, 3rd Floor. Tel +27 (0)11-717-2700
Private Bag 3, Wits 2050, www.wits.ac.za. Fax +27 (0)11-717-1265



Ref: W-CJ-160714-1

16/07/2014

TO WHOM IT MAY CONCERN:

Waiver: This certifies that the following research does not require clearance from the Human Research Ethics Committee (Medical).

Investigator: Malebina Botsane (student no 753448)

Project title: Sponsorships and gifts from infant formula companies to healthcare professionals: Ethical issues.

Reason: This study is a review of information in the public domain. There are no human participants.

A handwritten signature in black ink, appearing to read "Peter Cleaton-Jones".



Professor Peter Cleaton-Jones

Chair: Human Research Ethics Committee (Medical)

Copy - HREC(Medical) Secretariat: Anisa Keshav, Zanele Ndlovu.

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