

Sponsorship of health professional associations by manufacturers and distributors of commercial milk formula

Case studies

Context

The World Health Organization (WHO) has recommended *(1)* that, in order to promote, protect and support breastfeeding, prevent obesity and noncommunicable diseases, promote healthy diets, and ensure that caregivers receive clear and accurate information on feeding, companies that market foods for infants and young children should not "sponsor meetings of health professionals and scientific meetings." Likewise, health workers, health systems, health professional associations and nongovernmental organizations should not "allow such companies to sponsor meetings of health professionals and scientific meetings".

In resolution 69.9 on Ending Inappropriate Promotion of Foods for Infants and Young Children (2), the World Health Assembly called upon Member States and health care professionals to implement these recommendations. WHO and the United Nations Children's Fund (UNICEF) have published an Information Note that explains what is meant by sponsorship of health professional and scientific meetings by companies that market foods for infants and young children (3). The document provides a non-exhaustive list of marketing activities that may establish conflicts of interest in health care systems and among health care professionals.

Purpose

This brief describes how six Health Care Professional Associations (HCPA), in different countries and years, carried out a process that led to an end of their collaboration with companies that market foods for infants and young children as far as sponsorship of HCPA events are concerned. The six case studies were drafted by members of the six HCPAs and revised by a WHO working group in collaboration with the authors.



Indian Academy of Pediatrics, India, 1992-93

What prompted the <u>Indian Academy of</u> <u>Pediatrics</u> (IAP) to end sponsorship and when did this happen?

In 1981, UNICEF & WHO adopted the International Code on Marketing of Breastmilk Substitutes. Based on the recommendations of this Code, the Indian Government set up a working group to develop a national code; IAP was invited to take part in this group. The IAP was soon put under pressure by representatives of the commercial milk formula (CMF) industry, who offered funds to the IAP if it decided to promote a voluntary code of conduct, instead of a law. IAP members voted overwhelmingly against this offer and in 1983 decided to refuse all support from industry for IAP conferences (4). Eventually, the Indian Government enacted and passed the Infant Milk Substitute Act (IMS Act) in 1992–93; the IMS Act was revised and strengthened in 2003. The IMS Act provisions regulate production, supply, distribution of Infant Milk Substitutes, Feeding bottles & Infant foods. Article 9.2 of the IMS Act states that "No producer, supplier or distributor ... shall offer or give any contribution or pecuniary benefit to a health worker or any association of health workers, including funding of seminar, meeting, conferences, educational course, contest, fellowship, research work or sponsorship" (5) IAP decided to abide by the IMS Act and the International Code. This decision was confirmed by a Resolution passed by a majority vote at the 1997 annual IAP meeting. It was also reinforced by two letters, sent by IAP presidents to all members in 2019 and 2022, in which members were alerted about new companies and new products entering the Indian market.

How did the process unfold and how were members involved?

After going through the recommendations of the International Code, the IAP activists working for the promotion, protection and support of breastfeeding became motivated to do more. They started discussions and created awareness about the benefits of proper nutrition education regarding maternal and child health amongst various stakeholders including policy makers. Potential infringements to the decision to abide by the IMS Act were notified to the IAP Secretariat and rejected. When the issue was raised at annual or other IAP meetings, there were always lively discussions, but the majority of members remained firmly in favour of refusing sponsorship by the CMF industry.

Which arguments were most effective in motivating the association's decision makers or members to take action?

In addition to the decision to abide by the IMS Act and the International Code, the various points or arguments included were:

- a) Mother's milk is best suited for the baby.
- b) Mother's milk is nature's gift. The mother's milk is "eco-friendly".
- c) Avoid artificial, commercial, costly, contaminated and preservative containing tinned or packaged commercial food.
- d) The home-made food is clean, safe, cost effective, and culturally acceptable.
- e) Bottle feeding may be injurious to the health of a child because of various disadvantages.
- f) Proper nutrition is the birth right of mother and child dyad.

It became understood that CMF companies sponsor meetings to stay in touch with paediatricians and influence them. Sponsorship is always effective, as it creates a relationship between donor and recipient with the inherent obligation to reciprocate. Sponsorship of paediatric conferences undermines breastfeeding and should therefore be avoided.

Was there any resistance to the change and how did IAP deal with counter arguments?

There were many hurdles, counter arguments and resistance at various levels to these changes. Many workshops, Continuous Medical Education (CME) events, and conferences (at district, state, regional and national levels) were organized to create awareness, clarify doubts and misconceptions, and provide evidence-based unbiased scientific information to various stakeholders. Scientific studies were conducted and published in books and peer-reviewed indexed journals with proven authenticity. The issues related to maternal and child nutrition were included in undergraduate and post graduate curriculums. Individual gueries or confusions were discussed and solved whenever required. Parents, adolescents (boys and girls), media personalities, NGOs and government authorities were included and counselled in various programs.

What kinds of financial support did IAP receive

from industry and what has replaced it? (e.g. sponsorship for conferences, journals, posts, education and training, travel, etc., quantify if possible)

Before the enactment of the IMS Act, support from the CMF industry was significant to our members and included many inducements like sponsorship for conferences, quiz programs, workshops, CME events, research grants, publishing journals, posts in various companies or associations, quest lectures, education and training of health workers, overseas/international travel or tours, hotel accommodations etc. Gradually the IAP members were made to understand their ethical, moral and legal responsibilities. Fortunately, with time the situation started improving; some of the members started understanding that the law of the land needs to be respected. Though the situation has not improved as fast as expected, the reforms are slowly and steadily moving in the right direction.

IAP has stopped taking any direct or indirect support from CMF industry since almost 28 years and we are not only proud of it, but are totally committed to the cause of promoting breastfeeding. Our members pay from their pockets for most of the CMEs/seminars. We have substantial discount in the early bird registration for every conference may it be the city/district/subspecialty or the national. We also have a concept of AWESOME in some scientific meetings (Academics With Excellence Science Only Minus Extravaganza), where 100% of funds are generated only from the attending delegates' registration fees and zero industry support. Finally, we do get support from other Pharma companies not related to CMF, such as vaccine/antibiotics manufacturers.

IAP is committed to support exclusive breastfeeding for the first six months and with huge experience of almost 3 decades of staying away from CMF industry and under the present leadership is ready to provide any guidance to any country in this regard.

In what way has IAP drawn a line? (e.g. has IAP adopted a clear position statement, and has it ended all, some, or future funding)

A clear position has been taken by IAP (including its sub-specialty chapters and branches) from time to time on different occasions. A definite line has been drawn. A clear position statement has been reiterated by IAP in 2022 to ending all present or future funding by CMF, feeding bottles and infant food companies (6). It is expected that all members will not accept sponsorships or inducements from CMF companies. They will not attend programmes as delegates or guest faculties organized by such companies.

What have been the costs and benefits of ending sponsorship?

It is difficult to assess or comment on the costs of ending CMF sponsorship, but the benefits are enormous. There may not be significant improvements in various statistics, but gradually we are marching towards achieving the Millennium Development Goals. The people understand the advantages of breastfeeding and proper complementary feeding. The establishment of mother's milk bank throughout the country also resulted in decreased use of CMF. These changes are one of the reasons for the gradual improvement in neonatal and infant morbidity and mortality rates in India.

Associazione Culturale Pediatri, Italy, 1998

What prompted <u>Associazione Culturale Pediatri</u> (ACP) to end sponsorship and when did this happen?

The ACP was created in 1974. Since then, it holds annual conferences and it publishes a quarterly journal, <u>Quaderni ACP</u>. In 1998, during the annual conference held in Taormina, Sicily, the ACP general assembly voted in favour of a code of ethics titled: "Commitment to self-regulation in the relationship with industry". This code was published the same year in Quaderni ACP, signed by the members of the scientific board.

The reason for this commitment was, and still is, the fact that paediatricians' professional activities are permeated by marketing, in particular by companies producing vaccines, drugs and baby foods. ACP considered it necessary to frame its relationships with industry based on principles of independence and transparency, to reduce or avoid the risks of corrupting individual and collective professional behaviours, and of infringing international and national standards, agreements and codes.

In 2012, 14 years after the first version was approved, ACP updated and partially modified its code of ethics, to take into account the evolving discourse on conflicts of interest, to clarify some aspects that might have appeared contradictory, and to further specify the scope of its application. Meanwhile, some professional behaviour had been regulated by Italian law and was no longer subject to self-regulation.

How did the process unfold and how were members involved?

The revision process saw the involvement of members of the ACP Executive Committee, the heads of various working groups, the director of all editorial activities, the editor-in-chief of Quaderni ACP, and the past president at the time the first the code of ethics was adopted. The draft of the revised code was circulated among all ACP members and regional groups for further comments, and was presented at the 2012 annual conference. After receiving feedback, a new version of the code was prepared and presented for final approval in 2013. The assembly, after accepting some proposed amendments, approved the code of ethics in its current form.

Which arguments were most effective in motivating the association's decision makers or members to take action?

The purpose of this code of ethics is to provide children and their families with a professional practice inspired by transparency and independence from commercial interests. Accepting to be influenced by marketing would not be compatible with, for example, the promotion and support of breastfeeding, as well as the promotion of complementary feeding using home foods, as opposed to ultra-processed industrial foods. Breastfeeding and healthy infant and young child feeding are considered as important priorities by ACP.

Was there any resistance to the change and how did ACP deal with counter arguments?

We had and we still sometimes have forms of resistance. Those who oppose the decision to end sponsorship argue that collaboration with industry is useful for the development of new and safer products. Our counter arguments focus essentially on the evidence-based literature showing the negative influence of marketing on the practice of paediatricians. The recent Lancet series on breastfeeding represents a milestone in this respect. Other counter arguments are based on ethical imperatives and on our commitment with families and children.

What kinds of financial support did ACP receive from industry and what has replaced it? (e.g. sponsorship for conferences, journals, posts, education and training, travel, etc., quantify if possible)

As a national association, we occasionally received some financial support from industry; for example, by manufacturers of natural remedies. Since 2006, we have put an end to all forms of advertisement in Quaderni ACP. However, we have never accepted funds nor advertisement from manufacturers of breast-milk substitutes and other products under the scope of the International Code since 1998. The cost of running our activities (national and subnational conferences, Quaderni ACP, other educational activities, some operational research) is totally covered by the members of our association. For example, the registration fee for an educational webinar may range between 20 and 80 euros, for a local ACP conference between 100 and 200 euros. The fee for the last national conference was 250 euros for members, 300 for non-members, 50 for students. The overall cost of a pre-pandemic national conference was around 40 000 euros, but the revenue was always a few thousand euros higher, the surplus being used for other activities. The current annual membership, including Quaderni ACP and other occasional publications, costs 120 euros. The annual budget is transparently posted in the ACP website and can be seen by anybody. In 2021, for example, the revenues amounted to 196 446.77 euros (about two thirds from membership fees) and the expenses to 190 865.39 euros, with a carry over to 2022 of 5 581.38 euros.

In what way has ACP drawn a line? (e.g. has ACP adopted a clear position statement, and has it ended all, some, or future funding)

After the adoption of our code of ethics, we put an end to all kinds of sponsorships by the commercial milk formula and other industries. We hope that we will be able to maintain our position in the future.

What have been the costs and benefits of ending sponsorship?

Putting an end to sponsorship did come with a cost. Our conferences' registration fees are not very high, but certainly attending is not free of charge, as for other paediatric associations. This has resulted in a decline in attendance, especially in post-Covid-19 time. We are constantly working on this and it is sometimes hard to resist, but we think that it is the only way to be independent and transparent; this is a major benefit. Our code is based on assumptions that refer to ethical and deontological principles that go beyond the purely legal aspects that govern the relationship between industry, individual physicians and medical organisations and associations. We have a clear understanding of the risks associated with conflicts of interest arising from such relationships. The guiding idea, for associations that act purely under the law, is that anything that legislation does not expressly forbid is allowed. We do not agree with this idea.

Royal Australasian College of Physicians, Australia and Aotearoa New Zealand, 2012

What prompted the <u>Royal Australasian College</u> of <u>Physicians</u> (RACP) to end sponsorship and when did this happen?

The RACP holds an annual congress. It also publishes a monthly paediatric peer reviewed indexed journal called Journal of Paediatric and Child health (JPCH). There are no clear records on when congress sponsorship by commercial milk formula (CMF) manufacturing companies ended, but at least since 2012 the RACP congress has not accepted funding from CMF manufacturers. JPCH was receiving funding from CMF companies till March 2019. This was approximately AUD 100 000 from 2013–2019. In March 2019, the Paediatric and Child Health Division (PCHD) of the RACP felt that this funding did not align with the RACP's strong stance on breastfeeding being the best practice. The PCHD raised it with the RACP board.

How did the process unfold and how were members involved?

The counter arguments included:

- "We are paediatricians, not the general public"
- "The JPCH does not allow false claims in any advertising and claims about allergy are checked by experts"
- "Not all women can breastfeed, so there is a need for infant CMFs"
- "Some special infant CMFs are vital for children with severe food allergies"
- "Advertising revenue is needed for the JPCH's business model".

Despite these arguments, the PCHD agreed that this sponsorship needs to end. RACP Board decided to form a College Journal Committee (CJC). CJC decided in its first meeting not to accept sponsorship from CMF manufacturers from here on.

Which arguments were most effective in motivating the association's decision makers or members to take action?

The strongest argument was that continued sponsorship does not align with the PCHD's strong stance with supporting breastfeeding. The leadership at PCHD had complete clarity on this issue.

Was there any resistance to the change and how did RACP deal with counter arguments?

There was some resistance with statements raised above. A financial argument was also made. Many constituents confused the issue with the college trying to advocate for a ban on all advertising from CMF companies, but it was clarified that the advocacy was limited to the college's activities only.

What kinds of financial support did RACP receive from industry and what has replaced it? (e.g. sponsorship for conferences, journals, posts, education and training, travel, etc., quantify if possible)

The cost of replacing these were offset by increasing the attendance fee. The RACP board also was committed to offsetting some of the cost of the congress so that the sponsorship arrangements align with the membership's expectations.

In what way has RACP drawn a line? (e.g. has RACP adopted a clear position statement, and has it ended all, some, or future funding)

RACP works on a traffic light system of accepting sponsorship funding. Pharmaceutical manufacturers (including CMF manufactures) are considered high risk and funding is not accepted from this group either.

What have been the costs and benefits of ending sponsorship?

Ending this sponsorship did come with a cost. The congress' registration fee has progressively increased and currently stands at AUD 1 210. This has also resulted in a progressive decline in attendance; this can't be attributed to only the CMF sponsorship since RACP does not accept sponsorship from any pharmaceutical company too. Currently only 20–30% of the congress cost is covered by sponsorship. The rest comes from registration fees as well as offsets from the RACP membership approved by the board.

Paediatric Society of Ghana, Ghana, 2014

What prompted the <u>Paediatric Society of Ghana</u> (PSG) to end sponsorship by CMF companies and when did this happen?

The PSG was prompted to end sponsorship of our meetings by the fact that exclusive breastfeeding rates in Ghana were rapidly falling. Whilst there obviously were many factors contributing to this, the influence of commercial milk formula (CMF) company advertising, both directly to the public (for example through labelling on the tins in violation of the Code and of the laws of Ghana) and indirectly through the role of health workers, was certainly a contributing factor. Health workers, knowingly or otherwise, were helping to create the impression that infant formula was equivalent to breast milk, such that families who were facing various challenging breastfeeding situations felt reassured to immediately turn to formula feeding as an acceptable alternative.

How did the process unfold and how were members involved?

Prior to 2014 (or thereabouts!), the PSG had no written position on sponsorship by the formula industry. At our Annual General Scientific meeting, a motion was brought to the table to stop accepting formula industry sponsorship at our meetings and to amend the Constitution of the society accordingly. The strongest arguments supporting this decision were those that made reference to the Code and the Ghanaian breastfeeding law, which despite its loopholes and some deficiencies, was strongly against health workers allowing themselves to be influenced by CMF companies.

Which arguments were most effective in motivating the society's decisions makers or members to take action?

There were some, particularly more senior members, who expressed the opinion that it was better to work with the formula industry rather than work against them. It was pointed out, however that it was possible to work with them, when necessary, without accepting sponsorship. Indeed, we could work much more effectively with them when there was no glaring conflicts of interest situation clouding judgment and tying our hands. There was the need to clarify over and over that this action was against irresponsible advertising and NOT against the use of formula feeds, which we all accepted was needed sometimes.

Was there any resistance to the change and how did you deal with counterarguments?

There was no real resistance to the change once the constitutional change was made. There has been one attempt since to get the provision taken out of the Constitution, which was not successful. The main challenge has been that whilst the PSG as an association has maintained the position and has not accepted sponsorship from any CMF company since the constitutional change was made, individual paediatricians and paediatric health facilities have continued to accept sponsorship. especially from Nestlé Ghana Ltd. This has included sponsorship of training which was approved by the Ministry of Health. Nestlé Nutrition Institute (NNI), for example, sponsored several young paediatricians for a course in child nutrition and pictures of the award ceremony for this course were all over the internet, which was of significant concern.

Nestlé continues to donate equipment to some of our health institutions, sponsoring Helping Babies Breathe Trainings and other such activities, which are often run by members of the PSG. Other Paediatric Training Conferences, not directly under PSG, also continue to accept sponsorship. It is not unusual to see paediatricians speaking on the platform of formula industry sponsored meetings. Whilst such activities serve to undermine the position of the Society, the fact that PSG still does not accept formula industry sponsorship makes a strong statement.

What kinds of financial support did you receive from industry and what has replaced it? (e.g., sponsorship for conferences, journals, posts, education and training, travel, etc); quantify if possible.

PSG is a relatively small organization with fewer than 400 members. We currently have members who are nurses, including paediatric and neonatal nurses, physician assistants, and a few others. Before the constitutional change, we regularly received funding from formula industry for our meetings and other activities. In the scheme of things, our meetings are not very expensive, and we have continued to hold our annual meetings with some support from WHO, UNICEF, some pharmaceutical companies and other organisations which produce products for children other than infant formula. Members also pay yearly dues which help support some of the activities.

In what way have you drawn a line? (e.g., have you adopted a clear position statement, and have you ended all, some, or future funding)

In 2020, PSG drew up and adopted a document titled "PSG guidelines for relationship with industry" in which the Society restates its ongoing commitment to exclusive breastfeeding and its compliance with the WHO Code. The policy states that funding will not be accepted from industries that are "perceived to violate WHO International Code of Marketing of Breast Milk Substitutes." This would appear to be in contradiction to the WHO Code which sets out to regulate advertising by companies that manufacture CMF and not those that are "perceived to violate the Code". Since the Constitution was amended to state that we would no longer accept funding from CMF manufacturers, no further funding has been accepted at the level of the Society.

What have been the costs and benefits of ending CMF sponsorship?

The fact that many of our individual members continue to receive funding and sponsorship from the formula industry has somewhat watered down the position of the PSG as an advocate body for breastfeeding. Despite this, however, we have been able to maintain good standing in the eyes of other international organisations like WHO Ghana, UNICEF etc. We have had speakers from these organizations on our platforms which could not have happened if we had continued to accept CMF sponsorship at these meetings. We have, with difficulty, been able to make up the funding gap as we are a very small body with relatively inexpensive meetings. Many of our meetings recently have been held virtually, reducing the need for travel costs, hotel accommodation, etc. The support and attendance have generally been good.

Conclusion

We recognise the need to continue to advocate maintaining the position of not accepting sponsorship of our meetings by CMF manufacturers and their subsidiaries. However, we need to do more to get individual members to buy into this position. As a lower-middle income country, the ability of CMF manufacturing companies not only to sponsor our meetings but to give direct support to healthcare of children in Ghana, which the Government does not always provide, makes it difficult to refuse sponsorship especially when such sponsorship comes with the provision of lifesaving equipment which is not available in the facility.

Royal College of Paediatrics and Child Health, United Kingdom of Great Britain and Northern Ireland, 2019

What prompted <u>Royal College of Paediatrics and</u> <u>Child Health</u> (RCPCH) to end sponsorship and when did this happen?

The College reviewed its position on receiving funding from CMF companies in 2019 following concerns raised by some members.

The College now has a publicly stated position expressly disavowing acceptance of financing from CMF companies, and a framework of due diligence to be applied in assessing the ethical and practical issues around future income generation from commercial sectors. Following the decision, the College reviewed its due diligence process. CMF companies now fall under an exclusionary category, along with other prohibited organisations, meaning the College will not accept income from them under any circumstances (7).

A significant challenge raised by the global debate around CMF was the extent to which on-paper governance arrangements at the top of large global producer firms reliably shape appropriate marketing practices further down the chain of commercialisation. In many low- and middle-income countries, third-party marketing entities were documented pursuing ethically problematic sales strategies with inadequate oversight and regulatory control, in breach of the International Code (8).

This insight calls for redoubling efforts to ensure the robustness of due diligence processes which, whilst able to affirm stated practice in nominal terms, may ultimately camouflage local practices which fall below expected standards. Due diligence processes should, therefore, be structured to ensure adequate access to sources of information – beyond those of the subject organisation – to enable a reasonable degree of confidence in the coherence between stated and actual practice in the health arena.

Which arguments were most effective in motivating the RCPCH's decision makers or members to take action?

The College has had long-standing and complex internal discussion and debate around seeking or accepting financing from commercial sector actors as sponsorship or other (e.g. consulting) payment for expert analysis, advice or endorsement. This includes the question of accepting income from companies associated with the production and marketing of commercial milk formula (CMF). The critical concern in this area is balancing the need for the College to generate income streams to support its operational delivery of activity in line with institutional strategy, with providing assurance that the College can maintain its independent clinical and public health mandate and function.

In the case of CMF producers, the College was engaged over several years in internal debate. This included the level of engagement the College should pursue with industry to influence the composition of products, but also between the clinical necessity of certain specialist CMF products critical for babies with specific conditions, and the unethical or poorly governed marketing practices (across high-, middle- and low-income countries) through which generic CMF products were (and are) commercialised widely with well-documented adverse impact on the health of newborn and infants.

How did the process unfold?

The College attempted to reconcile differing perspectives across its membership, including amongst those strongly opposed to CMF producers as a net bad to mothers and babies globally, those supportive of some engagement with producers around specialist products, and those supportive of commercial income generation more generally (whether as a matter of principle, as relating to potential private sector sources of research funding and public private collaborations more widely around child health, or as a matter of necessary income acutely among paediatric associations and societies in low- and middle-income countries).

The process towards a summary decision in the case of CMF and related commercial interests took place over an extended period of time and through a series of overlapping interactions between the College, external advocacy groups opposed to CMF sponsorship, groups within the membership, and actual or potential sponsor companies. Challenges in achieving professional consensus were reflected in periodic (and sometimes highly critical) public media coverage.

How were members involved?

The matter was subject to a vote by College

members at its Annual General Meeting (AGM) and considered by Council, the College's policy-making body, which decided to stop receiving any funding from CMF companies (9).

Was there any resistance to the change and how did RCPCH deal with counter arguments?

It is worth reflecting that the College's lack on clarity and decision-making around CMF income risked significant loss of credibility among a substantial part of the membership and more widely. It is worth reflecting too, that the actual amount of income to the College expected from such commercial relationships was, at the time, relatively small. What became clear over the period of this internal and then public debate is that transparency of process and clear rationalisation of risk and benefit in any such commercial relationships are key to good institutional governance and sustaining member engagement and support.

The College seeks to promote an open, transparent exchange and debate on matters of health - with a particular emphasis on maternal, newborn and paediatric health - within and between countries and between stakeholders across the spectrum of public and private interest. It seeks to do so on the basis of the best available scientific knowledge, whilst recognising diverse contexts around the world in which such knowledge - and the resulting health and care - are delivered. The College continues to advocate for well-evidenced health practices and strongly supports breastfeeding, including the promotion of breastfeeding in policy and practice, whilst recognising the need for supplementary options in situations where this is not achievable (10).

It is clear that future commercial interactions will need to be subject to a standard due diligence framework assessment but also be subject to a case-by-case analysis of the bona fides – vis-a-vis child health and welfare – of any entity with which the College proposes to engage for financial purposes. Where an entity demonstrates negligence or limited demonstrable concern, on its own terms and through its own governance and management practices, for children, the College should take a precautionary approach to the development of any kind of income-bearing relationship.

What kinds of financial support did RCPCH receive from industry and what has replaced it? (e.g. sponsorship for conferences, journals,

posts, education and training, travel, etc., quantify if possible)

Prior to this decision, the College received in the region of £40 000 per annum from CMF companies in the form of event sponsorship and exhibition and advertising – a relatively small element of overall institutional financing. This income has broadly been replaced by growth income from the College's journals and digital products.

In what way has RCPCH drawn a line? (e.g. has RCPCH adopted a clear position statement, and has it ended all, some, or future funding)

The College now has a publicly stated position expressly disavowing acceptance of financing from CMF companies, and a framework of due diligence to be applied in assessing the ethical and practical issues around future income generation from commercial sectors (7). Following the decision, the College reviewed its due diligence process. CMF companies now fall under an exclusionary category along with other prohibited organisations within its due diligence policy, meaning the College will not accept income from them under any circumstances.

What have been the costs and benefits of ending sponsorship?

In summary the College considers that the benefits of ending commercial milk formula sponsorship have themselves generated greater institutional clarity on this funding question, further valuable input to wider questions of due diligence with funders, and greater ability for RCPCH to engage with the wider international community.

Were there any costs in terms of poorer relationships with formula companies?

No because the College's relationships with formula companies were on commercial basis only.

Department of Paediatrics and Child Health, University of Cape Town, South Africa, 2019

What prompted the <u>Department of Paediatrics</u> <u>and Child Health</u> (DPCH) to end sponsorship and when did this happen?

Our engagement with industry started with an innocent question back in 2015 when the Advocacy Committee of the DPCH was preparing to co-host our 2016 University of Cape Town Paediatric Refresher Course (UCT PRC) and the question was asked if we should we be worried about any of the potential sponsors? That question marked the first introduction to the International Code of Marketing of Breast Milk Substitutes (the Code), our local Regulation 991 (R991) to enforce the Code, and the accompanying guidelines for industry. We discovered too late that two commercial milk formula (CMF) companies were already sponsoring the event, and when we objected to Nestlé's presence, we were told by our head of department that we had overstepped our mandate. Subsequently we asked all three companies to abide by R991 and the National Department of Health (NDOH) guidelines for industry.

We were particularly embarrassed as a WHO staff person was our keynote speaker and, when the CMF companies went on to violate the provisions of R991 at the 2016 PRC, he challenged their presence in his opening address and called on the DPCH to adopt a firmer stance moving forward.

The following year we thought we were better prepared. We developed guidelines for the organisers of the 2017 conference to pre-empt further contraventions of R991 and recommended that:

- All organising committees and events organising companies should be made aware of R991 and the associated NDOH Guidelines for Industry before accepting any sponsorship from CMF companies, and that
- b) CMF companies would be required to:
 - i. agree in writing to abide by R991, and
 - ii. submit in advance details of the materials they intended to display for scrutiny by the organising committee and the Advocacy Committee.

Yet, despite this, the organising committee agreed

to Nestlé hosting a breakfast symposium (Nestlé funded speaker), despite this being in clear contravention of R991 and the industry guidelines. [The local regulations allow industry sponsorship, provided funding is into a common pool and there are no health, nutrition or medical claims, no promotion, and no gifts of any kind including refreshments.]

By 2018, we recognised that the provisions in R991 were being challenged and contested by industry, so we drew up stronger guidelines, that signalled our position to not only abide by the local regulations but also to uphold the spirit and intent of the Code: "The DPCH expects all exhibition stands, promotional, educational and scientific material to be *fully compliant* with Regulation 991 of the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 and the associated Guidelines to Industry and Health Care Personnel issued by the NDOH; and within the spirit of the International Code of Marketing of Breastmilk Substitutes adopted by the World Health Organization in 1981."

In addition, we reserved the right to review and approve any exhibition stands, pamphlets, websites or other promotional and educational materials used to promote and/or share scientific information about the range of CMF and designated products as defined in section 1 of R991. Should the above materials in our view be in violation of R991, we committed to a) distance ourselves publicly from the exhibit, and b) report the violation to NDOH.

Despite these very clear guidelines, we again saw industry transgressing with the glitzy South African product launch of Nan Supreme, a CMF with added human milk oligosaccharides (HMO), and a series of health claims by Pharmaco about their Novolac CMF range. The conference organisers then called them out during the PRC and invited a representative from the provincial DOH to document the non-compliance and report them to national office. Nestlé and Pharmaco then called for a meeting with the DPCH head where they were accompanied by their lawyers and compliance officer and insisted that they had done nothing wrong. This was accompanied by a veiled threat that there would be consequences.

It was this final interaction that prompted us to develop a firm position statement for our department to decline further funding from industry. We also recognised that this needed to extend beyond conference sponsorship to include funding streams for training and service posts, research and teaching, as resultant conflicts of interest had led to certain staff members within the department supporting industry's presence at the PRC. Our position statement was formally adopted by the DPCH in November 2019.

How did the process unfold and how were members involved?

It helped to have a strong committed Advocacy Committee who championed the issue within the DPCH. We were able to draw on Committee members' expertise in breastfeeding, infant and child nutrition, national and global policy frameworks, and the broader commercial determinants of health and nutrition. It also helped to have a new Head of Department (HoD) who had been an active member of the Advocacy Committee and who understood the history and stakes involved. We also valued the support and guidance of the NDOH on how to interpret contraventions of R991. We were particularly blessed to have the wisdom of the late Professor David Sanders who helped contextualise our own experience and link this to the intransigence of 'Big Food' and the broader commercial determinants of health.

Which arguments were most effective in motivating the association's decision makers or members to take action?

We drew on a number of different arguments:

- a) the significant benefits of breastfeeding vs the considerable dangers of CMF feeding in the South African context where two thirds of children live below the poverty line and one third do not have access to adequate water and sanitation.
- b) data on the expansion of CMF sales and how this contributes to South Africa's low breastfeeding rates, with immediate and long-term negative impacts on health,
- c) efforts by WHO/WHA and the national NDOH to regulate industry,
- how industry has continued to violate these guidelines internationally and at our own PRC.
- e) We also shared the International Society for Social Paediatrics and Child Health and the British Medical Journal position statements and the WHA calling for an end to industry funding and conflicts of interest.
- f) Evidence presented in the 2016 Lancet

Breastfeeding series.

g) Finally, we linked these concerns to our ethical duty to our patients, and broader concerns in South Africa about corruption and state capture.

These different arguments may have resonated more or less with different members of the DPCH, but the combined effect was compelling.

Was there any resistance to the change and how did the DPCH deal with counter arguments?

There was resistance to change from two leaders in the department who opposed the adoption of the position statement - both of whom had ties to the CMF industry and one of whom had an industryfunded health education project vulnerable to funding withdrawal.

What kinds of financial support did the DPCH receive from industry and what has replaced it? (e.g. sponsorship for conferences, journals, posts, education and training, travel, etc., quantify if possible)

This is difficult to quantify. There was a history of repeated CMF sponsorship of up to 7 stands at the PRC, a subspecialist training post in Paediatric Gastroenterology and possibly some undisclosed funding as well (this despite a request by HoD for disclosure.) We have also become aware of persistent CMF industry links to our Paediatric Allergy Department through its head and the Allergy Foundation of South Africa (AFSA).

In what way has the DPCH drawn a line? (e.g. has the DPCH adopted a clear position statement, and has it ended all, some, or future funding)

Our position statement does draw a clear line, but there is uncertainty in respect of monitoring and enforcement. This is something that ideally should have been included in our position. Similarly, it is important to include a clause that recognises the need to raise awareness in students and clinicians, many of whom are unfamiliar with the Code, R991 and conflicts of interest.

What have been the costs and benefits of ending sponsorship?

While the costs of ending sponsorship are unclear, members of the Advocacy Committee have gone on to champion this issue nationally and globally through a series of journal articles: reporting other violations to the NDOH; collaborating with a broader civil society coalition to call out industry violations in the mainstream media; and supporting the United

Neonatal Association of South Africa to adopt a similar position, so there is a sense of a growing movement/momentum.

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