

OPINION

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Date: 7th May, 2011

QUERIST: NESTLE NUTRITION INSTITUTE (INDIA)
IN THE MATTER OF: Infant Milk Substitute Feeding Bottles and Infant
Foods (Regulation of Production, Supply and
Distribution Act, 1992 (IMS Act))

Ex-Parte Opinion

The Querist sought my opinion on the following queries:

- QUERY 1** Whether NNI (India) is entitled to conduct scientific activities for dissemination of nutritional information in view of Section 9 of IMS Act?
- QUERY 2** Is the conducting of scientific workshops by NNI (India), wherein only key experts, outstation Speakers & Chairperson are provided boarding and lodging expenses, taxi fare, airfare and working meals for the participants, in line with the provisions of Section 9(2) of IMS Act?

Before giving my opinion in these queries, I consider it appropriate to deal with the historical background which led to the enactment of IMS Act.

1. India's National Family Health Survey (NFHS) was conducted in 1992-93 under the auspices of the Ministry of Health and Family Welfare. The survey provided national and state-level estimates of fertility, infant and child mortality, family planning practice, maternal and child health, and the utilization of services available to mothers and children. The International Institute for Population Sciences, Mumbai, had coordinated the project in cooperation with 18 population research centers throughout India. The NFHS survey is carried out every ten years. The last survey was conducted in 2005.

According to the available statistics, infant mortality declined 23 percent in India between 1981 and 1990, and child mortality declined 34 percent during the same period. Nevertheless, infant mortality rates are still high in India and remain a matter of concern. Among children born during the 12 years before the survey, 88 out of 1,000 are estimated to die during the first year of life and 121 are estimated to die before reaching the age of five. According to the statistics, malnutrition is a major contributory cause of high incidence of infant mortality, physical and mental handicaps. It is universally recognized that breast feeding is an integral part of providing biological and emotional basis for healthy child development. Breast feeding of infants is the best start in life of the infants. The anti-effective properties of mother's milk protect infants against diseases. The effect of breast-feeding on child spacing, on the health and well being of the mother, on family health and on national economy is well recognized. Breast-feeding is, indeed, a key aspect of self-reliance and primary health care and is rightly encouraged."

2. National Health Policy adopted by the Government of India affirmed that the effective delivery of health care services depends very largely on the nature of education, training and appropriate orientation towards community health of all categories, by medical and health personnel. Lack of awareness on issues like malnutrition, common diseases, high incidence of infant mortality, lifestyle diseases and physical and mental handicaps have formed subject matter of various reports. It was found that recent developments in medical science were not being properly projected.
3. In view of the vulnerability of infants in the early months of life to the risks involved in inappropriate feeding practices, including unnecessary and improper use of infant milk substitutes, feeding accessories and infant foods, it was considered necessary to regulate the marketing of such products world wise. For proper nutrition and health of the world's children, the World Health Assembly adopted in May, 1981 an International Code for marketing of Breast Milk Substitutes while emphasizing and maintaining natural benefits of breast feeding. The Government of India recognized this Code and adopted the "Indian National Code for Protection and Promotion of Breast-Feeding" (hereinafter referred to as the Code) in December, 1983. The Code prohibits advertisement of infant milk substitutes and feeding bottles and also prescribes measures to ensure that in the marketing of infant milk substitutes no

impression is created that feeding of these products is equivalent to, or better than, breast-feeding.

It was in furtherance of the objective of the code that the IMS Act was passed by the Union Parliament and came into force w.e.f. 1st August, 1993. The object of the IMS Act as given in its preamble is:

"An Act to provide for the regulation of production, supply and distribution of infant milk substitutes, feeding bottles and infant foods with a view to the protection and promotion of breast-feeding and ensuring the proper use of infant foods and for matters connected therewith or incidental thereto"

4. Problem of health and diseases as well as nutritional imbalance pose a serious challenge. Such challenge has to be met by innovative ideas by all those who are concerned with it as medical professionals, paramedical, nutritionists, dieticians etc. The most appropriate method for dealing with the concerns is through exchange of ideas including scientific studies, experience from case profiles and exchange of thought process relating to developments of new trends in medical science. This gap was sought to be filled through professional education, aimed at fostering and developing experience for health care providers which would enhance their competence to respond with sensitivity to the needs of the population more particularly the needs of infants.
5. In order to address this serious concern, I find from the brief for opinion and the material brought to my notice during the conference with the legal team of the querist, that Nestlé India Limited has a long term commitment towards the continuing nutrition education of health professionals. Paramedical, Nutritionists and Dieticians for the purpose of dissemination of scientific information amongst medical field. Nestlé India Limited [hereinafter referred to as Nestlé for easy reference] is a subsidiary of Nestlé S.A. of Switzerland and is registered as a Public Limited Company under the Companies Act, 1956 in India. Globally, Nestlé seeks to promote safe and adequate nutrition for infants by encouraging and supporting Breastfeeding as the best start in life and by manufacturing high quality breast milk substitutes for use when a safe alternative to breast-milk is needed or is considered necessary i.e.

when mother's milk is either not available to the infant or when specially adopted formula is need for the growth of the infants. Nestlé Nutrition Institute (the NNI) was established in 2007 in India.

6. According to the brief for opinion and information provided to me during conference with the legal team of the NNI, (India) the main aim and purpose of the NNI, (India) is to contribute to the improvement of public health, provide enhanced access to up-to-date information about medical advancement in the said field to health professionals etc.. In order to achieve the above objectives, NNI, (India) organizes seminars and conferences for health care professionals, Paramedical, Nutritionists and Dieticians to disseminate scientific information from time to time. NNI, (India) shares and disseminates information to health professionals in such areas through constant exchange of knowledge and nutrition expertise. This **educational** initiative of NNI, (India) comprises organizing workshops, conferences, lectures and seminars. The subject topics are wide and varied and include **Nutrition Therapy in Critical Care; Global Trends in Preterm Nutrition; importance of probiotics in infancy and childhood; role of balanced nutrition for infants and young Children, science of weaning & best weaning practices, diabetes in India; problems in nutrition and principles of correction, Global Trends in Maternal and Pediatric Nutrition.** The key note speakers are persons of eminence or experts in their fields. The participants are the stake holders concerned with the subjects related to infant and mother health care, lifestyle diseases, critical care etc. NNI, (India) India also collaborates with various institutes including National Diabetes, Obesity and Cholesterol Foundation (N-DOC) for exchange of scientific knowledge.

7. Nestle India Limited promoted, NNI (India). it and provides a budgetary grant to it for undertaking its scientific activities. It is independent of Nestle India Ltd. The activities of NNI (India) are monitored by an independent Advisory Board comprising of eminent health professionals attached to various fields of medical science and experts in their own rights. None of the members of the Advisory Board are employees of Nestle India Limited. The services rendered by the Advisory Board are purely aimed at guiding the NNI, (India) towards its various scientific activities. The Advisory Board has nothing to do with commercial activities of Nestle India Limited, as such. Members of the Advisory Board do not get any remuneration or fee for the services they render to NNI, (India). The Advisory Board is an independent body and

governs and monitors the activities of NNI, (India), according to its own wisdom, uninfluenced by any commercial interests.

According to the Articles of the NNI, the goals and scope of its activities have been catalogued in Section 2 as follows:-

Goals and scope of activities

1. NNI's purpose is to:

- contribute to the improvement of public health,
- foster communication and establish links to the medical and scientific community as well as public institutions,
- provide enhanced access to up-to-date information,
- train health professionals, and
- encourage research and training

in the fields of nutritional and related sciences, including infant nutrition, children and adult nutrition, clinical and medical nutrition, performance and weight management nutrition.

2. In order to pursue the above-mentioned goals NNI shall in particular

- Organize seminars and conferences for health professionals,
- Draft, edit and publish articles and publications, provide any other information material and establish and develop communication platforms for health professionals
- Assist health professionals in their health training.

These objectives of the NNI which has been registered as a not for profit association under Swiss Civil Code in June 2010 have been adopted by the NNI in India.

8. According to the material made available to me by the querist, I find that during NNI, (India), activities, the attendances of Health Care Professionals, Paramedical, Nutritionists and Dieticians and others is voluntary. During its scientific activities, there is no promotion or display of Infant Nutrition Products. In fact, during the lectures, seminars or conferences organized by NNI, (India), there is no reference or discussion or detailing of any Infant Nutrition Products. No remuneration or payment is made to the participating health professionals by NNI, (India), and the

dissemination of scientific information is not related to promotion of any infant food/nutrition products.

9. According to the brief for opinion, during the course of NNI, (India's) scientific activities, while the participants are not provided any payment or remuneration, but, if a speaker, who is an expert in the area of discussion is coming from out station, NNI, (India) arranges for and pays for the experts' travel, boarding and lodging. It also helps prepare presentation materials for a speaker and provide pads, pens and folders for participants. It arranges for working lunch for the participants. No payment or pecuniary benefit is provided to the participants in NNI, (India) activities.
10. In substance the activities of the NNI, (India) are aimed at encouraging scientific studies and continuing education towards betterment of the health care particularly of the infants. The scientific conferences, seminars or lectures are aimed at developing scientific temper and encouraging spirit of inquiry towards emerging trends in medical science and health care. In fact the activities of NNI, (India), are in a way to further constitutional obligations.
11. **Article 51A** of the Constitution of India which was inserted by the Constitution (42nd Amendment Act) 1976, dealing with **Fundamental Duties**, provides in Sub-article (h), that:

*"It shall be the duty of every citizen of India-
(h) to develop the scientific temper, humanism and the spirit of inquiry and reform;"*

It thus, appears to me from the activities of NNI, (India) which are purely scientific in nature and have no commercial angle attached to them at all, are activities in furtherance of the discharge of the Duties of the Citizens, as envisaged by Article 51A of the Constitution of India.

Even at the International level, the Heads of State and Governments who gathered at the United Nation Headquarter in New York in September 2000, at the dawn of the new millennium, adopted a historic declaration. They recognised that, in addition to their support and responsibilities to their individual societies, they have collective responsibilities at the Global level. In the Millennium. Developments Goals formulated in September 2000, one of the specific Goal relates to "Reduction of Child Mortality". All 189 Nation's signed the declaration and undertook to meet the

Millennium Development Goals by the year 2015. The scientific activities of NNI, (India) appear to have a close linkage towards realization of the said Goal of Reduction of Child Mortality and matters connected therewith.

12. Keeping in view the above background and noticing that NNI, (India) is an independent institute unconnected with commercial activities of the Nestle India Limited and is governed by an independent Advisory Board to carry out various scientific activities towards achieving excellence in the field of health care, I shall now examine some of the relevant provisions of the IMS Act to answer the queries raised for my opinion.

13. Under the IMS Act:-

"Infant milk substitute" is defined in Section 2(1)(g) as any food being marketed or otherwise represented as a partial or total replacement for mother's milk;

"Infant food" is defined under Section 2(1)(f) as any food being marketed or represented as a complement to mother's milk to meet the growing nutritional needs of the infant after the age of six months upto the age of two years;

Section 3 deals with prohibition in relation to infant milk substitutes, feeding bottles and infant foods, which includes advertisement, promotion etc..

Section 4 deals with prohibition of incentives for the use or sale of infant milk substitutes or feeding bottles or infant foods, which includes inducement of any other kind:

Section 5 prohibits donations of infant milk substitutes, feeding bottles and infant foods except to orphanage:

Section 8 deals with Health Care system and it permits dissemination of scientific information to a health worker, which is as follows:

8. Health Care system - (1) No person shall use any health care system or the display of placards or posters relating to, or for the distribution of, materials of the purpose of promoting the use or sale of infant milk substitutes or feeding bottles or infant foods:

Provided that the provisions of this sub-section shall not apply to -

(a) The donation or distribution of informational or educational equipment or material made in accordance with the proviso to clause b of section 5; and

(b) The dissemination of information to a health worker about the scientific and factual matters relating to the use of infant milk substitutes or feeding bottles or infant foods along with the information specified in sub-section (1) of section 7.

Section 9 deals with inducement to health workers for promoting use of infant milk substitutes etc. It is as follows:

9. Inducement to health worker for promoting use of infant milk substitutes, etc.,

(1) *No person who produces, supplies, distributes or sells infant milk substitutes or feeding bottles or infant foods shall offer or give, directly or indirectly any financial inducements or gifts to a health worker or to any member of his family for the purpose of promoting the use of such substitutes or bottles or foods:*

(2) *No producer, supplier or distributor referred to in sub-section (1), shall offer or give any contribution or pecuniary benefit to a health worker or any association of health workers, including funding of seminar, meeting, conference, educational course, contest, fellowship, research work or sponsorship.*

14. From the provision as noticed above, it is obvious that the IMS Act does not prohibit scientific studies or exchange of ideas and thoughts by experts, towards achieving the objective of the Act and for providing better health care. As a matter of fact, Section 7 of the Act itself envisages provision of providing educational or other materials which relate to the benefit and superiority of breast feeding and which does not promote the use or sale of infant milk substitutes or feeding bottles or infant food.
15. Section 9 of the Act (Supra) places a prohibition upon persons who produce, supply or distribute or sell infant milk substitutes or feeding bottles, to offer or give, directly or indirectly, any financial inducements or gifts to a health worker or any members of his family. It also places prohibition on the producer, supplier or distributor of the said products, to providing any contribution or pecuniary benefit to a health worker or any association of health workers, including funding of Seminars, meetings, conferences, educational courses, fellowship, research work or sponsorship. These prohibitions relate to persons including enterprises, which produce, supply or distribute or sell infant milk substitutes or feeding bottles or infant foods and does not take within its fold institutes like NNI which does not carry out any of the above noticed activities.
16. Section 9, in my view, does not in any way prohibit the conduct of scientific activities for dissemination of nutritional information through seminars, lectures and conferences of health professionals, paramedical, nutritionist and dietitian through such institute which do not fall in the enumerated categories given in Section 9(1) and

(2). So long as no remuneration or payment is made to the participants, in cash or in kind, by the NNI, (India), the participants at the conferences etc do not offend Section 9 of IMS Act. Providing venue for conduct of lectures, seminars or for holding of conferences and making available pads, pens and folders containing material for use during the discussions at the lecture, seminar or conference, cannot amount to providing pecuniary benefits. Besides, Section 9 essentially places the prohibition on the producer, supplier or distributor of infant milk substitutes or feeding bottles or infant foods and would have no application or relevance to the scientific activities of a body like NNI, (India), which neither produces nor supplies or distributes or sells infant milk substitutes or feeding bottles or infant foods and whose activities are aimed essentially at undertaking scientific studies and dissemination of knowledge of development in the field of medical sciences. I find from brief for opinion and the material on the record, that NNI, (India) does not offer or give directly or indirectly any financial inducement or gift to any health worker as defined in Section 2(j) for the purpose of promoting the use of milk substitute or feeding bottles or infant foods.

17. NNI, (India) seeks to contribute to the improvement of public health by sharing up-to-date information amongst health professionals, para medicals, dietitians etc through its scientific activities at conferences, lectures, workshops and seminars etc. information which relates to scientific or medical advancement, for better health care through continuing nutrition education. As already noticed, there is no promotional activity or display of infant nutrition products during the lectures/conferences organized by NNI, (India), primarily because it is not engaged in advertising or promoting infant milk substitutes or feeding bottles or infant food.
18. The topics which are discussed at the conference are of a general nature aimed at exchange of ideas on issues mainly relating to Maternal and Pediatric Nutrition. In this connection I may refer to the scientific conference which was scheduled for 16th April, 2011. It was organized to discuss "Global Trends in Maternal and Pediatric Nutrition". The lead paper was presented by Prof. Hania Szajewska M.D., Prof. and Chair, Department of Pediatrics, Medical University of Warsaw. Similar, topics concerning infant nutrition and health care trends form subject matter of other scientific seminars and lectures. Dialogue and discussions on crucial issues concerning health care improvement techniques are a universally accepted method for arriving at or exploring meaningful results.

Keeping in view the above discussion and the objective of NNI (India), I now briefly answer the two queries, noticed in the opening part of this opinion.

QUERY 1

19. I have dealt with the provisions of Section 9 in Paras 15 and 16 of this opinion. Even at the cost of repetition, I wish to emphasise that Section 9 of IMS Act does not in any way prohibit the conduct of scientific activities for dissemination of nutritional information, through advancement of medical research, through seminars, lectures and conferences attended by health professionals and paramedicals, nutritionists, dieticians and others. Therefore, Section 9 of IMS Act would *ipso-facto* not apply to the scientific studies being conducted by NNI, (India) through its activities. It does not offer or give directly or indirectly any financial inducement or gift to the participants at the lecture, seminars and conferences. The NNI, (India) does not in any way indulge in any promotional activity as envisaged by Section 2 (j) since it does not employ directly or indirectly any method of encouraging any person to purchase or use infant milk substitute, feeding bottle or infant food.
20. The NNI, (India) through its activities does not take part in the promotion of infant milk substitute, feeding bottles or infant foods or supply or distribute samples of infant milk substitute or feeding bottles or infant foods or offer any other type of gifts or inducement for the purpose of promoting the use or sale of infant milk substitute, feeding bottle or infant foods. Since, none of the activities of NNI, (India) fall within the ambit and scope of Section 9 of IMS Act and also since, NNI, (India) even to promote its scientific studies, does not offer or gift any contribution or pecuniary benefit to a health worker or any association of health workers or funds any seminar, conference, educational courses conducted or organised by producer or supplier or distributor of infant milk substitute or feeding bottles or infant foods, NNI (India) it is not forbidden or debarred to conduct scientific activities aimed at dissemination of nutritional information through different facets. It is entitled the conduct to scientific activities for dissemination of nutritional information and such activities do not fall foul with the provisions of Section 9 of IMS Act.


Query No. 1 is answered in the above terms.

QUERY 2

21. As I have already opined that the prohibition envisaged by Section 9(2) of IMS Act *stricto-senso* applies to **producer, supplier or distributor of infant milk substitute, infant foods or feeding bottles**. It does not take within its fold purely scientific studies carried out by an institute like NNI (India). The participants at the seminar, conference or lectures also do not fall in the category to whom Sub-section 2 of Section 9 (Supra) would be attracted. Providing board and lodging or air fare to the out station participants, does not fall foul with Section 9 (1) of the IMS Act. These facilities would not attract the provisions of Section 9(2) of IMS Act, as the facilities to the outstation keynote speakers and experts are in the nature of courtesies for contributing their knowledge and information on issues relating to nutrition, child mortality, child health, life style diseases etc and dissemination of knowledge aimed at improvement of health care system.

Query No. 2 is answered accordingly.

I have nothing more to say at this stage.


(A.S. Anand)