

September 27, 2019

Shri M. Venkaiah Naidu
Vice-President of India
Vice-President's Secretariat,
6, Maulana Azad Road,
New Delhi - 110 011

Sub: Flourishing Unethical partnerships in nutrition action, request for support to avoid conflicts of interest : Request for an appointment

Hon'ble Sh. Venkaiah Naidu Ji,

India enacted the *Infant Milk Substitutes Feeding Bottles, and Infant Foods (Regulation of Production, Supply and Distribution) Act 1992, and Amendment Act 2003. (IMS Act)* This was made possible due to untiring efforts of Sh. Ram Naik, Hon'ble Governor of UP, Sh. MM Joshi, Late Smt. Sushma Swaraj, Smt. Sumitra Mahajan and Late Sh. Arun Jaitley.

Objective of the enactment of IMS Act was to protect mothers and children from the pervasive promotion of baby food industry. The Statement of the Objects of the Bill, clearly recognized that it contributes to poor health, disease, malnutrition and even deaths. The IMS Act bans any kind of promotion of baby foods for consumption by children under- 2 years of age including advertising, sponsorships, commission on sale or gifts etc. Nestle was recently found violating this law, and for this reason, the ICMR recently cancelled a 5 hospital study funded by Nestle (Attached).

We write to you to register our serious concern regarding your presence as Chief Guest at the 'Outlook Poshan Awards' event sponsored and supported by multi-national manufacturers of processed baby foods and infant formula such as Reckitt Benckiser and DSM. Presence of esteemed dignitaries such as yourself provides legitimacy to the organizers of such events and partnerships that run counter to the letter of the IMS Act (as mentioned above) as well as the spirit of the government's own Poshan Abhiyan.

We find it deeply problematic that an event meant to recognize individuals and institutions for their exemplary work towards a nutritious India should be organized in partnership with multinational private food companies who contribute to making India the global capital for childhood malnutrition. We believe that such partnerships with private food companies are unethical and present conflicts of interest that should have been avoided.

We appreciate your comment in one of your letters to BPNI: "Breastfeeding- a gift of God is a natural antidote to malnutrition". In the same spirit we write to you in this matter.

We understand your presence provides much needed inspiration to the award winners, but we are concerned that it has the potential to be misused and may even affect negatively the reputation of the office of the Vice President.

We therefore request you to avoid such events and direct your advisers to review and analyze such invites before acceptance.

We would be happy to come and explain this to you this matter, and request for an appointment for discussing the possible policy implications in this regard.

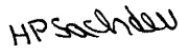
Looking forward to a positive response,

Sincerely yours,

Nutrition Advocacy in Public Interest (NAPi) and Alliance Against Conflict of Interest (AACI) Members.



Sh. Keshav Desiraju
Former Secretary, Health, GOI



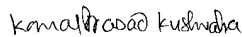
Prof. HPS Sachdev
Senior Pediatrician & Epidemiologist



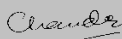
Dr. Vandana Prasad,
Community Pediatrician,
PHRN, and Jan Swasthya
Abhiyan



Dr. Arun Gupta
Child Health & Nutrition
Advocate



Prof. K P Kushwaha
Pediatrician & Former Principal,
BRD Medical College Gorakhpur



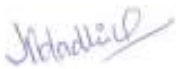
Chander Uday Singh
Senior Advocate,
Supreme Court of India,



Jacob Puliyeel
Senior Pediatrician, St
Stephens Hospital New
Delhi.



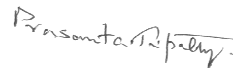
Dr. Vandana Shiva
Founder Navdanya



Dr. J.P. Dadhich
Child Health & Nutrition Advocate

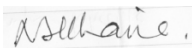


Dr. Mira Shiva
Initiative for Health, Equity and
Society (IHES)



Dr. Prasanta Tripathy
Co Founder Ekjut

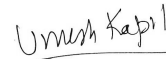
Dr. Sathyamala



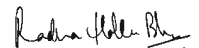
Dr. Navdeep Singh Khaira
Director, Nephrology Division,
Fortis Hospital, Ludhiana Punjab



Dr. Omesh Kumar Bharti
Corporation Health Officer
Municipal Corporation, HP



Dr. Umesh Kapil
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Dept of Epidemiology ,
Biostatistics And Clinical
Research , Institute Of Liver
& Biliary Sciences, ND



Radha Holla Bhar
Independent Consultation



Dipa Sinha
Right To Food Campaign



Nupur Bidla
PhD Scholar (Social Work)

Kavita Srivastava
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INDIA

Nestle violates law in India, conducts clinical trials on premature infants for baby food

In complete violation of the law, Nestle has conducted clinical trials on 75 premature babies in five hospitals on substitutes for breast milk



Ashlin Mathew · 
Published: 3 Aug 2019, 5:56 PM

Engagement:
5.52 K

Breaking the law, Nestle has conducted clinical trials on 75 premature babies in five hospitals on substitutes for breast milk in complete contravention of the Infant Milk Substitutes Act. It was found by Breastfeeding Promotion Network of India (BPNI) on screening the trial registry of Indian Council of Medical Research (ICMR) that Nestle has sponsored a research titled “Multicentric Observational Study to Observe Growth in Preterm hospitalised infants”.



The trial was conducted on 75 premature babies between the age of 28-34 weeks. The objective of the study was to assess the growth and feeding intolerance in preterm infants. One of the exclusions was that the infant could not be fed milk substitute within 48 hours. From 2017 onwards, the trial suggested that the infant could be given breast milk.

BPNI complained to the ministry of health and family welfare and on receiving the complaint health secretary Preeti Sudan directed the ICMR director Balram Bhargava to monitor compliance of this clinical trial with law. Reprimanding ICMR for not having paid attention to their duty, Sudan directs them to ensure that all such clinical trials are first screened for infringement of the IMS Act.

Nestle violated Section 9(2) of the IMS Act. The Section 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.

Section 9 of the IMS Act states that 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.

Dr Monjoni Mitra of Medclin Research is the trial co-ordinator and research director of the trial. The five hospitals which participated in the research – Cloudnine Hospital (Bengaluru), Institute of Child Health (Kolkata), Manipal Hospital (Bengaluru), Sir Ganga Ram Hospital (New Delhi) and Calcutta Medical Research Institute (Kolkata)— are private institutions. R Kishore Kumar, Apurba Ghosh, Ravi Shankar Swamy, Neelam Kher and Saugata Acharyya were the doctors involved in these respective hospitals for the trials.

“They are conducting these trials on premature babies. It is extremely risky. Babies are most sensitive during this period. What would have happened if anything went wrong with these babies,” asks Amulya Nidhi, co-convenor of Swasth Adhikar Manch.



Office of Secretary (MS&FW)
e-office No. 1439073
Date: 23/07/19



Breastfeeding Promotion Network of India
(Registered Under Societies Registration Act XXI of 1860, Delhi R.No. 5-23144)
BP-33, Pitampura, Delhi-110 034
Tel: (91) 011-27312705, 27312706, 42683059
Email: bpni@bpni.org
Website: www.bpni.org

BPNI/IMS Act/2019/002

July 17, 2019

To,
Dr. Harsh Vardhan
Hon'ble Minister
Ministry of Health and Family Welfare
Government of India
Delhi -110011

JS (RM)
23/7/19

Sub: Violation of Section 9(2) "Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply & Distribution) Act 1992, and Amendment Act 2003" (IMS Act).

Dear Dr. Harsh Vardhan Ji,

India enacted the "Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply & Distribution) Act 1992, and Amendment Act 2003" (IMS Act) which came into force on August 1993. An offence committed under the law is cognizable.

The Government of India notified "Breastfeeding Promotion Network of India (BPNI)"wide No G.S.R. 540 (E), dated the 27th June 1994, to monitor the compliance with the above Act.

As per the section 9(2) of the IMS Act, "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".

Perusal of the clinical Trial Registry (Attached) maintained by the Indian Council of Medical Research (ICMR) has revealed that Nestle India Limited, a producer of infant milk substitutes is sponsoring research titled "Multicentric Observational Study to Observe Growth in Preterm hospitalized infants" in following hospitals with their coordinators/principal investigators.

Dr. Monjori Mitra of Medclin Research Pvt. Ltd, is the Trial Co-coordinator and Research Director Clinical Trial.

1. Cloudnine Hospital, Dr. R Kishore Kumar
2. Institute of Child Health, Kolkata, Dr. Apurba Ghosh.
3. Manipal Hospital, Bangalore, Dr. Ravi Shankar Swamy,
4. Sir Ganga Ram Hospital, New Delhi, Prof. Dr. Neelam Kler
5. The Calcutta Medical Research Institute, Kolkata, Dr. Saugata Acharyya

Take action under the Act as directed
Please send report of any breach to JS (RM) for 23/7/19.

The study is not even approved by any independent. ethics committee.

Today
30-7-19
Dr (CHZ)

As a policy, BPNI does not accept funds of any kind from the companies manufacturing baby foods, feeding bottles etc. and from organization/industry having conflicts of interest.

AS directed by DCCCH-F pl. put up urgently
SO(CH)



While conducting such clinical trials, the approval of the Drug Controller General of India (DCGI) is required. "In the application, Nestle mentions that regula So, who then monitors such trials? Also, the application does not disclose who all are there in the

ethics committee within these hospitals to approve such trials. Are there paediatricians, nutritional experts and what expertise do they have for approving such trials. In fact, the trial was conducted at Calcutta Medical Research Institute even before the in-house ethics committee approved the trial,” underscored Nidhi.

“The Ministry has directed ICMR to regulate a trial that is already underway. The question is how are such trials happening under the watch of ICMR? You can’t regulate a trial retrospectively. It has to be done before the trials begin,” explained Dr Sylvia Karpagam, public health doctor and researcher.

“This is not the first time that Nestle has tried to enter the market. They don’t follow protocols. They have been trying to bring in un-regulated baby food into the market. This research has not even been approved by an independent ethics committee. Nestle is violating the IMS Act. They should adhere to the law. We are talking about food for infants,” observes Karpagam.

“When such trials are held, doctors get monetary benefits. They begin to promote powder food for babies even when it is not necessary. They keep telling the mother that the baby is not being fed well. There is no need for any other liquid or powder for a baby till six months,” says Karpagam.

Unregulated clinical trials are a norm in India. “In a report by PricewaterhouseCoopers on emerging markets in India, it had stated that the country is a good ground for clinical trial,” highlighted Karpagam.

According to a Supreme Court ruling, clinical trials can be approved in India only in three instances. If it is related to an unmet medical need of the country; In case of innovations vs existing therapy and on basis of the risk benefit analysis.

“Nestle’s clinical trials don’t fall under any of these categories. It is not a ‘need’. Here, premature babies are being put at risk. The country spends crores to improve infant mortality rates and her babies are put at risk with this trial. Moreover, Nestle has only commercial interests on its mind,” insists Nidhi.

ICMR History with clinical trials

Since 2007, ICMR was part of clinical trials for administration of anti-cervical cancer HPV vaccines to prevent cervical cancer in among 24,000 girls in the tribal belts of Andhra Pradesh and Gujarat. In 2010, six tribal girls from Gujarat and Andhra Pradesh involved these trials died.

The vaccines, produced by Merck and GlaxoSmithKline, were given under an “observational study” conducted under the aegis of Path (Programme for Appropriate Technology in Health), an organisation funded by the Bill and Melinda Gates Foundation. These programmes were conducted in 2007 while the vaccines were approved later.



Under rules, a firm interested in trial is supposed to approach the Drug Controller with a protocol to get approvals, but in India there have been several evidences of weak monitoring.

The government had in 2010 stated that 1,725 persons have lost their lives to drug trials in four years from 2007 to 2010.

A Parliamentary committee report in 2010 found that ICMR had signed a memorandum of understanding to provide technical support to the project in 2006 even before the Drugs Controller General of India (DGCI) approved its use in the country, which actually happened in 2008. An ICMR official was implicated in this for favouring this project.

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Infant Milk Substitutes Act

Breastfeeding Promotion Network of India

Dr Monjoni Mitra

R Kishore Kumar

Dr Sylvia Karpagam

Drugs Controller General of India





icmr
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भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

प्रजनन जीवविज्ञान, मातृक और बाल स्वास्थ्य प्रभाग
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No. 5/7/1667/2019/CH-RBMCH
Dated:- 19.09.2019

Dr. Arun Gupta
Central Coordinator,
Breastfeeding Promotion Network of India (BPNI),
BP-33, Pitampura, Delhi-110034

Subject:- Continued infringement of the IMS Act 1992 and 2003. Ref. DO letter of Secretary Health and Family Welfare Government of India (Z-280201/47/2017-CH, dated 2nd August 2019), further information on Nestle subsidiary 'Nestec' sponsoring the research in hospitals

Dear Dr. Gupta,

This has reference to your letter no. BPNI/2019/IMS ACT/04 dated 26/08/2019 on the above mentioned subject. The complaint is in relation to the following studies:

- Title of the study: Study of milk composition from adequately nourished and undernourished mothers (CTRI/2014/11/005199) registered on: 13/11/2014, last modification on 21/05/2019
- Title of the study: Infant feeding practice and gut comfort: A multi – country –sectional observational study (CTRI/2018/12/016645) registered on 13/12/2018, last modification 09/01/2019

Both the studies are identical to the one for which ICMR has taken a unanimous decision. As per the recommendation of the committee the CTRI is being directed to take necessary action.

As desired, a copy of the action taken report submitted to the MOH&FW is enclosed.

Yours sincerely

(R.S. Sharma)

Encl: as above

**ICMR Report on Trial No. CTRI/2018/12/016715 registered under ICMR-CTRI
and Violation of IMS Act by Nestle India Ltd.**

The members of the committee perused the relevant material and discussed at length on all the issues and arrived at the following unanimous considered opinion:

1. That the complaint is well founded, and the study in question is violative of Section 9(2) of IMS Act 1993 as amended in 2003, given the fact that the study falls under the definition of research work within the meaning of Section 9(2), and the study is funded and sponsored by Nestle India Ltd., which is a producer/ supplier/ distributor of IMS defined under the Act.
2. In the light of above observations, the committee recommends the following immediate actions:
 - a. The study should be terminated immediately by the appropriate authority. The investigators should be asked to change the CTRI registration status to 'terminated' citing the reasons for the same.
 - b. DCGI should examine whether the respective institutional ethics committees, which permitted this study, were constituted in accordance with existing regulations. Further, the respective ethical committees may be directed to explain how they permitted such study in violation of Section 9(2) of IMS Act.
3. The committee feels that following step is necessary to act as a deterrent for similar acts of commission and omission in future, given the fact that the complainant (BPNI) in this case has been notified by Government of India to monitor compliance of IMS Act:
 - a. Invoke the provisions of prosecution of the violators of Section 9(2) of IMS Act under Sections 20, 21 and 22 of the Act.
4. The CTRI should be familiarized regarding the provisions of IMS Act in relation to research work. If CTRI has any reason to believe that there is an infringement of this Act in an Indian study submitted to it for registration, it should defer its registration, and should bring it to the notice of appropriate authorities.
5. It is recommended that the IMS Act should be displayed on the websites of Ministry of Health and Family Welfare, Medical Colleges and Hospitals (Government and Private), ICMR and CDSCO for better implementation.