



30 September 2022

To: University of Leeds School of Healthcare

RE: Concerns about conflicts of interest with research project funded by Lansinoh Laboratories Inc

Attention: Rachel De Souza, School of Healthcare Research Ethics Committee (SHREC)

Faculty of Medicine and Health Research Ethics & Governance Administrator

Room 9.29, Worsley Building

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I am writing to you on behalf of the Baby Feeding Law Group UK (BFLG-UK), a coalition of 31 charities, organisations, health professional bodies and independent members who work together to protect infant, young child and maternal health by ending marketing practices which commercialise infant feeding, mislead consumers and threaten breastfeeding.

It has been brought to our attention that there is a current research project being conducted by the School of Healthcare at the University of Leeds entitled "Developing Nipple Care Pathway Guidelines to Support New Breastfeeding Mothers" that has received funding from Lansinoh Laboratories Inc. Several BFLG UK members have been sent letters and participant information sheets during September 2022 inviting them to participate in this research. The research letter indicates that a range of experts from different disciplines will be contacted, including health professionals such as midwives, lactation consultants, general practitioners (GPs), gynaecologists, doulas, health visitor, community pharmacists, and mothers with lived experience of breastfeeding.

We are concerned that Lansinoh funding the research creates a direct conflict of interest for any health worker who works with breastfeeding mothers and infants. Lansinoh produces, sells and therefore profits from nipple cream sales while this research seeks to develop guidelines on nipple care for breastfeeding mothers. It is also problematic that the invitation to participate in the research is being distributed through Lansinoh employees as well as by requesting breastfeeding organisations to disseminate the invitation to participate among their networks of breastfeeding mothers, and therefore Lansinoh is directly involved in participant recruitment.

The World Health Organization (WHO) recommend measures to avoid conflict of interest in nutrition policy development and service delivery as well as professional education and research.¹ The WHO defines

¹ World Health Assembly (WHA). 2018. Maternal, infant, and young child nutrition: Safeguarding against possible conflicts of interest in nutrition programmes – Draft approach for the prevention and management of conflicts of interest in the policy development and implementation of nutrition programmes at country level. <https://apps.who.int/iris/handle/10665/274165>



conflict of interest as arising “when a vested interest has the potential to unduly influence official or agency judgement/action through the monetary or material benefits it confers on the official or agency.”²

That Lansinoh is funding research on nipple care guidelines for breastfeeding infants means that a company that could benefit from the end result of the research could potentially unduly influence the research. This is not objective. Furthermore, participants being sent the invitation to take part in the research from Lansinoh employees could influence participants to think about nipple cream and even a particular brand of nipple cream when responding to the research questions. Current best practice guidelines from the NHS do not include the recommendation of nipple cream for women who might be experience nipple pain or cracked nipples while breastfeeding.³

Lansinoh also produces and sells feeding bottles, which are included in the scope of the International Code on the Marketing of Breast-milk Substitutes. It is not appropriate for a manufacturer of products within the scope of the Code to fund research related to breastfeeding. The need to protect breastfeeding from conflicts of interest, particularly from the baby food and associated feeding products industry has been widely documented.^{4,5} The World Health Assembly (WHA) infant and young child nutrition resolution from 2005 (WHA 58.32)⁶ urges Member States “4) to ensure that financial support and other incentives for programmes and health professionals working in infant and young child health do not create conflicts of interest” and “5) to ensure that research on infant and young child feeding, which may form the basis for public policies, always contains a declaration relating to conflicts of interest and is subject to independent peer review.”

While some of the research invitation letters to health professionals indicate that Lansinoh is funding the research, others (for example, those being sent to breastfeeding mothers) have not been as transparent, and all invitation letters and participant information sheets currently have no declaration relating to conflicts of interest. We perceive this to be an ethical challenge. The BFLG UK strongly recommend that the University of Leeds reconsiders the appropriateness of this funding in relation to industry-sponsored research. In order to ensure that the research is objective and not unduly influenced by commercial interests, Lansinoh funding and involvement in the research needs to be removed.

² World Health Organization (WHO). (2016). Addressing and managing conflicts of interest in the planning and delivery of nutrition programmes at country level: report of a technical consultation convened in Geneva, Switzerland, on 8–9 October 2015.

https://apps.who.int/iris/bitstream/handle/10665/206554/9789241510530_eng.pdf?sequence=1&isAllowed=y

³ NHS website. 2019. Sore or cracked nipples when breastfeeding

<https://www.nhs.uk/conditions/baby/breastfeeding-and-bottle-feeding/breastfeeding-problems/sore-nipples/>

⁴ Lhotska et al. (2020). Protecting Breastfeeding from Conflicts of Interest. *Journal of Human Lactation*.

<https://journals.sagepub.com/doi/epub/10.1177/0890334419885859>

⁵ Ching C. 2022. Conflicts of Interest & Undue Influence Associated With the Baby Food Industry

Repository. <https://www.babymilkaction.org/wp-content/uploads/2022/09/CONFLICTS-OF-INTEREST-UNDUE-INFLUENCE-ASSOCIATED-WITH-THE-BABY-FOOD-INDUSTRY-Repository-2.pdf>

⁶ World Health Assembly (WHA). 2005. Resolution 58.32 on Infant and Young Child Nutrition.

https://apps.who.int/entity/nutrition/topics/WHA58.32_icycn_en.pdf



We would also like to bring to your attention that the *Journal of Human Lactation*⁷, one of the leading peer-reviewed journals in the research area of breastfeeding, does not accept publication of research that has been funded by a company that does not uphold its obligations under the International Code of Marketing of Breast-milk Substitutes. Therefore, the creation of a conflict of interest through the funding of this research may result in limitations as to where the findings of this study can be published.

Your response to this letter would be appreciated.

Yours sincerely,

A handwritten signature in black ink that reads "Catherine Pereira-Kotze".

Catherine Pereira-Kotze, on behalf of the Baby Feeding Law Group (BFLG)
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⁷ <https://journals.sagepub.com/author-instructions/JHL>

Baby Feeding Law Group UK Members:

Association of Breastfeeding Mothers (ABM), Association for Improvements in the Maternity Services (AIMS), Baby Milk Action, Best Beginnings, Breastfeeding Network (BfN), the Centre for Lactation, Infant Feeding and Translational research (LIFT), Code Monitoring Northern Ireland, Community Practitioners and Health Visitors Association (CPHVA), Doula UK, The Fatherhood Institute, First Steps Nutrition Trust, GP Infant Feeding Network (GPIFN), HENRY, Hospital Infant Feeding Network (HIFN), Human Milk Foundation, Institute of Health Visiting, Lactation Consultants GB (LCGB), La Leche League GB (LLLGB), Leicester Mammias, Local Infant Feeding Information Board (LIFIB), Midwives Information and Resource Service (MIDIRS), National Breastfeeding Helpline, NCT, Royal College of Midwives (RCM), Save the Children, UK Association of Milk Banking (UKAMB), Unicef UK Baby Friendly Initiative, Unison, Women's Environmental Network (WEN), World Breastfeeding Trends Initiative, and Dr Robert Boyle (independent member)
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