Ontario Public Health Association
l'Association pour la santé publique de l'Ontario
Established/Établi 1949

The mission of OPHA is to provide leadership on issues affecting the public's health and to strengthen the impact of people who are active in public and community health throughout Ontario.

700 Lawrence Ave. W., Suite 310
Toronto, Ontario M6A 3B4

Tel: (416) 367-3313
1-800-267-6817 (Ont)
Fax: (416) 367-2844
E-mail: info@opha.on.ca
www.opha.on.ca

April 23, 2004

To: The Honourable Pierre Pettigrew
Minister of Health
Minister's Office - Health Canada
Brooke Claxton Bldg., Tunney's Pasture
P.L. 0906C
Ottawa, Ontario K1A 0K9

Dear Pierre Pettigrew:

The Ontario Public Health Association (OPHA) represents the interests of more than 3,000 community and public health practitioners across Ontario. The mission of OPHA is to provide leadership on issues affecting the public's health and to strengthen the impact of people who are active in public and community health throughout Ontario. The Breastfeeding Promotion Workgroup of the OPHA focuses on the promotion, support and advocacy for breastfeeding.

We would like to express our considerable concern regarding the health and safety of the infants participating in the TRIGR (Trial to Reduce Insulin-Dependent Diabetes in the Genetically at Risk) study as well as with the informed consent used in this research.

The TRIGR study looks at the use of Nutramigen, a special protein-hydrolysed formula produced by Mead-Johnson, a division of Bristol-Meyers Squibb. This study is based on the theory that the hydrolysed formula will help prevent genetically at-risk infants from developing Type I diabetes.

Research has shown that breastfeeding is the best way to help prevent or lower the risk of diabetes. Two recent studies continue to support this fact: Monetini, Cavallo et al. (2001)[1] and Kimpimäki, Erkkola et al. (2001)[2] . Research has also shown that when samples of formula are given to clients, they are far more likely to stop exclusively breastfeeding and either supplement with the formula or stop breastfeeding altogether. While the TRIGR website states that mothers in the study will be encouraged to breastfeed for 6 months, they will also be offered free formula for a minimum of two months thereafter. This disincentive to breastfeed creates an increased risk for their infants of developing Type I diabetes.

It is unclear what this study will prove as it will be difficult to attribute results to either the formula or breastfeeding, since the breastfed infants will also receive the hydrolysed formula. We are concerned that any positive effects identified may be attributed to the effects of the formula. The involvement of a formula company in research of this nature presents ethical concerns and a conflict of interest which needs to be addressed.

The issue of informed client consent presents a third concern. Unanswered questions include:

- What information is being offered to parents upon which they can base their decision to be part of this study?
- Are parents being informed that long-term breastfeeding is known presently to be the best way to help prevent Type I diabetes, as well as many other illnesses and diseases?
- Are parents informed of other, lower-risk alternatives, such as banked human milk?

Currently, the Information and Consent letter provided to the clients states "Risks: There is no known risk associated with the hydrolyzed trial formula…" In this instance, informed consent should indicate that parents consent to participate in the study only after being told of the risks associated with the use of formula of any kind and of not breastfeeding.

As an alternative to the use of formula, the OPHA would support the use of human banked milk because of its reduced risk in triggering diabetes in at-risk populations. It is our belief that governments should support human milk banks rather than conduct extensive research into new formulation. As with other research curtailed because of ethical concerns (such as hormone replacement research), we appeal to the Government of Canada to examine the points made within this document.

We eagerly await your written response and hope that Health Canada will act on the concerns expressed.

Sincerely,

Peter Wiebe
OPHA President

cc. Lori Levere, OPHA Breastfeeding Promotion Workgroup Chairperson

[1] "The results of this study indicate that breastfeeding within the first 4 months of life prevents the generation of antibody response to bovine beta-casein despite the mothers' consumption of cow's milk during the breastfeeding period. These finding may have relevance for disease prevention." (Bovine beta-casein antibodies in breast- and bottle-fed infants: their relevance in Type I diabetes [Electronic version] *Diabetes/metabolism research and reviews*, Jan-Feb, 17(1), 51)

[2] "These observations suggest that short-term breastfeeding and the early introduction of cow's milk-based infant formula predispose young children who are genetically susceptible to Type 1 diabetes to progressive signs of beta-cell autoimmunity." (Short-term exclusive breastfeeding **predisposes** young children with increased genetic risk of Type 1 diabetes to progressive beta-cell autoimmunity [Electronic version]. *Diabetologia*, Jan, 44(1), 63)