Erratum on p. 19 October 7, 2025

TO: Sara Brenner, MD, MPH, Principal Deputy Commissioner September 11, 2025
AND TO: Dr. Marty Makarny, MD, MPH
US Food and Drug Administration
10903 New Hampshire Ave.,
Silver Spring, MD 20993
United States of America
By email to: sara.brenner@fda.hhs.gov and CommissionersOffice@fda.hhs.gov and by upload to https://www.federalregister.gov/documents/2025/05/14/2025-08419/infant-formula-nutrient-requirements-request-for-information#open-comment

Re: **Docket number FDA-2025-N-1134: In response to consultation (styled "Operation Stork Speed") on infant formula,** especially including to (1) fully implement WHO guidance on marketing breastmilk substitute; (2) mandating comprehensive risk-warnings and safe preparation instruction on labels; (3) conducting research to disaggregate the causes death attributed to sub-optimal breastfeeding in the US and internationally; (4) establishing better protocols for microbiological testing; and (5) investigating the extent to which implementation and enforcement lapses are caused by undue influence of formula companies in public policy reform.

Dear Dr. Brenner,

I am submitting these comments on behalf of the Centre for Health Science and Law (CHSL).[1]

I would like to commend the Food and Drug Administration for hosting the expert panel on infant formula, for Commissioner expressing his support and attending the panel, and for requiring panellists to declare financial conflicts of interest.

Canadian infants and mothers have a special interest in the regulation of infant formula in the United States for two important reasons. First, virtually all infant formula consumed in Canada is imported from the United States; infant formula is one commodity where the United States enjoys a 100% trade surplus, with approximately $260 million worth of formula (23,000 metric tons) imported exported from the United States to Canada in trade that is, essentially, one-way.[2] According to FAO Trade Statistics, 88% of the infant foods imported to Canada comes from the United States and another 9% comes from 6 European countries.[3] Second, trade between our two countries is governed by the World Trade Organization agreement and the Canada-US Mexico Free Trade Agreement which put an onus on all three countries to come to some common understand about the health risks posed by infant formula to children, including in labelling and

advertising. As such, the safety of Canada's infant formula supply depends heavily on the sufficiency of efforts by U.S. food regulators and inspectors.

A. Overview

In 2024, CHSL supported a joint statement address to the Canadian Minister of Health (attached as Appendix I, and linked) endorsed by 35 mostly Canadian scientists and representatives of child and health protection groups urging the Minister of Health to:

1. **acknowledge the high risk of harm to infants**, including death, due to suboptimal breastfeeding, even in high income countries (like Canada and the United States);
2. **acknowledge the true low extent of exclusive breastfeeding** which is often overstated two-fold due to the traditional method of surveying parents;
3. **implement breastfeeding protection advice of the World Health Organization** (which seems consistent with similar-sounding commitments in the Make America Healthy Again initiative)—i.e., the WHO *International Code of Marketing of Breast-milk Substitutes* and subsequent relevant resolutions of the World Health Assembly—that governments worldwide have repeatedly endorsed in Geneva meetings, particularly imposing restrictions on the advertising and promotion of infant formula and establishing conflict of interest safeguards throughout healthcare and child protection systems to protect breastfeeding;
4. **fix food safety inspection protocols for infant formula** (in Canada and the United States) that limit the capacity of regulators to detect harmful pathogens such as *Cronobacter* (a.k.a., *C. sakazakii*);
5. **consistently advise preparing formula with water that is hot enough to kill harmful bacteria** enhance formula preparation instructions on labels that currently counsel parents to use water too cool to kill harmful bacteria that is sometimes found in powdered infant formula that puts vulnerable children at risk of potentially life-threatening infection,
6. **ensure human milk is only distributed through non-profit systems** not commercial systems that foreseeably deprive infants from low-income families in North America and low-income countries from their mother's milk for sale to high-income families, regardless of the health needs of the recipients. (The current Canadian non-profit system is based on donations of milk and prioritizes distribution to orphan infants and those with high-risk medical conditions on a triage basis. The US system of commercially collecting and distributing human breastmilk has no direct impact on Canada's healthcare system; our analysis in included as Appendix II.)

1. Acknowledge the persistent risk of formula-feeding and sub-optimal breastfeeding to infants' health.

Powdered infant formula is, by far, the most acutely dangerous food consumed by humans in the world, considering that it combines the health risks of intrinsically contaminated powdered infant formula, contaminated drinking water, errors in sterilizing bottles, and abstaining from the protective advantages of human breastfeeding.

Although the lion's share of deaths due to suboptimal breastfeeding occur in the Global South, especially Sub-Saran Africa.[4] (The United States generally no longer exports infant formula to Africa.) Alive & Thrive's "Cost of Not Breastfeeding Tool" estimates that 284 American infants die annually as a result of suboptimal breastfeeding and 12,385 American mothers die later in life as a result of Type II Diabetes, breast cancer, and ovarian cancer by foregoing the health protective effects of breastfeeding.[5] According to a recent update by *Drugwatch*, 760 US lawsuits seeking accountability for American babies who suffered grave illnesses or death as a result of consuming contaminated infant formula were launched in recent years, so far culminating in $495 million in court-ordered compensation.[6]

The 2023 Abbott formula contamination crisis led to the deaths of at least two infants (something that Abbott still disputes), it seems clear that many more American infants are regularly harmed by infant formula and, by extension, failing to breastfeed. The true extent of the risks of formula-feeding was partly revealed by the formula contamination crisis, which was largely recast as the over-reliance of Americans on a single formula manufacturing plant.[7]

However, the current Commissioner of the United States Food and Drug Administration recently wrote:

> *"While Cronobacter infections seem very rare, that may be because only two states – Minnesota and Michigan – require reporting Cronobacter infections to public health departments.*
>
> *Other cases may go unreported or reported as other illnesses such as meningitis, which can be caused by Cronobacter. Unless detailed studies are done, the diagnosis as a Cronobacter illness may be missed. The lack of mandatory reporting significantly hampers the ability to fully understand Cronobacter's public health impact.*
>
> *Additionally, there is no robust library of genetic data for Cronobacter that would be helpful to definitively link clinical samples to their source – i.e., certain foods or environments – and to identify repeat sources of clinical illnesses. The ability to match the exact genetic sequence of pathogens causing infection in a patient to those isolated from the source has revolutionized our ability to detect and control small and large outbreaks quickly. Unfortunately, right now, the isolate library housed by National Center for Biotechnology Informatics (NCBI) only has roughly 1,300 Cronobacter isolates compared with over 525,000 for Salmonella.*
>
> *Without this genomic data, it will remain difficult to determine the source of Cronobacter infections – and equally as challenging to prevent future ones. We're encouraging industry and public health partners to help us build this library by conducting more frequent whole genome sequencing (WGS) and sharing the findings so that we can all benefit from the data. [See: https://www.fda.gov/food/microbiology-research-food/whole-genome-sequencing-wgs-program]"*[8]

In sum, there are systemic shortcomings in the inspection practices for detecting harmful microorganisms.

Failure to avoid unsafe levels of *Cronobacter species*, for example, exposes infants to the possibility of an infection with a mortality rate of 40% to 80%.[9] *Cronobacter* has been linked to

several cases of necrotizing enterocolitis, particularly among hospitalized infants born prematurely. Younger children and ones with co-morbidities would be more susceptible to harm, especially from higher microbiological loads. In a review of 31 cases of *Cronobacter* infections, three quarters were in infants younger than one month old, and three-quarters were premature or experienced complications of childbirth.[10] However, previously healthy full-term infants are also known to become infected. Infants born at more advanced gestational ages might even be at greater risk than early preterm infants for having *Cronobacter* meningitis, as opposed to isolated bloodstream infections.[11]

The WHO recommends exclusive breastfeeding to six months, and continued breastfeeding to two years or beyond; the WHO *Code* and subsequent relevant resolutions of the WHA recommend numerous restrictions on the advertising and promotion of breastmilk substitutes to protect breastfeeding.[12] This is because suboptimal breastfeeding is estimated to kill 823,000 infants and young children annually worldwide due to severe diarrhoea and pneumonia.[13] This amounts to 0.6 % deaths of 134 million[14] live births annually worldwide which is double the 420,000 deaths[15] caused by food poisonings among adults and older children. Because other food poisoning deaths are not prevented by universal health care and clean water[16] in high-income countries (e.g., 238 deaths/year in Canada according to the Public Health Agency of Canada (PHAC)[17,18] it seems likely that formula-related deaths are likely undercounted in Canada and the United States. This risk rivals the crude death rate of smoking for adults worldwide: 0.6% or 8 million deaths per year of 1.3 billion mostly current smokers.[19]

Although the Seattle-based Institute for Health Metrics and Evaluation's Global Burden of Disease (GBD) database estimates for disease risks do not always comport with WHO expert estimates, it reported 563,000 diarrheal disease incidents in 2019 (mainly enteric infections) among Canadian children in their first year of life—slightly more than one per infant; this could reflect multiple infections with some vulnerable infants and other infants with few or none.[20] South African babies had approximately the same incidence rate of diarrheal disease, but a 148-fold higher risk of death due to diarrheal disease. If these numbers are accurate, the pathogen exposure may be approximately equal in the two countries, but the consequences of infection are vastly different. Likewise, a two-fold higher rate of lower respiratory tract infections among infants in South Africa corresponded to a 48-fold higher risk of death.

In addition to increasing the risk of infection-related serious acute illness and death, suboptimal breastfeeding is also believed to raise the risks of permanently impaired cognitive function, overweight, type 2 diabetes, and, possibly, leukemia and type 1 diabetes in children, as well as closer birth spacing and increased incidence of breast and ovarian cancers in mothers.[21] Formula-originated invasive *Cronobacter* (a.k.a., *C. sakazakii*) infections in infants, including bloodstream infections and meningitis, can result in permanent neurologic disability.[22]

That number of deaths may have risen in step with marginal population growth in the past seven years and with the approximately 50% rise in *per capita* formula sales in the 14-year doubling cited by the *Lancet* Series Group. Because most infants whose deaths are attributed to sub-optimal breastfeeding die within weeks or months of birth during exclusive formula feeding periods, the risk of death during the exposure period may be greater than 1% and double the crude odds ratio for tobacco-related deaths. And because sub-optimally breastfed babies die within weeks or

months of the risk exposure—not decades from adolescence (as for tobacco)—society has an even more solemn civic duty to protect babies who are, in every sense, utterly dependent and helpless from the time of risk exposure until death. Tobacco death rates declined by nearly 40% between 1990 and 2017[23] and, unlike formula, tobacco use is on the decline.

Furthermore, a 2021 Congressional report on contamination of baby food with toxins found that:

> *According to internal company documents and test results obtained by the Subcommittee, commercial baby foods are tainted with significant levels of toxic heavy metals, including arsenic, lead, cadmium, and mercury. Exposure to toxic heavy metals causes permanent decreases in IQ, diminished future economic productivity, and increased risk of future criminal and antisocial behavior in children. Toxic heavy metals endanger infant neurological development and long-term brain function…These results are multiples higher than allowed under existing regulations for other products. For example, the Food and Drug Administration has set the maximum allowable levels in bottled water at 10 ppb inorganic arsenic, 5 ppb lead, and 5 ppb cadmium, and the Environmental Protection Agency has capped the allowable level of mercury in drinking water at 2 ppb. The test results of baby foods and their ingredients eclipse those levels: including results up to 91 times the arsenic level, up to 177 times the lead level, up to 69 times the cadmium level, and up to 5 times the mercury level…[And] naturally occurring toxic heavy metals may not be the only problem causing dangerous levels of toxic heavy metals in baby foods; rather, baby food producers like Hain are adding ingredients that have high levels of toxic heavy metals into their products, such as vitamin/mineral pre-mix.*[24]

The contamination of vitamin pre-mixes with all four investigated heavy metals—arsenic, cadmium, lead, and mercury—is especially concerning because vitamin and mineral supplements (mainly vitamin A, iron, Zinc, and iodine) are often promised to deliver IQ-boosting benefits to malnourished children in Low- and Middle-Income Countries. If vitamin pre-mixes are prone to contamination with brain-harming toxins, those benefits might be partially or even overwhelmingly counterbalanced. The Congressional Sub-Committee also expressed concern that four large companies refused to participate in the investigation.[25]

2. Acknowledge the true extent of exclusive breastfeeding.

The 2023 *Lancet* series on breastfeeding prominently repeats a common error by conflating the statistical average of exclusive breastfeeding over the first six months of life with the percentage of infants achieving the public health recommendation to continue exclusive breastfeeding to the end of a full six months and partial breastfeeding to two years or beyond. The paper states that the global breastfeeding rate is nearly 50% (or specifically 48%) at pages 4 and 9 of Paper 1, page 3 of Paper 2, and the abstract of Paper 3.

However, national data housed by UNICEF indicate that breastfeeding rates decline sharply during the first 6-months such that the average greatly exaggerates the extent to which the goal of exclusive breastfeeding for the entire six months is achieved, likely by two-fold. For instance, the

unweighted average of the most recent surveys of children ages 0-6 months for 136 countries is 42%. Of the 98 countries reporting results for infant age sub-groups, the unweighted average of exclusive breast-feeders fell from 68% exclusively breastfeeding in the first 48 hours after birth,[26] 41% at age 0-1 months, to 31% at age 2-3 months, to 25% at 4-5 months, and presumably even fewer by the sixth month. The last of these statistics is rarely cited and was not cited at all in the 2016 or 2023 *Lancet* series, it more closely approximates attainment of the public health recommendation.

Likewise, the data depicted in Figure 2B of "Breastfeeding Paper Number 2" by Rollins, et al. indicates that per capita sales of breastmilk substitutes approximately doubled during the period 2005-2019. Although the precise percentage increase in *per capita* sales of each or four types of breastmilk substitutes was acknowledged in a passing reference on page 3 of the same paper--i.e., standard (64%), follow-on (77%), growing-up (214%), and special formula (95%)—the trend is described elsewhere only as a simple increase, not a near-doubling of per capita sales. While *per capita* sales are not a mirror-image statistic of breastfeeding rates, formula feeding generally displaces breastfeeding and switching back to breastfeeding after even a short period of formula feeding often requires a great deal of perseverance, support, and know-how.

These quantitative characterizations of the status of breastfeeding and formula sales foreseeably diminish political will to address the problem of sub-optimal breastfeeding and formal marketing.

They report global exclusive breastfeeding rates as nearly 50%,[27] but UNICEF's Data Warehouse indicates that the recent unweighted mean for ages 0-6 months for 136 countries is 42%, and declined from 68% for newborns,[28] to 25% at 4-5 months, and presumably even less by the sixth month. No data for Canada is included in the UNICEF database. Overstating breastfeeding rates foreseeably dampens political will to tackle formula marketing. UNICEF's Data Warehouse contains no breastfeeding survey data for Canada.

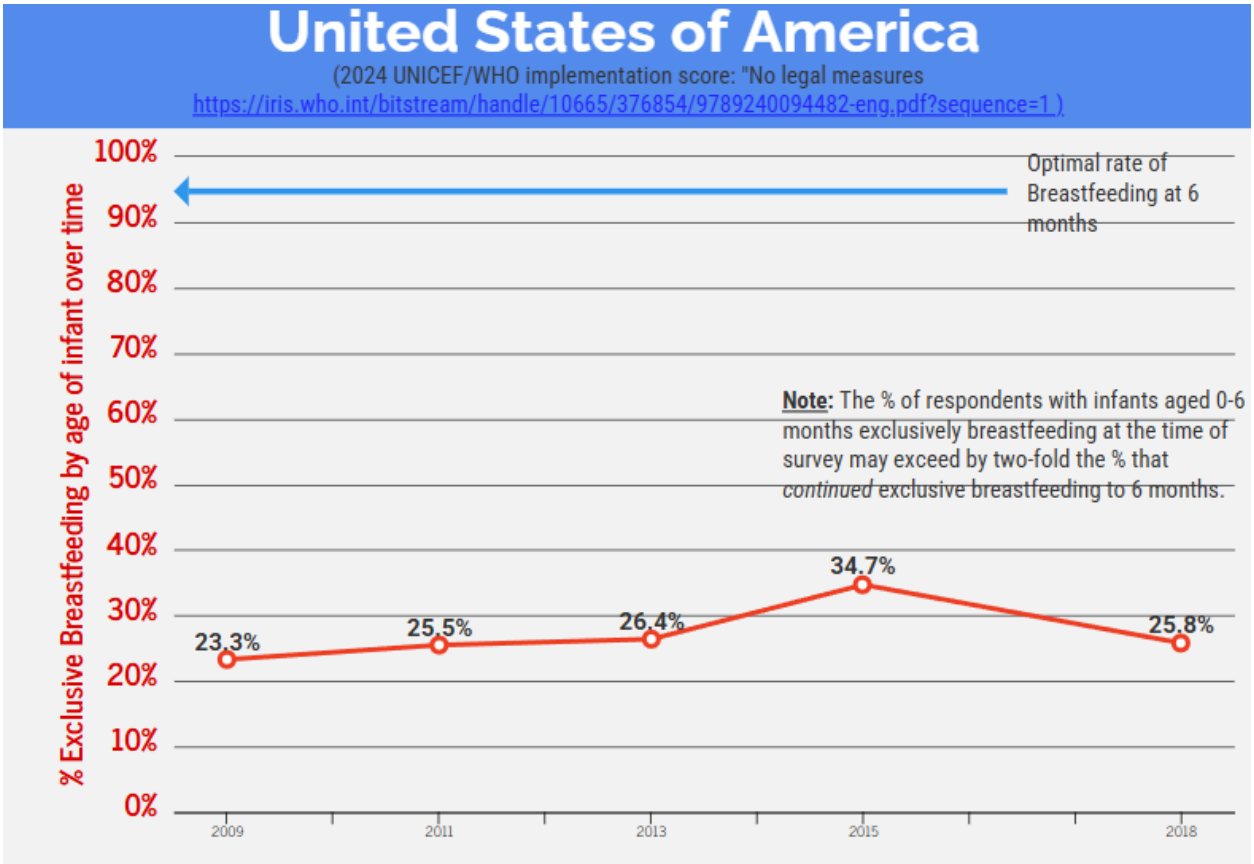
Either the risk of suboptimal breastfeeding has been underestimated by half or the success of achieving the WHO population targets is generally over-estimated two-fold. The goal of exclusive breastfeeding from birth to six months (26 weeks) appears nearly identical to a commonly cited measure of progress in achieving exclusive breastfeeding: exclusive breastfeeding among babies aged 0-5 months. However, the statistic is typically a two-fold overstatement of the extent of achieving the target because it is measured by inquiring about exclusive breastfeeding about a sample of babies ages 0-5 months old. Because exclusive breastfeeding rates often decline steadily after birth to near-zero levels at six months, the average over the first six months of life better represents the proportion of babies that are exclusively breastfed to three months.

The most accurate way of measuring the goal would be a survey of mothers in week 27 of their children's lives when their memories of the prior week's feeding would be reliably fresh. However, it would be challenging and expensive to locate an adequately powered sample (e.g., at least 300 respondents) born in the same week in any country.

Surveys of the rate of exclusive breastfeeding to six months in Canada indicate that, though initiative rates are very high (98%), only 15%-35% of infants are exclusively breastfed to six months, though the higher number is based on a survey of women who had given birth in the

previous five years when detailed recollections might have eroded over time.[29] A 2023 Lancet breastfeeding series repeats the common error of conflating the statistical average of exclusive breastfeeding over six months of life with advice to continue exclusive breastfeeding to the *end* of six months (plus partial breastfeeding to two years or beyond).

The following table indicates the persistently low level of exclusive breastfeeding in the United States, even by the statistic that likely misleads the actual achievement of the public health recommendation and the extent to which that estimate falls short of the public health goal.



3. Aspire to meeting benchmarks for best protect American infants in US Federal Regulations: WHO Guidance, EU regulations, and common law duty to warn, and MAHA objectives.

a. WHO guidance

The World Health Assembly reinforces its collective support for the WHO's *International Code of Marketing of Breast-milk Substitutes* every two years since its adoption in 1981 and the world-leading model for restraining advertising and promotion of breastmilk substitutes to protect and support breastfeeding. Although the United States has not officially ratified the *Code,* neither

Canada nor the United States governments have significantly implemented WHO guidance into domestic regulations. The United States was the only country to vote against the Code at the 1981 meeting of the World Health Assembly.[30] UNICEF rates Canada and the United States as tied for last place in the extent to which they have implemented WHO guidance on the marketing of breastmilk substitutes with four of 37 other OECD countries.[31] Both Canada and United States are characterized as having ""no legal measures in place" to curb the advertising and promotion of breastmilk substitutes. This ignoble position is partly a result of the persistent failure of the Government of Canada (and likely decades of US federal governments)—for more than four decades—to reports its own compliance with the *Code*. (The government of Canada recently announced plans to significantly revise its regulatory approach to breastmilk substitutes in light of its commitments under the *International Code*, however its detailed proposal to do fell short of that and appeared to be contrary to the spirit of the *Code*. (See the joint statement of Canadian experts dated February 2024.[32])

The February Lancet Breastfeeding Series Group series on formula marketing and promotion of breast-milk substitutes offers a damning indictment of the unconscionable marketing practices of formula companies.[33] Such marketing is expressly prohibited by laws in many countries[34] and generally prohibited by standard consumer protection and food marketing laws that prohibit misleading or deceptive advertising and labelling of foods and goods and services, generally.

The International Labour Organization also urges employers to provide new mothers with paid postpartum maternity leave to help them breastfeed at home, as well as accommodations at work to facilitate daycare, breastfeeding, and expressing milk after mothers return to work.[35]

A 2023 *Lancet* Breastfeeding Series Group lamented aggressive commercial advertising and promotion activities by formula companies, weak maternity leave and social insurance protections during exclusive breastfeeding, lacklustre workplace breastfeeding supports for working mothers, and failures to implement *Code* guidance in health systems—including research and care settings. Poor legal protections for breastfeeding contributed to a two-fold per capita rise in global formula sales 2005-2019.[36] The *Code* and underpinning evidence stress that formula feeding undermines breastfeeding.

b. European Union regulations governing the marketing of breastmilk substitutes

The European Union banned nearly all direct-to-consumer advertising of breastmilk substitutes by regulation that states, in part:

> *Article 10*
> ***Requirements for promotional and commercial practices for infant formula***
> *1. Advertising of infant formula shall be restricted to publications specialising in baby care and scientific publications.*
> *Member States may further restrict or prohibit such advertising. Such advertising shall contain only information of a scientific and factual nature. Such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breast feeding.*

2. There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formula directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.
3. Manufacturers and distributors of infant formula shall not provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts, either directly or indirectly via the health care system or health workers.
4. Donations or low-price sales of supplies of infant formula to institutions or organisations, whether for use in the institutions or for distribution outside them, shall only be used by or distributed for infants who have to be fed on infant formula and only for as long as required by such infants.[37]

c. Common law duty to warn

I will not attempt to characterize the US common law duty to warn, but our common law systems are broadly similar. The Supreme Court of Canada has established manufacturers' common law duty to warn consumers about the risks of harm from the use of products that seems applicable to infants and mothers from sub-optimal breastfeeding, exposure to harmful bacteria and other risks associated with supplanting breastfeeding.

While no Canadian statute or regulation specifically requires formula manufacturers to disclose the possibility of serious illness or death of consuming infant formula, the Supreme Court of Canada held that there is a general duty to disclose risks to consumers in *Hollis* v. *Dow Corning Corp*:

> *"A manufacturer of a product has a duty in tort to warn consumers of dangers it knows or ought to know are inherent in the product's use. This duty is a continuing one, requiring manufacturers to warn not only of dangers known at the time of sale, but also of dangers discovered after the product has been sold and delivered. All warnings must be reasonably communicated, and must clearly describe any specific dangers that arise from the ordinary use of the product. The duty to warn serves to correct the knowledge imbalance between manufacturers and consumers by alerting consumers to any dangers and allowing them to make informed decisions concerning the safe use of the product.*"[38]

Hollis cited with approval in paragraph 20 the Supreme Court of Canada's own 1972 decision in *Lambert* v. *Lastoplex Chemicals*:

> *Manufacturers owe a duty to consumers of their products to see that there are no defects in manufacture which are likely to give rise to injury in the ordinary course of use. Their duty does not, however, end if the product, although suitable for the purpose for which it is manufactured and marketed, is at the same time dangerous to use; and if they are aware of its dangerous character they cannot, without more, pass the risk of injury to the consumer.*[39]

Lambert has been cited with approval by dozens of Canadian courts, including recently by the Alberta and Ontario Courts of Appeal.[40]

As noted above, 760 US lawsuits are seeking accountability for American babies who suffered grave illnesses or death as a result of consuming contaminated infant formula were launched in recent years, so far culminating in $495 million in court-ordered compensation.[41]

d. The Make American Healthy Again initiative

The Make America Healthy Again initiative appears to compel strong government action to protect infant nutrition. There appears to be a great deal in the general principles set out recent Make America Healthy Again to suggest that the current federal government is uniquely intent on protecting breastfeeding in the United States. For instance, the September 2025 report states, in part:

> *"Over 60% of children's calories now come from highly processed foods, contributing to obesity, diabetes, and other chronic conditions.* ***Chemical Exposure:*** *Children are exposed to an increasing number of synthetic chemicals, some of which have been linked to developmental issues and chronic disease. The current regulatory framework should be continually evaluated to ensure that chemicals and other exposures do not interact together to pose a threat to the health of our children. [page 1]…****Infant Formula:*** *FDA will modernize nutrient requirements for formula, increase testing for heavy metals and other contaminants to help ensure access to high-quality and healthy infant formula sold in the United States, and encourage companies to develop new infant formulas.* ***Breastfeeding:*** *USDA and HHS will work to increase breastfeeding rates, whether through the Special Supplemental Nutrition Program for Women, Infants, and Children or other policies, that support breastfeeding mothers, and will work with other Federal partners to develop policies to promote and ensure a safe supply of donor human milk…****Conflicts of Interest:****…[Health and Human Services] will establish a public database to disclose financial relationships, mandate recusal requirements consistent with the Federal Advisory Committee Act for individuals/organizations with conflicts of interest, and prioritize the use of independent, conflict-free research for Federal health guidelines. [page 9]…****Agency Foundation Capture:*** *The HHS Secretary will direct the FDA, CDC, and NIH to review participation in any projects or initiatives funded by food and pharmaceutical companies through the CDC Foundation, Foundation for the NIH, or the Reagan-Udall Foundation. The Secretary of HHS will require more transparency, as well as additional guardrails needed to protect public health from corporate influence. [page 10]…Ensure the use of gold standard science for regulatory decision-making and update outdated methodologies as necessary. [page 13]…* **** "Food for Health":*** *Emphasize how proper nutrition prevents and can help reverse chronic diseases and maintain general health.* **** "Real Food First":*** *Prioritize whole, minimally processed foods over packaged and highly processed alternatives.*[42]

However, as with any government broad objectives, the regulatory and spending decisions are what really matter for children and parents; commissioning research related to law and government spending may take years to produce findings, and should not be substitutes for action when the path to better health is already clear from previous research. For instance, according to the Center for Budget and Policy Priorities, the current federal budget would reduce fruit and vegetable

benefits for millions for breastfeeding mothers from $52 to $13 per month;[43] breastfeeding mothers need to eat more nutritious foods than usual, not less, to generate breastmilk for their infants.

4. Research: Disaggregating the risks of sub-optimal breastfeeding due to indications that scientists, health professionals, and regulators may have underestimated risk of formula contamination

Like the US, Canada is a high-income country where residents enjoy near-universal access to quality health care, safe drinking water, reliable refrigeration, and reliable access to electricity or other properly ventilated sources of energy for cooking, cleaning, and food preservation. Canada also enjoys a capable, generously resourced, and technologically well-equipped public healthcare service, by global standards.

(a) Epidemiological and outbreak studies of food pathogens are insufficient.

However, the Public Health Agency of Canada's first and only comprehensive analysis of prevalence of illness due to food-borne pathogens was published only recently, in 2015. It found that 66% hospitalizations and 56% of deaths due to such pathogens were attributed to "unspecified agents."[44] Even this important effort reflects a systemic failure to adequately explore sources of contamination even in the case of deaths. The study did not consider *Cronobacter*, even though Canadian outbreaks in powdered infant formula were reported in 1990, 1992, and 2007[45] and, as noted above, the estimated fatality rate for *Cronobacter* infections is 40%-80%. Doubtless *Cronobacter* infections were among the 66% of hospitalizations and 56% of deaths attributed to "unspecified agents."[46] Likewise, the *WHO Estimates of the Global Burden of Foodborne Diseases 2007-2015*[47] did not report estimates for death or disability attributable to *Cronobacter*. The Canadian report was painstakingly detailed on pathogens and infections with comparatively minor adverse health effects or rare fatalities. Only two of the 30 pathogens that were passed through food and led to more than 10 deaths per year in the period 2000—2010. Relying on the Hospital Morbidity Database (HMDB)[48] maintained by the Canadian Institute for Health Information (CIHI), researchers found that:

- *Listeria Monocytogenes* caused 100-223 hospitalizations and 23-55 deaths per year; and
- *Salmonella spp., nontyphoidal serotypes* caused 774-950 hospitalizations and 2-27 deaths per year, approximately 80% of which were related to foodborne pathogens.[49]

(Minor acute gastrointestinal illness is common in Canada; an estimated 1.3 episodes per person occur each year in Canada, which translates to more than 40 million incidents.[50])

As long ago as 1961, reports of invasive *Cronobacter* infections were described in the scientific literature.[51] Then, 17 years ago, *Cronobacter* and *Salmonella enterica* were recognized in guidance developed by the Codex Alimentarius Commission. The 2008 Codex *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* concluded, following negotiations by food safety officials from nearly 60 countries:

> *Two FAO/WHO meetings of experts on the microbiological safety of powdered infant formula considered cases of illnesses in infants associated with PF consumption*

either epidemiologically or microbiologically. They identified three categories of microorganisms based on the strength of evidence of a causal association between their presence in PF and illness in infants: A) microorganisms with a clear evidence of causality, namely, Salmonella enterica and Enterobacter sakazakii...[52]

A 2009 study of infant formula prepared in 18 South African hospitals commissioned by UNICEF and the South African Ministry of Health found that 27% of sealed containers of infant formula (35 out of 130) were contaminated with clinically significant bacteria. Researcher found that 27% of bacteria detected (45 out of 165 detected bacteria) were identified as *Klebsiella spp.* which the report described as "a serious problem for most neonatal units in South Africa and has in the past contributed to many infant deaths."[53] This also indicates that some formula samples were found to contain more than one clinically significant contaminant. While the researchers reported witnessing unhygienic conditions and practices in the hospital that could have contributed to the rise in the rate of contamination in the prepared products, they did not consider the possibility that the powdered infant formula might have had heterogenous distribution of pathogens (as presumed by other leading experts[54]) and that efforts to prepare bulk quantities for the maternity ward might have increased the likelihood of detecting pathogens. (Nor did the researchers speculate on whether preparation by trained hospital staff might have been safer than preparation by parents at home.)

The Canadian Food Inspection Agency's annual Children's Food Project to test for pesticide, chemical, veterinary pharmaceutical residues, aflatoxin, and other contaminants in food is significantly under-powered (143 samples in 2018-2019) and does not test for bacterial contaminants.

Even when a surveillance system was in place in France in 2005, it failed to detect a cluster of *Salmonella Agona* infections due to contaminated powdered infant formula because its algorithm was based on the number of cases occurring among persons of *all* ages during a five-year reference period, rather than age-specific incidence rates.[55] Recent data from the Canadian National Studies on Acute Gastrointestinal Illness estimated that, for every patient with a verotoxigenic *E. coli*, *Salmonella* or *Campylobacter* infection detected by the national surveillance system, up to 49 people with such infections are missed in the community.[56]

Because reporting is not mandatory in most countries (and in most of the United States), the true incidence of invasive infant *Cronobacter* infections is unknown. Estimates from laboratory-based surveillance in the United States Center for Disease Control estimated that from 1961-2018 invasive *Cronobacter* occurred at a rate of 0.49 cases/100,000 infants.[57] In 2008, the World Health Organization (WHO) reported the yearly incidence to be at least 0.14/100,000 infants in the Philippines and 1.76/100,000 infants in England and Wales, although these are thought to be underestimates,[58] and, in light of the challenges described above, the degree of under-estimation could be large.

Salmonella is a well-known, common, and persistently concerning foodborne human pathogen. The incidence of salmonellosis among infants was reported to be more than eight times greater than the incidence across all ages in the United States.[59] It is unclear whether the reportedly higher incidence of salmonellosis among infants is due to greater susceptibility, or a higher likelihood for

medical care to be sought or stool cultures performed than for older people. It is generally recognized that outbreaks and sporadic cases of salmonellosis due to powdered infant formula are likely to be under-reported.[60] A study of six outbreaks of *Salmonella* infection associated with powdered infant formula during the period 1985–2005 involving 287 infants found that most were identified because the *Salmonella* strains were unique in some way (e.g., the occurrence of a rare serotype or a distinguishing biochemical aberrancy). In many regions of the world, *Salmonella* serotyping is rarely performed, and surveillance networks rarely mandate reporting of *Salmonella* infection.[61]

Statistics Canada reports the deaths of approximately 1,700 infants (aged 0-12 months) per year, but only particularizes causes of death for approximately 1,000. Even among the purportedly specific causes, most are truly "risk factors" or "vulnerabilities" that could mask deaths due to illness caused by contaminated infant formula. For instance, Statistics Canada cites these "causes:"

- *"Disorders related to short gestation and low birth weight, not elsewhere classified:" 214 deaths;*
- *"Congenital malformations, deformations and chromosomal abnormalities:" 345 deaths; and*
- *"Newborns affected by maternal complications of pregnancy:" 144 deaths.*[62]

Even among the purportedly specific causes, most are truly risk factors or vulnerabilities (such as low birth weight and malformations, and complications of pregnancy) that could mask dozens or even hundreds of deaths due to illness caused by contaminated infant formula. All these causes appear to be risk factors that are consistent with vulnerable to severe consequences of infection with intrinsically contaminated powdered infant formula. By sharp contrast, the average number of annual deaths of Canadian children aged 1-4 years old is 37. The first year of life appears both dangerous and under-examined.

Some deaths may be attributed to the WHO's own guidance to governments (and FDA's guidance to consumers, health professionals, and mandated on labels) to cool boiling water for 30 minutes at room temperature before re-hydrating powdered infant formula.[63] (See below.) Some may be attributed to the vagueness of product label and advertising safety warnings that appear to vastly understate risk.

The coordinator of microbiological risk assessment at the World Health Organization from 2003 to 2019 was a former Nestlé and Danone scientist—the first and second richest infant formula manufacturers in the Global Fortune 500 list—which revolving-door appointment seems to have been at odds with the spirit of the WHO *Code* and possibly a contributor to deficiencies in WHO formula safety guidance.[64]

(b) Challenges in clinical settings

Identifying a case of infection due to a food-borne pathogen in a hospitalization record, death registry or surveillance database requires that a specimen (stool, blood, or urine) be submitted and tested in a qualified laboratory and that the positive test result be recorded and reported to the proper surveillance system.[65] Digitalization of medical records even in high-income Canada with a single-payor public healthcare system is a stubbornly slow and fragmented process. Lack of

digitalization of medical records makes it nearly impossible to identify such risks unless they are required to be tested and reported.

Cronobacter infection can be very difficult to accurately diagnose, partly because it initially presents as a minor illness with nonspecific symptoms, but becomes serious to the point of untreatable quickly as one published case report explained:

> *At 3.5 weeks, the baby was admitted to the hospital with a high temperature but was subsequently discharged without treatment [then re-admitted at 6.5 weeks]…Cronobacter spp. were isolated from a brain abscess. At 11.5 weeks, the infant was released but had suffered severe brain damage.*[66]

The hospital's 2005 investigation of the outbreak in France, noted above, revealed that the contaminated infant formula was sold under two different brand names, both of which had been manufactured on the same assembly line and initially tested negative for *Salmonella.* Subsequent tests revealed *S. Agona* contamination from one of 176 samples of formula A provided by the company, 4 of 27 packages of formula B provided by the families, and 6 of 420 environmental swabs from the production line.[67]

(c) Challenges for laboratories and food regulatory food inspections

The systematic lack of attention to harmful bacteria known to sometimes be present in powdered infant formula is compounded by (and likely influenced by) several analytical and detection challenges. Powdered infant formula is distinct from ready-to-feed liquid formula that has been commercially sterilized. For infants at greatest risk that are medically incapable of being breastfed, commercially sterile liquid infant formula is recommended if it is available and if an effective point-of-use decontamination procedure is used, [68] however it is generally much more expensive than powdered infant formula.

Laboratory facilities and testing procedures to detect the most worrisome bacteria such as *Cronobacter sakazakii* are too often unavailable—or availed by health professionals—even in high-income countries.[69] For instance, Canada now has only two laboratories accredited to test for *Cronobacter*: in Kingston, Ontario and Calgary, Alberta.[70] The Canadian Food Inspection Agency is headquartered in Ottawa and the largest population centre, Toronto, is hub of the processed food industry, and a point of entry for most U.S. food imports.

Likewise, (as noted above) former United States Food and Drug Administration Deputy Commissioner Yiannas, a former Walmart Vice-President, indicated that *Cronbacter* is distributed heterogeneously in powdered formula and testing samples are so small, that it is extremely unlikely to locate contamination in inspections and that it is only mandatory in two of 50 U.S. states to report *Cronobacter* contaminations in food to the Centres for Disease Control.[71] However, the Representatives and witnesses appeared to focus on additional and the need to create redundant manufacturing capacity beyond the 20 plants serving the U.S. population (and barely explicable bureaucratic inaction) and not at all focussed on promoting breastfeeding.

As one review concluded:

> *A common feature in the reported outbreaks of Salmonella infection was the low levels of salmonellae found in the PIF. Such levels are not easy to detect and may be missed by some of the conventional methodology or the sampling plans currently used. In most of the investigations, the epidemic strain of Salmonella species was isolated from bulk, storage, and/or retail packaged samples. This was not achieved without a great deal of effort. There are no data available to adequately describe the distribution of salmonellae in PIF, but it is considered to be sporadic or heterogeneous, leading to difficulties in detection. For example, in the investigation of the outbreak of Salmonella Ealing infection, intensive bacteriological sampling by 33 laboratories found no pathogens in 4554 samples of 658 batches of product. Finally, 1 laboratory reported the isolation of Salmonella Ealing from an opened packet of PIF taken from an infected infant's home. This facilitated targeted testing based on a specific manufacturing code, leading to the isolation of Salmonella Ealing from 4 of 267 sealed packets [19]. This highlights the difficulty for food microbiology laboratories, which could not have cultured an adequate sample of products without a targeted strategy.* [72]

The Codex-recommended test sample size is 10 grams which is equivalent to 1% of the powder in a one-kilogram container of infant formula.[73] This is, itself, a small sample within a sample of the food supply. If there is contamination, but not throughout the container, there is a risk that a 1% test-sample will produce a false negative result. The recommended Codex Committee on Food Hygiene technique for testing samples presumes a homogenous sample.[74] However, as noted above, contamination of powdered infant formula is considered to be sporadic and heterogeneous, leading to difficulties in detection.[75]

The same expert report mentioned above, including WHO and FAO food safety experts, also noted that, even using a five-fold larger sample (50 grams) which they considered to be small:

> *The other significant feature of this investigation was the very low number of salmonellae estimated to be present in the powder (1.6 organisms per 450 g); a low number of salmonellae would have been difficult to detect by the quality control sampling practiced at that time (using only 50-g samples) [citations omitted].*[76]

An outbreak of *Cronobacter* in Belgium reported that 10 infants had been fed the same formula. Initial analyses indicated that the formula powder was not contaminated so the babies resumed consuming it. It only became evident that those tests were inaccurate when one infant developed *Cronobacter*-associated necrotizing enterocolitis."[77]

According to *The Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children*, the two reputedly most worrisome pathogens found in powdered infant formula are alternately difficult to detect either wet or dry processing environments, respectively, though both appear in finished products:

- *Salmonella is rarely found in dry processing areas*

- E. sakazakii (Cronobacter species) is more frequently found than Salmonella in dry processing areas and is found regularly when using appropriate sampling and testing methods.[78,79]

Detection challenges might have been at play in a recent Canadian Food Inspection Agency (CFIA) study of bacterial contamination in powdered infant formula which found no *Cronobacter spp.* in 997 test samples and no *Salmonella spp.* in 2,965 test samples.[80] The CFIA asserted that "very few studies similar to ours have been published." The CFIA study prevalence numbers appear to be much lower than found in any published literature. For instance, a 2004 study cited by CFIA found that 2.4% (2 of 82 samples) of packages of infant formula purchased from retailers in the UK and other European countries contained *Cronobacter spp*. (*Enterobacter sakazakii*).[81] Importantly, at the rate of 2.4% of samples being contaminated, and considering that an infant consuming powdered infant formula exclusively for six months would consume an average of one to two containers per week (packages are typically 600-1,000 grams),[82] this would expose the majority of formula-fed babies to some *Cronobacter* at some point during the first six months of their lives (i.e., 26 x 2.4% = 62%).

Chinese studies also have reported detecting higher prevalence of contamination, possibly because Chinese researchers have been especially active in developing more reliable detection techniques.[83] The motivation to ensure the safety of infant formula there is high. An estimated 85% of Chinese babies are reputedly formula-fed.[84] Though improvements to paid maternity leave policies were promised in connection with the adoption of a three-child policy, benefits of the current three-month leave are reportedly often not honored by employers, which likely imposes high pressure on new mothers to stop breastfeeding early.[85] Likewise, China's efforts to restrict commercial advertising and promotion of breastmilk substitutes as recommended by the World Health Organization are especially weak (scoring 25 on a 100-point scale even without considering law enforcement efforts).[86]

These factors highlight the difficulty for food microbiology laboratories, which could not have cultured an adequate sample of products without a targeted, energetic, and inconvenient strategy.[87]

(d) The need for research to disaggregate the risks to better understand the proximate causes of premature death of suboptimal breastfeeding

The FDA, CDC, or HHS should take steps to better quantify population attributable risk to the foreseeable causal pathways of illness and death attributed to sub-optimal breastfeeding.

Though some health risks can be attenuated by access to high quality health care and consistently safe tap water and other hygiene measures, it is possible that a large number of deaths of infants currently attributed to sub-optimal breastfeeding may actually be due to an undetected high rate of contaminated infant formula known as intrinsic contamination (and poor access to risk-compensatory health care). Unlike any other period of life, infant feeding is often entirely homogenous up to six months. Approximately a week's food supply may be unwittingly drawn from the same contaminated source: a single can of powdered infant formula. So long as doubt remains about the causal pathway of illness due to sub-optimal breastfeeding, bottle-feeding parents (or breastfeeding mothers considering a switch) may underestimate risks of doing so and marshal insufficient or misdirected mitigation measures.

Formula manufacturers and distributors benefit from this attributional ambiguity which likely aids the steady annual rise in global sales in breastmilk substitutes[88] and the paucity of class action litigation[89] to fix financial responsibility on manufacturers (which are mainly based in High-Income Countries) for harm to infant-victims (mainly living in Low- and Middle-Income Countries).

(a) Research needed:

Of the aforementioned estimated 823,000 annual deaths, presumably the vast majority of deaths due to sub-optimal breastfeeding are attributable to the following more proximate causes:

i. **impaired immunity:** Under-developed immune systems in infants caused by a lack of breastfeeding increase vulnerability, but ill-health still requires exposure to adangerous bacteria or viruses, including exposure to bacteria through food and water. [90]
ii. **contaminated formula:** It is not technologically feasible to produce sterile powdered infant formula.[91]
iii. **unhygienic preparation:** Contamination can occur by food preparation in the home or hospital environment or poorly sanitized feeding bottles, etc.
iv. **contaminated water:** Mixing powdered infant formula with contaminated water that has not been boiled can itself cause illness and death. Presumably, a small fraction of the 485,000 deaths worldwide due to contaminated drinking water among people of all ages occurs in children under age five, and fewer still among children under six months of age.[92] Cleaning feeding bottles with contaminated water also contributes to risk. (Notably, impure water was not suggested as a possible vector of *Cronobacter* infection by a U.S. Centres for Disease Control team that included a lead expert on waterborne disease infection.[93])
v. **lack of refrigeration:** Poor access to refrigeration and reliable electricity can contribute to risk, especially where parents cannot afford to discard unused formula.
vi. **lack of quality healthcare:** Poor access to health care to treat infections and noncommunicable diseases can convert a dangerous infection to lethal one.

c) WHO's long-standing, widely disseminated guidance on preparation of powdered infant formula (informing some advice to American consumer from the US FDA and other federal agencies) is incorrect, poorly actionable, and dangerously misleading.

The World Health Organization's efforts to promote breastfeeding have been laudable, particularly guidance (promoted with other UN agencies, especially UNICEF) that national governments restrict the advertising and promotion of breastmilk substitutes.[94]

However, since 2007, WHO's model advice on the safe preparation of powdered infant formula has counselled caregivers to boil water and cool it to 70°C by letting it stand at room temperature for no longer than 30 minutes. The inference is that 70°C water is hot enough to kill harmful bacteria that may be present in the powdered infant formula. However, cooling an amount of boiling water suitable to prepare 125-250 mL of formula for 30 minutes at room temperature (approx. 20°C) reduces its temperature far below 70°C to approximately 40°C and passes the temperature of the highest risk of bacterial proliferation: 50°C along the way.[95] This misleading WHO guidance has been adopted extensively by national public health authorities worldwide

during the past 15 years. The US Food and Drug Administration still sends conflicting messages, e.g., even in the same document recommends cooling boiling water for only five minutes, but also cooling to room temperature.[96]

A half-cup of boiling water cools to 70°C at room temperature in an uncovered ceramic cup in approximately 3 minutes, and cools to 50°C in approximately 13 minutes which is the temperature most conducive to microbiological proliferation, but is still scalding hot. Though homes in rich and poor countries are often not equipped with high temperature thermometers, FDA food safety officials can easily fact-check this rate of cooling with a meat thermometer and a half-cup of coffee or tea water. Where permitted by law, Nestlé's website and label preparation instructions notoriously advise the use of water that is only 37° Celsius which is too cold to kill bacteria and was, apparently, chosen to avoid killing probiotics that are often featured in the company's health claims.[97] (Such health claims are also contrary to WHO guidance.[98]) However, the WHO's model guidance is essentially the same as Nestlé's in regard to the use of water temperature to kill bacteria.

A 2009 South African study of hospital-prepared formula noted that the U.S. Centre for Disease Control raised three concerns about using boiling water (i.e., 100° Celsius) to reconstitute powdered infant formula: speculation that it would (1) compromise vitamin content, (2) lead to clumping, and (3) activate some bacteria. All three concerns were largely dismissed by 2006 guidance from WHO/FAO.[99] The South African study actually measured the amounts of vitamins A, B1, B2, B6, C, and E when prepared with water heated to 40° and 70° Celsius. It found that the hotter water did not lead to statistically significant vitamin reductions. Although amounts of Vitamin C were substantially lower when (only) two of 10 powders were prepared with hotter water, the much bigger problem appeared to be widespread exaggeration of the amounts of Vitamin C reported on the package labels. Seven of the 10 products tested reported Vitamin C levels on labels that were two- to seven-fold higher than what was detected by the laboratory analysis regardless of water temperature.[100]

Moreover, the WHO advice sends mixed messages about scalding risk. According to Wikipedia, 60°C water can cause scalding tissue damage in three seconds, and household water heaters should be set no warmer than 45°C to avoid scalding and discomfort.[101] So the explanation that water should be cooled to 70°C before being added to powdered formular to avoid scalding injuries does not ring true.

Please consider revising FDA's and other federal government guidance to advise mixing the powder with boiling water (not [previously] "boiled" water), THEN cool the mixture long enough that it won't hurt the baby. Body temperature, obviously, is 37° Celsius and parents do not need special equipment to decide if something is close enough to body temperature to avoid scalding their babies.

We have proposed the following revisions to WHO guidance that have not yet been activated:

> ***Pour the correct amount of boiling water for the corresponding number of scoops into the sterilized feeding cup containing the powdered formula. Stir the mixture with a sterilized spoon to dissolve lumps, then cool the mixture until it is near body temperature before feeding to the baby. For example, check the temperature by placing a few drops on the caregiver's wrist.*** ~~*Taking care to avoid scalds, pour the correct amount of boiled water into*~~

~~*a cleaned and sterilized feeding bottle.*~~ *The water should be no cooler than 70ºC, so do not leave it for more than 5 ~~30~~ minutes after boiling.*

(**Source of current guidance:** WHO. How to Prepare Formula for Bottle-Feeding at Home. Geneva: WHO, 2007 at https://www.who.int/foodsafety/publications/micro/PIF_Bottle_en.pdf)
Note also: The guidance URL and the guidance itself also suggest bottle-feeding rather than cup-feeding, which is contrary to WHO guidance.

d) Investigate and rectify the extent to which implementation and enforcement lapses are caused by undue influence of formula companies in public policy reform.

While the biennial reports published jointly by the World Health Organization, UNICEF and non-governmental International Baby Food Action Network now score the sufficiency of national regulatory controls on the advertising and promotion of breastmilk substitutes worldwide (on a scale from zero to 100), it devotes no attention to enforcement practices.[102] Anecdotally, violations of national laws appear to be rarely penalized (or *publicly* penalized) by fines, injunctions, product recalls or other impactful measures to admonish and prevent illegal actions by formula companies. If national prosecutors exercise any prosecutorial discretion at all, it appears to nearly always favour the offending companies.

Reasons for this could include fear of challenging massive multi-national companies in courts (presumably less a concern for the US government); many formula companies have global national sales from all products[103] that vastly exceed the gross national incomes, let alone health ministry budgets of small and developing countries. Also, few national Parliaments authorize inspectors to institute spot fines (like speeding or parking tickets) so applying any penalty often requires court orders and over-coming burdens of proof and other procedural protections designed to protect the interests of the private citizens against the power of the state, not massive multi-national corporations.

Corruption or various forms of undue influence is a risk in both high-income countries where formula companies are based, manufactured and labelled and lower-income countries where officials are often paid capitulation-level wages. MAHA cited concerns about poor conflict-of-interest safeguards and government agency "capture…by corporate influence." In high-income countries, lax rules about campaign finance facilitate corporate payments to politicians to legally subvert the public interest without conferring a direct financial benefit to elected officials except job security through enhanced electoral success.

Understanding these lapses is essential to preventing the deaths of children. Perfect laws are useless without enforcement and strict enforcement is useless with porous regulatory standards.

e) Conclusions and Recommendations

In the *44 years since the International Code of Marketing of Breast-milk Substitutes* was adopted by the World Health Organization in 1981, the advice to national governments has been clear and

both reinforced and particularized by 20 subsequent resolutions of the World Health Organization.[104] Yet even governments that revise their regulations to tighten controls leave gaps as if the national food regulators fail to support their own Health Ministers and the expertise of the World Health Organization.

Globally, infant formula is, far and above, the least safe food based on its contribution to fatal acute illness. This is especially true in Low- and Middle-Income Countries. Outbreaks and sporadic cases of infection due to *Salmonella*, *Cronobacter*, *Klebsiella*, and possibly other contaminants in powdered infant formula are likely to be under-reported.[105] Regulators worldwide have exhibited exceptional forbearance in restricting the marketing of breastmilk substitutes, especially powdered infant formula: more regulatory safeguards than the United States, but far from robust implementation of model interventions. It is possible that the risk is similar in High-Income and Low-Income countries, but children are saved where access to comprehensive health care services is better.

The Food and Drug Administration, National Institutes of Health, Centres for Disease Control and Prevention, or National Academy of Medicine could conduct or commission a scientific review to help quantitatively disaggregate the relative contributions of various likely causal pathways for harm caused by sub-optimal breastfeeding to help parents better assess risks and better assess their ability to apply the available, partially effective mitigation strategies. WHO's guidance for reconstituting powered infant formula and government-mandated guidance to the public in our two countries is overdue for revision and vital to help curb the risk of intrinsic contamination by powdered infant formula.

To meet public health objectives related to breastfeeding, the sale and consumption of breastmilk substitutes need to fall sharply which curbing advertising and promotion is expected to help achieve. Children must be better served by:

(1) fully implementing WHO guidance on marketing breastmilk substitute (banning advertising and promotions) and prosecuting violations of national laws commensurate with the risk of harm to infants;
(2) mandating comprehensive risk-warnings and safe preparation instruction on labels;
(3) establishing better protocols for microbiological inspection of infant formula in factories and clinical laboratory detection in infected children;
(4) conducting research to disaggregate the causes death attributed to sub-optimal breastfeeding in the United States and internationally; and
(5) investigating the extent to which implementation and enforcement lapses are causes by undue influence of formula companies in public policy reform.

Taking these steps should be a calling of the highest order of child- and health-protection advocates and appears to be consistent with the stated views of all members of the World Health Assembly and the Make America Healthy Again initiative. The political will that seems to be reflected in the MAHA initiative and the advice of several of the independent members of the Expert Advisory Committee

Respectfully submitted,

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Attached:
Appendix I—Joint statement on infant nutrition endorsed by 35 organizations and issue experts
Appendix II—Brief on Human rights risks of commercializing the market for human milk

ENDNOTES

[1] The Centre for Health Science and Law provided technical assistance on implementing the WHO *International Code of Marketing of Breast-milk Substitutes* to approximately 10 countries and intergovernmental organizations in Africa 2018-2022 through UNICEF. This work involved intensive *Code* training by UNICEF in its New York headquarters in 2018 and by WHO and UNICEF in Johannesburg, South Africa in 2019. CHSL was a founding member of the Geneva Global Health Hub (G2H2) and a member of the International Association of Consumer Food Organizations. CHSL is one of the few health-focused Canadian NGOs accredited by the UN Economic and Social Council (ECOSOC). I have been personally active in international standard-setting advocacy and expert deliberations at the Codex Alimentarius Commissions (since 1998), World Health Organization (since 2005), UN General Assembly (since 2011), and several UN Human Rights Council committees and working groups (since 2018). In Canada, CHSL and its predecessor (the Canadian operations of the Center for Science in the Public Interest) have advocated nutrition labelling reforms, advertising restrictions, sodium reduction measures, a ban on trans fat, and a national, publicly funded school food program. I served as one of five voting members of the International Development Law Organization's "Healthy Diets and Human Rights Research Initiative Advisory Board along with a former Special Rapporteur on the Right to Food, current Executive Secretary of the UN Nutrition Committee, and *ex officio* representatives of UNICEF, WHO, and the UN Food and Agriculture Organization. I also served on a Justice Canada external advisory committee on the development of its Child Rights Impact Assessment tool that was announced in July 2023. CHSL contributed to the 2018-2022 child rights review of Canada by the UN Human Rights Council's Committee on the Rights of the Child.

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[4] The higher death rate is likely partly attributable to fragile health care infrastructure to treat infections before they become life-threatening, poor access to safe drinking water, and other disadvantages of poverty. For instance, the Cost of Not Breastfeeding Tool estimates that of approximately 600,000 deaths of children worldwide, 256,000 occur in Sub-Saharan Africa. According to the Cost of Not Breastfeeding Tool, suboptimal breastfeeding in Mexico is estimated to cause the deaths of 1,742 infants and young children due to acute infections and the deaths of 3,761 mothers due to chronic illness of later in life. Though now hosted at a Canadian NGO, the tool provides no data for Canada. See: Alive and Thrive Cost of Not breastfeeding Tool housed at Nutrition International in Ottawa, Canada. Available at: https://www.nutritionintl.org/learning-resource/the-cost-of-not-breastfeeding-tool/

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[10] Lai, K. K. 2001. *Enterobacter sakazakii* infections among neonates, infants, children, and adults—case reports and a review of the literature. Medicine 80:113–122.

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Available at: https://www.who.int/healthinfo/global_burden_disease/GlobalHealthRisks_report_full.pdf

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Diseases Journal – CDC. Importantly, though the principal author was Dr. Strysko is an Epidemic Intelligence Service Officer in the Waterborne Disease Prevention Branch, Division of Foodborne, Waterborne, and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases, CDC, Atlanta, Georgia, USA. His primary research interests are neonatal infections and waterborne diseases.

[94] UNICEF/WHO/IBFAN *2020 Status Report on the National Implementation of the Code of Marketing of Breast-milk Substitutes.* (New York: UNICEF, 2020); and The *International Code of Marketing of Breast-milk Substitute*, adopted by the World Health Assembly in 1981 by a vote of 118 to 1 (the United States dissenting). Available at: https://www.who.int/nutrition/publications/code_english.pdf) and supported and elaborated by 18 subsequent resolutions in the subsequent four decades, available here: https://www.who.int/nutrition/netcode/resolutions/en/)

[95] Joint FAO/WHO Technical Meeting on Enterobacter sakazakii and Salmonella Powdered Infant Formula (2006: Rome, Italy) at 43. Available at: http://www.fao.org/3/a0707e/a0707e.pdf See also: Fang T, Gurtler JB, Huang L. Growth kinetics and model comparison of Cronobacter sakazakii in reconstituted powdered infant formula. J Food Sci. 2012 Sep;77(9):E247-55. doi: 10.1111/j.1750-3841.2012.02873.x. Epub 2012 Aug 17. PMID: 22900603.

[96] US FDA. Handling Infant Formula Safely: What You Need to Know. (Silver Spring, Maryland: FDA). Accessed Sept 10, 2025 at: https://www.fda.gov/food/buy-store-serve-safe-food/handling-infant-formula-safely-what-you-need-know

[97] See: https://www.translated.nestlebaby.ca/en/baby-formula-preparing-and-storing

[98] The 63rd World Health Assembly in 2010 passed resolution 63.23 that urges Member States, in part:

> *to end the inappropriate promotion of food for infants and young children and to ensure that nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for, in relevant Codex Alimentarius standards or national legislation.*

[99] Joint FAO/WHO Technical Meeting on Enterobacter sakazakii and Salmonella Powdered Infant Formula (2006: Rome, Italy), Appendix D at page 89. Available at: http://www.fao.org/3/a0707e/a0707e.pdf

[100] UNICEF and South African Ministry of Health. *Final Draft Report: Report on the Study to Assess the Effect of Preparation Environment on the Microbiological Safety of Reconstituted Infant Formulae in Selected Public Hospitals and The Effect of Water Temperature on the Nutritional Quality of Reconstituted Formulae – South Africa.* Johannesburg: MOH, 2009 at 20 and 55.

[101] See: Wikipedia entry for "scalding": https://en.wikipedia.org/wiki/Scalding#:~:text=Scalding%20is%20a%20form%20of,Latin%20word%20calidus%2C%20meaning%20hot

[102] UNICEF/WHO/IBFAN Marketing of breast-milk substitutes: national implementation of the international code, status report 2022 . (New York: UNICEF, 2022). Available at: https://apps.who.int/iris/rest/bitstreams/1423442/retrieve

[103] See: https://fortune.com/ranking/global500/ and https://data.worldbank.org/indicator/NY.GDP.MKTP.CD

[104] See: https://www.who.int/teams/nutrition-and-food-safety/food-and-nutrition-actions-in-health-systems/code-and-subsequent-resolutions

[105] WHO. HIV and infant feeding: framework for priority action. Geneva: World Health Organization, 2003. HIV and Infant Feeding: New Evidence and Programmatic Experience (Report of the Technical Consultation, Geneva, Switzerland, 25-27 October 2006, held on behalf of the interagency task team (IATT) on preventing HIV infection in pregnant women, mothers and their infants (2007) at 2.

Appendix II
Human rights risks of commercializing the market for human milk

Producing human milk for a commercial market typically means that a new mother deprives her own infant to sell their own human breastmilk for a price that would be presumably higher than the prices of purchasing powdered infant formula needed to substitute, though the purchase price of the pooled human breastmilk would be manyfold higher for the end consumer. The new regulatory category creates financial incentives for mothers to put their own infants at risk and produces a product that would be priced at a level that is far too expensive for most families to afford. The sole source of nutrition for an infant's first six months of life is hugely consequential and the well-documented potential health risks of intrinsic contamination of powdered infant formula indicate a very real risk of severe illness or death due to sub-optimal breastfeeding.

The commercialization of human breast milk raises ethical and human rights concerns, including foreseeable risk of:

1) exploitation of financial disadvantaged women and children,

2) adequacy of informed consent for "donors" whose own infant are deprived of mother's milk,

3) accessibility of human milk to infants most in need, and

4) health and safety. Furthermore, some for-profit human milk companies are using marketing practices used by breastmilk substitutes companies that the World Health Organization (WHO) guidance warns against.[1]

Demand for human milk is increasing worldwide, especially in developed countries.[2] Financially vulnerable mothers may feel financial pressure to sell their milk thereby depriving their own babies and exposing their babies and themselves to the health hazards of suboptimal breastfeeding.[3] Therefore, is it likely for-profit human milk companies will target those women in lower-income communities who are more willing to sell their milk for money, rather than purchase pre-existing excess supplies (which would be less exploitative).[4]

Efforts to prevent the exploitation of vulnerable women and infants caused the government of Cambodia to ban the collection and commercial sale of human breast milk.[5] Ambrosia Labs is a US-based company that was purchasing milk from Cambodian women and selling it in the US.[6] The women were paid US$0.64 an ounce, while Ambrosia was selling the milk for US$4 an ounce. Cambodian public health authorities closed the operation, stating the commercialization of breast milk was undermining local children's nutrition as well as violating the *Law on the Management of Donation Transplantations of Cell Tissues and Human Organs*.[7] UNICEF described the sale of breastmilk from Cambodian women to Ambrosia as exploitation.[8] Low-income marginalized

groups are targeted in developed countries as well; for example, Oregon-based Medolac Laboratories launched a campaign to purchase breastmilk specifically from African-American mothers in Detroit, Michigan. After much public protest, Medolac stopped their campaign.[9]

The 10 WHO *Principles for promoting ethical practices in the donation and management of medical products of human origin* warns against exploitation, urging governments to prohibit financial rewards for human milk exchange and exploiting economically disadvantages "donors" with Principle 5 stating:

> *Policies governing compensation to persons who provide biological materials for use as medical products of human origin should seek to guard against the exploitation of vulnerable individuals and promote equity in donation. The best way to achieve these goals is to adhere to a policy of financial neutrality, in which persons who donate their biological materials for use as medical products of human origin should neither benefit nor lose financially as a result of the donation. Countries should ensure that the burden of donating these materials does not fall primarily on economically disadvantaged groups.*[10] [Emphasis added.]

Even if women nominally consent to sell their breastmilk, this does not mean the sale of human milk by intermediaries for profit is not exploitative. While the health risks of suboptimal breastfeeding to Canadian women and children have not been specifically quantified, it is likely that they are more than trivial. Properly quantifying and describing the risks of sub-optimal breastfeeding in relatable terms to "donor" mothers and infants is essential for informed consent. Likewise, the manner in which the donor milk is distributed is relevant to information consent; for instance, a mother might be more inclined to contribute her baby's milk if she knew that it would used to feed triaged, health-compromised pre-term orphaned infants than if it were sold to the highest bidder among mothers of healthy full-term infants. Furthermore, especially given the 525% price markup mentioned above, informed consent by "donor" mothers might require transparency about pricing and costs.

The structural inequalities and power imbalances raise concerns of gendered exploitation and the commodification of women's bodies. While Canada is a developed country, the commercialization of human milk as a practice can still exploit women and deprive children of their mother's milk, whether locally or internationally. Policy development regarding the sale of human milk in Canada must include a focus on women's rights and exploitation prevention. Parliament passed a government bill introduced by the current government to reduce poverty by 50% by 2030.[11] While compensating low-income new mothers for selling their breastmilk milk (presumably substantially more than $US4 an ounce and more than the cost of formula) might make a tiny contribution to poverty-reduction, it seems unconscionable. Will Health Canada's proposal transform Canada into a major importer of human milk from developing countries? In their paper entitled "A very lucrative liquid: the emerging trade in human milk as a form of reproductive exploitation and violence against women**,**" human rights scholars Steele and Hernadez-Salazar explore the potential moral hazard of impoverished women being trafficked for the harvesting of their breastmilk, characterizing this practice as analogous to organ trafficking but distinguished by being exclusively exploitive of women and young children.[12]

A survey conducted by Shenker et al, found for-profit human milk companies used marketing strategies traditionally associated with breastmilk substitute companies that WHO guidance considers to be unethical and recommends be prohibited by law. These practices include: "heavily

marketing their products into both private and state neonatal units (India, the United Kingdom, the United States, and Germany), providing funding for conferences and travel/hospitality for health care professionals (the United States and the United Kingdom), offering products to health care professionals with initial discounts (the United Kingdom and the United States)…and offering gifts to parents (Philippines and Myanmar)."[13] Donor human milk banks cannot compete financially with these for-profit companies' marketing budgets.

The Shenker et al article states, "Both PMCs (For-Profit Milk Companies) and nonprofit HMBs (Human Milk Banks) are using their social media channels to engage with and recruit prospective milk providers/donors, with no significant differences identified in the way both types of organizations interact with parents…" though there is some regional variability.[14]

The commercialization and marketing of human milk can also impact breastfeeding perceptions.[15] While mother's own milk is healthier for their infants (as pasteurised human milk can diminish or destroy immunologically active agents, growth factors, and probiotic species), a mother may be discouraged from breastfeeding if she falsely believes pasteurised human milk is equal to her milk.[16] Canadian regulations should protect, support and promote breastfeeding—not undermine it—while prioritizing the health and human rights of mothers and infants, not the financial gain of pro-profit corporations.[17]

Unlike for any other food or period of a consumer's life, substituting (typically) milk-based infant formula for human breastmilk is a dramatic, complete, and largely irreversible change in diet until the child's diet begins to diversify with the addition of whole foods at age six months. Suboptimal breastfeeding contributes heavily to acute illness and death (especially pneumonia and severe diarrhea) as well as lifelong noncommunicable disease, especially cognitive impairment and stunting.

Properly apprising mothers and other caregivers of the benefits of breastfeeding and risks of formula feeding is also conducive fulfilling many SDG Goals, especially and namely: #1 (no poverty), #2 (zero hunger), #3 (good health and well-being), #4 (quality education), #8 (decent work and economic growth), #12 (responsible consumption and production), and #13 (climate action). Breastfeeding instead of formula feeding is also conducive to pursuing the broad food system goals of reducing irresponsible uses of antimicrobials in cattle (the source of formula's main ingredient) and reducing food waste.

Endnotes

[1] N. Shenker et al. Comparison between the for-profit human milk industry and nonprofit human milk banking: Time for regulation? *Matern Child Nutr*. 2024 Jan;20(1):e13570 at 1. doi: 10.1111/mcn.13570. Epub 2023 Oct 13. PMID: 37830377; PMCID: PMC10749996. Available at: https://pubmed.ncbi.nlm.nih.gov/37830377/

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[11] Poverty Reduction Act S.C. 2019, c. 29, s. 315. Available at: https://laws-lois.justice.gc.ca/PDF/P-16.81.pdf

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[13] N. Shenker et al. Comparison between the for-profit human milk industry and nonprofit human milk banking: Time for regulation? *Matern Child Nutr*. 2024 Jan;20(1):e13570. doi: 10.1111/mcn.13570. Epub 2023 Oct 13. PMID: 37830377; PMCID: PMC10749996. Available at: https://pubmed.ncbi.nlm.nih.gov/37830377/ (page 8)

[14] *Ibid*, at 8.

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Hon. Mark Holland, PC, MP, Minister of Health
Brooke Claxton Building, Tunney's Pasture
Ottawa, Ontario, K1A 0K9 Postal Locator: 0906C
By email to: hcminister.ministresc@canada.ca

25 February 2024

Re: In response to Health Canada's proposal to "modernize" Divisions 24 & 25 of the Food and Drug Regulations, please take careful steps to fully implement the World Health Organization's (WHO) International Code of Marketing of Breast-milk Substitutes into Canadian law to:

1) protect the health of Canadian babies, infants, and their mothers,
2) prohibit inherently exploitative marketing practices, and
3) honour international human rights commitments.

Dear Minister Holland,

Please consider the following recommendations for protecting, promoting, and supporting breastfeeding in Canada

A. Canada has a duty to nationally implement the WHO advice to restrict the commercial advertising and promotion of breast-milk substitutes (formula) and products that come under the scope of the WHO *International Code of Marketing of Breast-milk Substitutes*.

We commend the government of Canada for expressly recognizing the importance of the WHO's *International Code of Marketing of Breast-milk Substitutes* and relevant subsequent World Health Assembly resolutions (hereafter referred to as the *WHO Code*) and its duty to implement the WHO *Code* within Canada's borders (and prohibit "cross-promotion," a specific form of advertising). The November 28, 2023 65-page proposal states:

> *The World Health Organization established the* International Code of Marketing of Breastmilk Substitutes[Reference8] *...to ensure the provision of safe and adequate nutrition for infants by protecting and promoting breastfeeding, while regulating the appropriate use of human milk substitutes*[Reference9], [See note[1]] *when necessary, through responsible marketing and distribution practices. As a signatory*[2] *of the WHO Code, Canada has an obligation to support and promote breastfeeding, facilitate breastfeeding by mothers through legislative and social action, and prevent inappropriate sales promotion of infant foods that can be used to replace human milk. However, the [Food and Drug Regulations] does [sic] not reflect the recommendations outlined in the WHO Code, particularly regarding the restriction of advertising or other forms of promotion, as well as the requirement to label human milk substitutes to provide the necessary information on the appropriate use of the product to not discourage breastfeeding.* [emphasis added]

B. The health risks of sub-optimal breast-feeding for infants and mothers in Canada are serious and likely underestimated.

The WHO recommends exclusive breastfeeding of infants until six months and (partial) breastfeeding until 24 months or beyond. The authors of the 2016 Lancet journal series on breastfeeding assumed that optimal breastfeeding in the global population would be reached when

95% of children younger than one month, 90% of those younger than 6 months would be exclusively breastfed, and 90% of those aged 6–23 months would be partly breastfed. Against that standard, sub-optimal breastfeeding causes the death of an estimated 823,000 infants of young children annually worldwide, mainly due to pneumonia and severe diarrhoea in the first six months. Sub-optimal breastfeeding is also estimated to cause the death of at least 20,000 mothers annually due to an increased risk of breast cancer, based on a 2016 estimate by a Lancet Commission[3] (a panel of experts selected by a world-leading medical journal) and an estimated 100,000 deaths of mothers annually due to breast and ovarian cancers, as well as cardiovascular, and metabolic disease.[4] Persisting concerns about the influence of such marketing were repeated in a February 2023 paper series in *The Lancet*.[5]

Globally, the number of infant and young child deaths is nearly double the 420,000 deaths[6] attributed to all other causes of food poisoning among people of all ages. There is a perception that annual formula-feeding-related infant deaths are near zero and rare in Canada thanks to mitigating impacts of medical care, clean water and other trappings of wealth; however, the Public Health Agency of Canada estimates that 238 annual deaths of adults and older child in Canada are caused by food poisoning from all foods, which indicates that infant food poisoning (among the annual 1,700 infant deaths from all causes,) are probably also not completely prevented in Canada by clean water, accessible healthcare, etc.[7] The first year of life appears both dangerous and under-examined. There is robust evidence that optimal breastfeeding also increases intelligence and reduces the risks of gastrointestinal and respiratory illness, otitis media infections in young children, other childhood infections, malocclusion (dental misalignment), and probably reduces the risks of overweight and diabetes, and protects against ovarian cancer and type 2 diabetes in nursing mothers.[8]

C. The November 2023 proposal still falls far short of fully implementing WHO advice.

According to WHO's biennial global surveys, Canada is tied for last place in the extent to which it has implemented WHO guidance on the marketing of breastmilk substitutes along with five of 37 other OECD countries.[9]

Health Canada was right in declaring that Canada is bound to implement the WHO *Code*, but the 64-page proposal revealed very little effort to actually do so, for instance:

1. **Canada must ban all advertising and promotion of breast milk substitutes and all products that come under the scope of the *Code* (especially considering WHO's recent guidance on the digital marketing of breastmilk substitutes) and effectively promote and support breastfeeding and optimal infant and young child feeding.** The proposal contains no blanket proposal to ban advertising and promotions of breastmilk substitutes and related products, only partial restrictions in narrow circumstances. Parliament has given the Governor-in-Council broad powers to make labelling regulations to:

   > *"to prevent the purchaser or consumer thereof from being deceived or misled in respect of the…performance,…merit or safety thereof, or to prevent injury to the health of the purchaser or consumer;,…*[10]

   For example, the European Union banned nearly all direct-to-consumer advertising of breastmilk substitutes with a narrow loophole for scientific and (ambiguously characterized) "baby care" publications.[11]

2. ***Comprehensively*** **implement the WHO *International Code of Marketing of Breast-milk Substitutes* and subsequent relevant WHA resolutions.** The WHO *Code* recommends many measures which the Government of Canada has reconfirmed approximately every two years at World Health Assembly meetings in Geneva since 1981. Health Canada should identify each measure then either include it in the next iterations of its proposal, or explain why it is necessary in all other countries, but not Canada. Canadian mothers and children need this protection. Specifically codify the primacy of the best interests of the child in interpreting these regulations.
3. **Mandate blunt warnings of formula-feeding risks on labels.** Mandate unvarnished warnings of the risk of pathogens (including *Cronobacter sakazakii*, ***especially*** in powdered infant formula) that can cause meningitis, necrotizing enterocolitis, sepsis, and potentially fatal diarrhoea and pneumonia. Require preparation instructions to effectively kill such ubiquitous microbial contaminants and require that such information be highlighted in larger font and bold-red caps commensurate with their importance for informed choice and risk mitigation. Such guidance is stressed in section 4.2 of the WHO *Code* and is consistent with the Supreme Court of Canada's explanation of manufacturers' general duty to warn.[12]
4. **Recognize the challenges in detecting harmful pathogens in powdered formula with standard laboratory techniques.** The proposal does not recognize the inadequacies of laboratory sampling techniques for detecting pathogens, especially *Cronobacter* species, in powdered formula. Former United States Food and Drug Administration Deputy Commissioner Yiannas indicated that *Cronobacter* is distributed heterogeneously in powdered formula and testing samples are so small, *"the probability of them finding contamination is virtually zero…"*[13] and that it is only mandatory in two of 50 U.S. states to report *Cronobacter* contaminations in food to the Centers for Disease Control which likely contributes to understating this risk.[14]
5. **Define and operationalize "conflict of interest" safeguards in the regulations.** The proposal makes no effort to recognize and operationalize conflict-of-interest safeguards to put firewalls around researchers, health care workers, child protection workers, and policy-makers and to flag this issue for university ethics committees as WHO guidance clearly urges.[15] For instance, the Ethiopian regulations include the following definition:

   > *"conflict of interest" means a situation where there is a risk that a secondary interest of an organization or individual could influence, or could be perceived to influence, the independence, objectivity of professional judgement, or actions regarding the primary interest to protect the best interest of the child or undermine public trust in those individuals, organizations and their guidance and activities;"* **(See: *Baby Food Control Directive 840 2021*)**

   The proposal describes meetings with unnamed industry associations in 2018 and a 2017 meeting of the University of Toronto Program in Food Safety, Nutrition and Regulatory Affairs which is funded by two of the world's largest formula manufacturers–Nestlé and Danone–among other food companies with interests in weak food advertising limits.
6. **Ensure that at-risk infants have optimum access to a safe supply of human milk through non-profit banks while ensuring that the human rights of recipients, donors and the infant children of donors are fully respected.** The proposal contains a surprise initiative to create a commercial market for human breastmilk without recognizing or proposing measures to mitigate the human rights abuses foreseeably resulting from a system that would tend to pay low-income women to sell their breast milk to for-profit companies (and deprive their children) for purchase by high-income mothers that can afford to pay for it.

7. **Ensure preparation instructions for powdered infant formula is reconstituted with water heated to at least 70º Celsius to kill harmful pathogens.** Instructions for preparing formula are routinely designed to use 40ºC water (approximately body temperature) or boiling water cooled for 30 minutes at room temperature (which produces the same result) which is far too cool to kill harmful pathogens that are commonly found in powdered infant formula, such as lethal *Cronobacter* bacteria.[16] Both types of flawed advice are repeated at the proposal on page 21 (section 4.1.3 (ii)(3)).
8. **Promote and incentivise provincial government efforts to protect, support, and promote breastfeeding.** Identify novel ways to provide national guidance on WHO *Code* implementation efforts that are generally within provincial jurisdiction, such as tying federal healthcare funding and oversight to the certification and monitoring of Baby Friendly Hospitals, public health units, and community health centres, and publishing model breastfeeding guidance instructions that require new-parent education to disclose whether the host facility is certified as baby-friendly.
9. **Establish a Standing Independent Expert Committee to Protect Breastfeeding.** Establish a national standing oversight committee, free of conflicts of interest, to advise the Minister of regulatory loopholes and enforcement lapses and to monitor the enforcement of related regulations.
10. **Require warning labels about greenhouse gas (GHG) emissions from applicable milk-based formulas.** A systematic review of research on the impact of breastmilk substitutes on the environment called for policies to protect exclusive breastfeeding and decarbonize infant formula.[17] Oxford University researchers found that GHG emissions from meat and other animal-origin foods are vastly higher than plant-based foods.[18] Recently, researchers illustrated a methodology for estimating GHG emissions for infant formula in Canada, Mexico and the United States,[19] and an international team announced the ongoing development of a Green Feeding Tool for making such calculations on a country-by-country basis.[20] Others called on the Word Health Organization to lead an effort to mandate warnings on products like infant formula that disproportionately contribute to climate change which WHO calls a "Public Health Emergency of International Concern."[21] Canadian regulations should mandate warnings, where applicable, that "This product is made of milk from ruminant animals (cows, sheep, or goats) which is a major source of climate-warming greenhouse gas." Parliament has given the government broad powers in sub-paragraph 30(b.01)(i) of the *Food and Drugs Act* to make regulations on labelling and advertising:

> *"for the purposes of managing risks to the environment"*[22]

11. **Ensure enforcement and compliance measures are commensurate with the risk and the importance of child protection.** Violations of regulations restricting the marketing of breast-milk substitutes should be prosecuted diligently. Simply serving unpublished warning letters to companies that breach regulations (without penalties) is not consistent with the rule of law or health protection. Establish a federal breastfeeding-protection government contact point to support the proposed Standing Independent Expert Committee to Protect Breastfeeding, oversee the monitoring of Baby-Friendly Hospital Initiative designations, and facilitate transparency to the public.

12. **Apply the Justice Canada "Child-Rights Impact Assessment Tool" to develop the next draft of the proposal and consult health groups, not just industry groups.** Canada has taken the important step of developing a child rights impact assessment tool and online course to help ensure that future regulatory and program decisions respect children's rights, though it is not (yet) mandatory, like gender-sensitive budgeting (federally) and environmental impact assessments. Please especially consider children's rights in relation to the proposal and the potential human-rights abuses of a commercial trade in human breast milk by using this tool in future iterations of this proposal.

Randi Leanne Parsons, RN, BScN, Co-Chair
Breastfeeding Committee for Canada

[signature forthcoming or protected]
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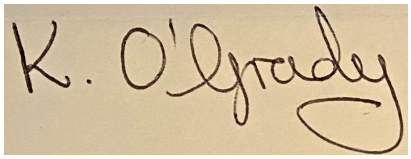

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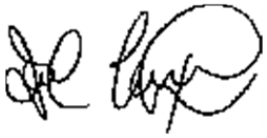

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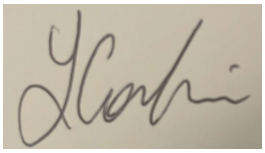

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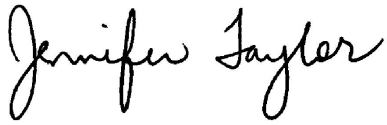

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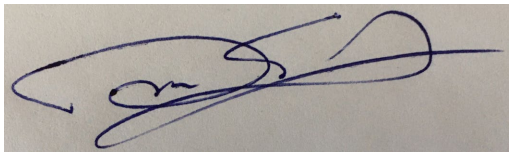

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ENDNOTES

[1] There was no update in 2017, though there have been 21 World Health Assembly resolutions to reinforce and particularize the Code guidance since it was adopted in 1981, all of which were supported by the Government of Canada. See: https://www.who.int/teams/nutrition-and-food-safety/food-and-nutrition-actions-in-health-systems/code-and-subsequent-resolutions

[2] The *Code* was adopted by vote in 1981 with only one opposed (the United States of America, the source of nearly all infant formula consumed in Canada. Canada voted in favour of the *Code* in 1981 and has not objected to the subsequent relevant resolutions adopted approximately biannually by the World Health Assembly in Geneva. The Code also addresses baby feeding bottles and other items used and advertised to undermine breastfeeding.

[3] Cesar G Victora, Rajiv Bahl, et al. for The Lancet Breastfeeding Series Group. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effects. *The Lancet*. Vol 387 January 30, 2016, Available at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)01024-7/fulltext estimated that 823,000 children die from suboptimal breastfeeding.

[4] Walters DD, Phan LTH, Mathisen R. The cost of not breastfeeding: global results from a new tool. *Health Policy and Planning*. 2019 Jul 1;34(6):407-417. doi: 10.1093/heapol/czz050. PMID: 31236559; PMCID: PMC6735804. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6735804/pdf/czz050.pdf

[5] Especially, Breastfeeding 1: Pérez-Escamilla R, Tomori C, Hernández-Cordero S, Baker P, Barros AJD, Bégin F, Chapman DJ, Grummer-Strawn LM, McCoy D, Menon P, Ribeiro Neves PA, Piwoz E, Rollins N, Victora CG, Richter L; 2023 Lancet Breastfeeding Series Group. Breastfeeding: crucially important, but increasingly challenged in a market-driven world. *The Lancet*. 2023 Feb 11;401(10375):472-485. doi: 10.1016/S0140-6736(22)01932-8. Epub 2023 Feb 7. Erratum in: *The Lancet*. 2023 Mar 18;401(10380):916. PMID: 36764313; and

Breastfeeding 2: Rollins N, Piwoz E, Baker P, Kingston G, Mabaso KM, McCoy D, Ribeiro Neves PA, Pérez-Escamilla R, Richter L, Russ K, Sen G, Tomori C, Victora CG, Zambrano P, Hastings G; 2023 Lancet Breastfeeding Series Group. Marketing of commercial milk formula: a system to capture parents, communities, science, and policy. *The Lancet*. 2023 Feb 11;401(10375):486-502. doi: 10.1016/S0140-6736(22)01931-6. Epub 2023 Feb 7. PMID: 36764314.

[6] Hoffmann S, Devleesschauwer B, Aspinall W, Cooke R, Corrigan T, Havelaar A, Angulo F, Gibb H, Kirk M, Lake R, Speybroeck N, Torgerson P, Hald T. Attribution of global foodborne disease to specific foods: Findings from a World Health Organization structured expert elicitation. *Public Library of Science One*. 2017 Sep 14;12(9):e0183641. doi: 18 | Page 10.1371/journal.pone.0183641. PMID: 28910293; PMCID: PMC5598938. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5598938/pdf/pone.0183641.pdf

[7] M. Kate Thomas, Regan Murray, Logan Flockhart, Katarina Pintar, Aamir Fazil, Andrea Nesbitt,1 Barbara Marshall,1 Joanne Tataryn, and Frank Pollari, Estimates of Foodborne Illness–Related Hospitalizations and Deaths in Canada for 30 Specified Pathogens and Unspecified Agents. *Foodborne Pathogens and Disease*. Volume 12, Number 10, 2015 DOI: 10.1089/fpd.2015.1966; Supplementary Table S1: Estimation and Uncertainty Model Inputs for 30 Major Know Pathogens and Unspecified Agents Transmitted Through Food. Available at: https://www.liebertpub.com/doi/10.1089/fpd.2015.1966 at page 824.

[8] Cesar G Victora, Rajiv Bahl, et al. for The Lancet Breastfeeding Series Group. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effects. *The Lancet*. Vol 387 January 30, 2016, Available at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)01024-7/fulltext estimated that 823,000 children die from suboptimal breastfeeding.

[9] UNICEF/WHO/IBFAN *Marketing of breast-milk substitutes: national implementation of the international Code, status report 2022*. (New York: UNICEF, 2022). Available at: https://apps.who.int/iris/rest/bitstreams/1423442/retrieve The others are the United States, Australia, Israel, Japan, and New Zealand.

[10] *Food and Drugs Act* (R.S.C., 1985, c. F-27). Available at: https://laws-lois.justice.gc.ca/eng/acts/F-27/page-5.html#h-234432

[11] European Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding states:

> *Article 10*
> ***Requirements for promotional and commercial practices for infant formula***
> *1. Advertising of infant formula shall be restricted to publications specialising in baby care and scientific publications.*
> *Member States may further restrict or prohibit such advertising. Such advertising shall contain only information of a scientific and factual nature. Such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breast feeding.*
> *2. There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formula directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.*
> *3. Manufacturers and distributors of infant formula shall not provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts, either directly or indirectly via the health care system or health workers.*
> *4. Donations or low-price sales of supplies of infant formula to institutions or organisations, whether for use in the institutions or for distribution outside them, shall only be used by or distributed for infants who have to be fed on infant formula and only for as long as required by such infants.*

See also regulation preamble recital 23. Available at: https://eur-lex.europa.eu/eli/reg_del/2016/127/oj

[12] The Supreme Court of Canada ruled, in *Hollis* v. *Dow Corning Corp*:

> *A manufacturer of a product has a duty in tort to warn consumers of dangers it knows or ought to know are inherent in the product's use. This duty is a continuing one, requiring manufacturers to warn not only of dangers known at the time of sale, but also of dangers discovered after the product has been sold and delivered. All warnings must be reasonably communicated, and must clearly describe any specific dangers that arise from the ordinary use of the product. The duty to warn serves to correct the knowledge imbalance between manufacturers and consumers by alerting consumers to any dangers and allowing them to make informed decisions concerning the safe use of the product.*

See: *Hollis* v. *Dow Corning Corp*., 1995 (Supreme Court of Canada), [1995] 4 SCR 634. Available at: https://canlii.ca/t/1frdr

[13] United States Congressional House Committee on Oversight and Accountability. FDA Oversight Part I: The Infant Formula Shortage, March 28, 2023 at time 40-44, 56-58 and 1:23-1:1:24. Available at: https://oversight.house.gov/hearing/fda-oversight-part-i-the-infant-formula-shortage/ and in writing at: https://oversight.house.gov/wp-content/uploads/2023/03/Yiannas-Testimony_-House-Subcomm_March-27-2023.pdf

See also: CHSL Submission re Public consultation on the Draft WHO Global Strategy for Food Safety, with particular reference to powdered infant formula. June 18, 2021 (corrected Nov. 23, 2021). Available at: http://healthscienceandlaw.ca/wp-content/uploads/2021/11/CorrectedNov23-3021.CHSL-Comments.WHO-Draft-Food_safety-Strategy.June18-2021.pdf

[14] *Ibid.*

[15] World Health Assembly, 69. (2016). Maternal, infant, and young child nutrition: guidance on ending the inappropriate promotion of foods for infants and young children: report by the Secretariat. World Health Organization. https://iris.who.int/handle/10665/252656

[16] WHO. How to Prepare Formula for Bottle-Feeding at Home. Geneva: WHO, 2007 at https://www.who.int/foodsafety/publications/micro/PIF_Bottle_en.pdf; Joint FAO/WHO Technical Meeting on Enterobacter sakazakii and Salmonella Powdered Infant Formula (2006: Rome, Italy), at page 43 and Appendix D at page 89. Available at: http://www.fao.org/3/a0707e/a0707e.pdf ; Fang T, Gurtler JB, Huang L. Growth kinetics and model comparison of Cronobacter sakazakii in reconstituted powdered infant formula. J Food Sci. 2012 Sep;77(9):E247-55. doi: 10.1111/j.1750-3841.2012.02873.x. Epub 2012 Aug 17. PMID: 22900603. 69 See: https://www.translated.nestlebaby.ca/en/baby-formula-preparing-and-storing

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[22] *Food and Drugs Act* (R.S.C., 1985, c. F-27). Available at: https://laws-lois.justice.gc.ca/eng/acts/F-27/page-5.html#h-234432