

Breastfeeding vs Infant Formula Controversy

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Abstract

A longstanding issue has been the aggressive advocating of infant formula and the downplaying of breastfeeding within industrialized nations. Unlike bottled formula, powdered infant formula is not sterilized. Microorganisms can potentially be incorporated into the mixture. The 2022 close-down of Abbott's Sturgis infant formula production plant for unsanitary conditions refocused attention on the question of how safe is infant formula. Pasteurized milk used to produce Infant formula can be adulterated by a bovine mycobacterium, *Mycobacterium avium* subspecies *paratuberculosis* (MAP). If a newborn becomes infected by MAP before its acquired immunity, a dysfunction immune response may be induced which is the catalyst for the later development of Crohn's disease. Current infant formula labels lack the necessary information that would allow mothers to make a fully informed decision about their infants' nutrition.

Keywords: Infant formula, Breastfeeding, Crohn's disease, *Mycobacterium avium* subsp. *paratuberculosis*.

Introduction

In early 2022, Abbott Laboratories infant formula plant at Sturgis, Michigan was ordered shut after regulators found unsanitary conditions. For years, Abbott has been in courts, successfully fighting allegations that infant illnesses and deaths were related to the ingestion of their brand of infant formula. The voluntary closing of the Sturgis plant precipitated a national shortage of infant is infant formula [1]. The crisis precipitated the question, how safe is infant formula? Publications of IBFAN working group on chemical and microbiological contamination of infant feeding products provide insight into the problem list of withdraws and recalls of adulterated products [2,3].

That the U. S. federal government had to subsequently import infant formula on an emergency basis from other countries underlines the perceived importance attributed to the availability of powdered formula within industrialized nations. Infant formulas are more closely crafted on cow milk formulation than breast milk. Compared to breast milk, infant formulas under-provide nicotinic acid, vitamin A, tocopherol, and vitamin B 12. The alleged health benefits attributed to breast feeding include a lower risk for asthma, obesity, type 2 diabetes, sudden death syndrome and ear/respiratory infections Unlike bottled formula, powdered infant formula is not sterilized. Microorganisms can potentially be incorporated into the mixture.

Infant formula production is a 46–70-billion-dollar global industry. To achieve a competitive advantage, companies have experimented with adding ingredients that could be claimed

as conferring a competitive advantage such as the addition of pro- or prebiotics to formulas. As currently constituted many infant formula formulations contain genetically engineered ingredients, particularly human milk oligosaccharide [3].

Mycobacterium avium Subspecies *Paratuberculosis*

Infant formula is not uniformly pathogen free. With active infection By *Mycobacterium avium* subspecies *Paratuberculosis*, milk-producing animals can secrete the organism into their milk [4-6]. Once in milk, MAP is poorly neutralized by pasteurization [4-7]. USDA's failure to address MAP dissemination into uninfected milking herds has resulted in virtually every large dairy herd having a significant number of MAP infected animals [8]. As early as 2005, MAP DNA was detected in 49% of 51 brands of infant formula manufactured in 10 different countries [9]. The presence of MAP in powdered milk and infant formula has been repeatedly confirmed [10-14].

For individuals with intact immunity, MAP is apparently a non-pathogen this is not necessarily so for individuals with significant immune system compromise. Crohn's disease is an immune-mediated disease secondary to a dysfunctional persistence of the immune system's pro-inflammatory response to MAP [15,16]. What has been shown is that Crohn's disease is an immune-mediated disease which is the product of two separate immune system interactions involving *Mycobacterium avium* subspecies *Paratuberculosis* (MAP) [14]. If a newborn is confronted by a meaningful MAP infectious challenge, the baby's inherent immunity may become so stressed in arresting continued *mycobacterium*

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replication that its pro-inflammatory response to MAP becomes fixed within immunological memory. Whenever re-challenged by MAP's presence in milk-based commercial products, the immune system responds by again unleashing a Th1 immune response against MAP at its site of mucosal attachment rather than exhibiting immunological tolerance. The requisite for actual disease is repetitive and concentrated to MAP and its antigenic array interaction with anti-MAP directed cytokines to overwhelm the regenerative capacity of the small bowel gastrointestinal mucosa.

The Hruska Postulate has explained why Crohn's disease is a new disease entity, why it has attained global epidemic status, but only in industrialized nations, why breast feeding confers protection, why the initial lesions involve the ileocecum, why strict vegetarian diets can be curative and why proper understanding of the events that combine to produce disease can preclude the development of strictures, loop-to-loop anastomosis, bowel perforation and fistula formation [16-18].

In many industrialized countries, new mothers on leaving the hospital are given a free case of infant formula which, depending on source of milk, may have been adulterated by MAP. Breastfeeding has been shown to confer relative protection against the future development of Crohn's disease [17-25]. USDA's failure to contain MAP infection in milk-producing herds and the societal shift away from breastfeeding created the global epidemic of Crohn's disease within industrialized nations.

To blunt the global epidemic expansion of Crohn's disease that has afflicted over five million individuals, it is argued that one needs only to encourage initial breastfeeding or use of non-milk based infant formula for the first three to four weeks of life. That such a recommendation may never be advocated in the United States is inferred by the U.S. delegation's actions at the 2021 Geneva meeting of the United Nations-affiliated World Health Assembly. A resolution stating that mother's milk is healthiest for children and countries should strive to limit inaccurate or misleading marketing of breast milk substitute was pending for a vote. The absence of clean water with which powdered infant formula is re-constituted causes an estimated 800,000 newborns to die of water born infections annually. U.S. delegation's opposition to the resolution reputedly stunned world health officials. The International Society of Social Pediatrics and Child Health (ISSOP) condemned" in most robust terms the American officials attempt at the World Health assembly to stop collaboration to protect, promote and support breastmilk feeding" [26]. The U.S. delegation had aggressively pursued removing language that called on governments to "protect, promote and support breast-feeding" and the section that called on nations to restrict the promotion of food products deemed deleterious to infants. Allegedly, the delegation threatened punishing trade measures or withdrawal of military aid if its demands were not listened to [27-30].

In the United States, 80% of infant formula production is almost equally divided between Abbott laboratories and Mead Johnson. Unlike Abbott a laboratory which owns Abbvie,

Mead Johnson's income was derived almost exclusively from its product line. In late 2015 through 2016, Mead Johnson was confronted with the possibility of product liability secondary to samples of its product line containing MAP DNA and the mycobacterium's relationship to Crohn's disease. The Federal Food, Drug and Cosmetic Act (21 U.S.C. 321 et seq.) identifies food as being adulterated "if it bears or contains any poisonous or deleterious substances which may render it injurious to health and is not neutralized by its subsequent processing". Provision 5 of the Federal Meat Inspection Act specifically defines adulterated as "If it contains any added poisonous or other added deleterious ingredient which may render such article injurious to health". Despite the probability of nonenforcement of federal statutes by government agencies and the fiscal resources to drag out litigation for many years, documentation of MAP adulteration within its product line could have compromised Mead Johnson's competitiveness in the global market. In 2016, Mead Johnson suddenly sold itself for 15.1 billion dollars to a foreign conglomerate [31-35].

Given the Federal Meat Inspection Act (21 U.S.C. 601), the Poultry Production Inspection Act (21m U.S.C. 45 et seq.), and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.), which reflect in part The Rio Declaration on Food Safety and The Sanitary and Phytosanitary Measures of the World Health Organization Principle, advocating breast feeding over infant formula should be a matter of U.S. policy. Principle 15 of the Rio Declaration states, "where there are threats of serious or irreversible damage, lacking full knowledge shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation". The World Health Organization Agreement on Sanitary and Phytosanitary Measures, Article 5.7 allows regulatory measures "where relevant scientific evidence is insufficient to demonstrate the safety of a product or commodity".

Conclusion

If governments were able to act in the best interest of the public trust, there would be little real controversy concerning breastfeeding vs infant formula. Breast feeding is recognized as among the most effective health promoting measures to advance infant and child health". The potential for adulteration of infant formula and powdered milk by MAP and MAP having the central role in the induction of the immune-mediated Crohn's disease further create an added imbalance in the debate.

Mothers should have the right to be able to make an informed decision on their infants' nutrition predicated on the best information available. If government agencies are to function in the public trust, a statement that Infant formula has the potential to be adulterated by a zoonotic bovine pathogen which, if ingested before the third or fourth week of life, could cause harm to the baby in the future needs to be on the product label of all milk-based formula packaging.

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