INDEPENDENT WOMEN'S FORUM

*Position Paper*

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# When Population-Wide Politics and Personal Medical Care Collide:

## The Campaign to End Infant Formula in Developing Countries

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### Executive Summary

This paper reviews the available literature on strategies for providing optimal nutrition to newborn babies, with a particular emphasis on the risks and benefits of breastfeeding versus formula feeding in developing regions.

While the available medical literature demonstrates that breastfeeding provides superior nutrition to the majority of infants born to healthy mothers, there are clearly circumstances under which breastfeeding cannot be achieved, or should not be attempted because the benefits would be outweighed by unique risks. In these circumstances, the literature demonstrates that U.S. Food and Drug Administration approved formula products provide superior benefits to other supplemental feeding strategies sometimes employed in developing regions, including the use of fresh cow's milk or starch gruel made of fermented sorghum rice.

However, public health officials have attempted to promote breastfeeding by casting a critical eye toward infant formula, in isolated cases even demonizing the suppliers of formula and arousing suspicion of their motives, in other cases excluding formula products from hospitals and local markets. This strategy may inevitably cause more harm if these practices prompt mothers to prefer breastfeeding when it is clearly not in their newborn's best interest, or worse to opt for other, far less nutritional and safe alternatives to breastfeeding.

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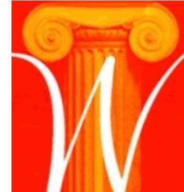
## Introduction

Scientific evidence continues to support breastfeeding as the primary source of newborn nutrition.[1] The role of breastfeeding has been studied especially closely in developing regions, where some of the most persuasive studies have been done demonstrating the benefit of strategies that promote safe breastfeeding. Based on this evidence, the World Health Organization and other non-governmental organizations have adopted strategies to promote breast-feeding and to lessen the role of baby formula. Sometimes, efforts to promote breastfeeding have actively sought to simultaneously make access to formula more difficult while increasing awareness about the benefits of breastfeeding. The World Health Organization and United Nations Children's Fund have even adopted a set of codes governing the promotion of baby formula products in some developing regions, in order to limit the ability of formula manufacturers to promote and distribute their products.

One of these efforts, the International Code of Marketing of Breast Milk Substitutes, was created jointly by the World Health Organization and UNICEF and was adopted in 1981. It was a response to a rise in infant disease around the world that was blamed, in part, to a fall in rates of breast-feeding. In addition to limits on advertising for formula, the rules also prohibit manufacturers of baby formula from providing mothers with free samples of milk powder.

At the same time, groups such as the International Baby Food Action Network, which acts as an official nutritional advisor to the WHO, have taken these efforts one step further, by engaging in more direct and aggressive actions and activist-style campaigns against manufacturers of breast milk. Among other things, they assert that manufacturers of baby formula promote their products in developing nations often at the expense of peoples' health.[2] They have also sought to prohibit formula manufacturers from making charitable donations of infant formula to hospitals in impoverished areas.

In January, in response to these and other efforts, the World Health Organization recommended the adoption of a resolution at the 58th World Health Assembly, which is the WHO's annual meeting, scheduled to take place in mid-May in Geneva. The resolution would call on health officials to take new steps to discourage formula feeding in favor of breast feeding. The immediate objective of the resolution is to compel infant-formula packages to carry warning labels.



Formula milk was intended to save lives when newborn children could not get breast milk, but critics like IBFAN charge that it was marketed for babies in general as infant formula companies sought to expand their sales across the globe for greater profits. Nobody can argue with the basic intention of policies and efforts that are aimed at promoting safe breastfeeding as the best and first choice for women who can provide adequate milk.

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Nor is there any serious dispute about the underlying scientific premise behind these policies: that breastfeeding should be a preferred practice among new mothers, and that the promotion of breast-feeding across a large population will improve the overall health of newborn babies. The science shows these things to be true, and it is incontrovertible. In addition, in developing nations, there are sometimes additional hurdles to using formula milk products, especially dry powder in regions where there may not be sufficiently clean water to use in order to reconstitute these formulas or effective strategies and education on the proper preparation of these compounds.[3] Based on these facts, breastfeeding is clearly a preferred strategy for the majority of women who can provide adequate milk.

But the political promotion of wider breastfeeding has, in some cases, taken a dangerous turn, by ignoring all of the variation that exists across any large population, the challenges new mothers face in developing regions, and the many reasons – some medical, some personal, and some social – that would prompt a minority of mothers to prefer and even require formula feeding for their infants.

When done right, evidence demonstrates that for many women formula feeding carries surmountable tradeoffs, and for some women and their babies, these tradeoffs could outweigh the benefits of breastfeeding. However, broad policies aimed at discouraging formula feeding, instead of instructing new mothers about her range of options and the benefits and tradeoffs associated with each, has the potential to wreak its own public health harm by leaving new mothers ignorant of options that their personal medical and social situations may demand. New mothers may be more likely to pursue breastfeeding even when it is a poorer choice for their babies. Or mothers may feel compelled to pursue formula feeding without the proper education and support that can make such a strategy more successful. Worse, they may reach for

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inferior formula substitutes such as fresh milk or starch gruel made of fermented sorghum rice.

Moreover, women in developed countries went through a period of what can be described as technological consolidation, where for a period of time formula feeding was preferred by many women when returning to work shortly after childbirth became more commonplace. Formula feeding was seen as a way to make this possible. Once workplaces began to accommodate women with extended maternity leaves or resources such as pumping rooms, the preference shifted back in favor of breast-feeding.

In contrast, similar social infrastructures do not yet exist in developing countries. As a result, blanket restrictions on access to formula or policies that discourage and even shame its use, could deny women in developing markets from similar opportunities to continue working through childrearing, until social infrastructures inside local workplaces begin to accommodate these practices, as they have begun to do in the United States and other developed countries. Moreover, women in developed countries have access to electric pumps, bottles, and refrigerators to store breast milk safely when they have to separate from their babies.

The same resources are often unavailable in developing countries. It could even be postulated, although no direct evidence is available, that women in developing regions who are employed in jobs may have better economic means to enable appropriate steps that need to be taken to promote successful formula feeding, such as proper preparation of the formula and access to clean water. To these ends, strategies that promote breast feeding at the exclusion of formula can potentially retard the economic ascendancy of women unless greater attention is given to making sure that breast feeding is promoted in the workplace.

In the next section of this paper we review the contraindications that some women, particularly those living in developing regions, might have to breastfeeding as a primary or sole source of nutrition for their newborns. Certain medical conditions provide the most immediate and profound contraindication, but there are also social and psychological reasons that sometimes inhibit breastfeeding. We will then discuss recent campaigns to promote breastfeeding as the sole source of newborn nutrition in the context of other policies that aim to

promote sweeping and uniform standards for good medical care, and the political, social, and most important medical consequences that these approaches to public health could have.

**Contraindications to Breast Feeding**

Ample medical evidence exists to support the role of breastfeeding as the first and best choice for providing nutrition to infants. The question needs almost no review. The literature is overwhelming and is affirmed by the American Academy of Pediatrics, among many other independent and authoritative medical groups.[4]

But the fact remains that some mothers are not able to breastfeed for various reasons. In such cases, mothers often turn to infant formula, a complex food product, used as the sole source of nourishment during the first four to six months of life.[5]

Because human milk is considered to be the ideal food for term infants, it has served as the model for the composition of formulas. One particularly important issue is the quantity, quality and composition of protein in formula. Although there is no doubt that the protein content of most of the term and preterm infant formulas leads to appropriate growth, the discussion on the type of protein to be used and on the actual protein requirement for both term and preterm infants continues.[6] But the underlying efficacy and safety of formula products are confirmed by rigorous studies and new formula products are subject to rigorous regulation by the Food and Drug Administration.[7]

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Still, some qualities of breast milk cannot be replicated by formula, which is why breast milk is a preferred source of nutrition. For example, it is well known that human milk contains a variety of immunological and anti-inflammatory components that cannot be found in bovine milk and hence in most of the infant formulas.[8] Recently, soluble cell adhesion molecules have been detected in human milk at various stages of lactation. Whether they have a biological function in the infant, e.g., as an anti-inflammatory agent, requires further investigation.[9] Although formulas need not exactly duplicate the composition of human milk, and indeed would require a standard that would be impossible to achieve owing especially to the immunological properties of human milk, formulas must nonetheless meet the FDA's strict nutritional requirements.[10]

While it is generally acknowledged that public health goals as well as personal preferences of many new mothers both argue in favor of the breastfeeding, in some cases, this may not be possible due to environmental, medical, and sociologic factors. This may be especially true in some developing countries, where the medical conditions that would contraindicate breastfeeding may be more prevalent and the availability of some of the nutritional as well as logistical resources that support breastfeeding less commonplace.

For example, in developing nations, many young women are becoming a more integral part of the workforce.[11] This circumstance may make it more difficult for these young mothers to breast feed their newborn children. Among other things, women may have only minimal maternity leave before they are required to return to work, and their workplaces may not have programs and facilities in place to support continued breast feeding. Studies of new mothers in developing nations demonstrate, for example, that work outside the home is the primary barrier to exclusive breastfeeding.[12] This is consistent with the experience in industrialized countries, where work outside the home is also a key barrier to breastfeeding. Numerous studies indicate that women who return to work in the first year postpartum stop breastfeeding sooner than women who do not.[13]

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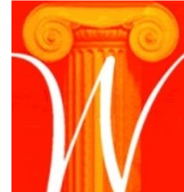
In addition to these practical, economic impediments, there are also many physiologic and medical barriers that prevent mothers who intend to breastfeed from doing so on a continuous basis through the infant's first year. Often these are common medical conditions that occur largely independent of a woman's surroundings or socioeconomic status, although some are related to good hygiene and proper education about breastfeeding, two elements that may be challenging to widely achieve in some developing regions.

Some of these medical conditions can occur with frequency. One fairly common medical condition that disrupts breastfeeding is condition is called nipple bleb, or a nipple blister, where skin overgrowth on the nipple results in a blockage of the milk ducts. A nipple bleb may be persistent and painful, making it almost impossible for a mother to breastfeed her infant. The blisters usually are evident for days to weeks and generally heal if further irritation is eliminated.



Other common conditions that prevent breastfeeding include recurrent mastitis, also commonly described as plugged milk ducts. This is a consequence of irregular breastfeeding, when mothers have a difficult time completing regularly scheduled feedings due to their own commitment problems or problems with the infant's ability to nurse. Cutaneous candidiasis, a yeast infection of the skin, often is also an often-undiagnosed cause of breastfeeding failure. Left untreated, it may result in painful soreness of the area around the nipple, called the areola as well as the breast. This makes it difficult for the mother to continue nursing.

Another issue that could discourage breastfeeding is known or suspected HIV infection of the new mother, and many argue that efforts to promote breastfeeding in a region need to take into account the local epidemiology of HIV infection. Studies have shown that the frequency of breast milk transmission is on the order of about 15 to 20 percent in some randomized clinical studies, and that the majority of infections occur early during breastfeeding.[14] In one study, the use of breast milk substitutes prevented 44% of infant infections.[15] Other studies confirm that the risks of exclusive breastfeeding by HIV positive mothers may outweigh any benefits.[16]

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In fact, some UNICEF recommendations now suggest that women in developing regions who are infected with HIV allow their babies to breastfeed from other women. This carries its own medical risks, including a higher risk of infection in the newborn. But the more common recommendations, that the benefits of breastfeeding, in regions where infection is a serious cause of infant illness and death, outweigh the risks of HIV transmission, has prompted women in several southern African countries to question the veracity of universal breastfeeding recommendation on the grounds that these guidelines fail to provide sufficient information for individual women to assess their own situation and offers no alternatives to HIV-positive mothers in developing countries.[17]

Some of the other physiologic conditions that could inhibit or prevent a mother from being able to safely breastfeed her newborn child are more specific to the difficult social and environmental conditions that new mothers must often confront in many developing countries. T hese include poor nutrition or sanitation, or poor access to the health services that help facilitate safe breastfeeding.

## One Sized Solutions Shortchange Patients

*This drive to compel breastfeeding in developing nations is in keeping with the WHO's approach to other public health solutions, an approach that favors cookie-cutter, one-sized-fits-all policies that are easy to execute and believed to maximize overall health statistics.*

While overwhelming medical evidence demonstrates that breastfeeding is, in most cases, a clearly preferred choice for childhood nutrition, there are sociological and well as physiological circumstances when some women need to primarily formula feed their newborn infants.

In recent years, non-governmental organization, including the World Health Organization, have campaigned against formula feeding in developing nations, and advocated strategies that promote breastfeeding, sometimes with an activist zeal. This drive to compel breastfeeding in developing nations is in keeping with the WHO's approach to other public health solutions, an approach that favors cookie-cutter, one-sized-fits-all policies that are easy to execute and believed to maximize overall health statistics. But the mass adoption of these generic approaches often comes at the predictable expense of a cohort of people who require the benefits of alternative, sometimes specialized strategies.

This is true when it comes to WHO's strategies to promote breastfeeding, as well as other health problems. For example, the same policy spirit and approach to problem-solving was in evidence in the World Health Organization's approach to maximizing its resources available for fighting HIV infection and AIDS in pandemic areas. In the name of easy and widespread execution of a public health program, the WHO accepts the reality that some people are going to suffer the health consequences of adhering to a strategy that it could be predicted, from the outset, that they would fail.

Yet at the same time, it is also true that the kind of very personalized care often available in developed markets may be difficult to achieve in a developing nation, and trying to may divert significant resources that could be better used providing a more basic level of medical intervention that could be more widely distributed. But the WHO's approach often ignores even basic public health alternatives in favor of single approaches, with the potential for significant public health harm.

Part of the problem is measurement: WHO often gauges its own success on metrics that measure the execution of its public health approaches rather than the end result, which is the overall benefits it

has achieved. Part of the problem is logistics: WHO understandably favors easily executed, and easily reproduced public health strategies that allow an organization with lean reasons to have the widest impact. Finally, part of the problem is aspirational: WHO does not seek to achieve a high standard for medical care in the developing world, but a minimum standard necessary to have the widest impact.

Noble this may be in some quarters; it nonetheless dooms developing nations to a low expectation for medical care, and an acceptance of medical failure, and sets a standard that may be hard for these nations to eventually climb out from. In the case of breastfeeding, that means that the evidence indicates that for a variety of reasons, some mothers in developing countries are going to prefer or require formula feeding for their new infants. But one-sized-fits-all policy prescriptions, that advocate breastfeeding as the only solution, and deny women information about the array of options and the critical risks and benefits inherent in each, could leave these women, and especially their babies, worse off.

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This paper reviewed the available literature on breastfeeding and on baby formula products. While breastfeeding is clearly superior to formula feeding for the majority of healthy mothers, there are also as clearly certain circumstances when formula feeding is a preferred, if not required strategy, in order to maximize the health of the newborn. However, public health officials have attempted to promote breastfeeding by casting a critical eye toward infant formula, in isolated cases even demonizing the suppliers of formula and arousing suspicion of their motives.

This strategy may inevitably cause more harm if these practices prompt mothers to opt for breastfeeding when such a strategy is clearly not in their newborn's best interest, or to prefer other, far less nutritional and safe alternatives to breastfeeding. For example, studies have shown that a significant percentage of rural mothers in some developing nations now prefer fresh milk or starch gruel made of fermented sorghum rice to well-regulated infant formulas.[18]

But even more importantly, such a public health agenda, which sets a medical strategy almost at the exclusion of all other options, prescribes a public health standard that does not aspire to be optimal, just achievable. It accepts a level of failure before the public health campaign has even begun, and sets a standard for performance and

**medical care that will become an enduring measure by which other suboptimal endeavors will eventually calibrate themselves.**

## Endnotes

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