Response to the Request for Public Comments for Use in Preparing for 2009 Reauthorization of the Child Nutrition Programs and the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)

Submitted by the United States Breastfeeding Committee on October 13, 2008

Infants who are not breastfed or provided with human milk are at increased risk for a number of acute and chronic diseases and conditions including acute otitis media, gastroenteritis, severe lower respiratory tract infections, atopic dermatitis, asthma, obesity, type 1 and 2 diabetes, childhood leukemia, necrotizing enterocolitis, and sudden infant death syndrome. Maternal outcomes of women who do not breastfeed include increased risk of type 2 diabetes, as well as breast and ovarian cancer.[1] The burden of this morbidity translates into billions of health care dollars spent on diseases and conditions that are preventable by breastfeeding.

In a 2001 analysis, Weimer estimated that $3.6 billion would be saved for just three diseases (otitis media, gastroenteritis, and necrotizing enterocolitis) if breastfeeding were increased from the 2001 rates of 64% initiation and 29% continuation at 6 months to the Healthy People 2010 goals of a 75% initiation rate and a 50% continuation rate at 6 months.[2] In 1993, the General Accounting Office estimated that if WIC were fully funded and serving all eligible recipients, any increase in breastfeeding would decrease total food costs as long as formula-supplemented breastfed infants received no more than 25% of the monthly amount of formula given to exclusively formula-fed infants. If partially breastfed infants received even less formula and exclusive breastfeeding rates increased, more money would be saved.[3]

USBC requests that legislative language be added to the Child Nutrition Act strengthening the commitment to breastfeeding by stating that exclusive breastfeeding for the first 6 months and continuing into the second year is the preferred method of feeding for all infants and young children.

USBC requests that anywhere in the Act where the term "nutrition education" is mentioned that the words "breastfeeding education and support" be added as appropriate.

Both education about breastfeeding and support for the breastfeeding mother are necessary to improve breastfeeding initiation, duration, and exclusivity rates. Breastfeeding peer counselors have been shown to increase breastfeeding initiation, duration, and exclusivity when provided

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[1] Ip S, Chung M, Raman G, et al. Breastfeeding and maternal and infant health outcomes in developed countries. Evidence Report/Technology Assessment No. 153. AHRQ Publication No. 07-E007. Rockville, MD: Agency for Healthcare Research and Quality. April 2007.
[2] Weimer J. The economic benefits of breastfeeding: A review and analysis. Food and Rural Economics Division, Economic Research Service, USDA, Food Assistance and Nutrition Research Report No. 13.
[3] US General Accounting Office. Breastfeeding: WIC's efforts to promote breastfeeding have increased. GAO/ARD publication No. 94-13. December 1992.

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with the time necessary to adequately assist breastfeeding mothers.[4] Additionally, access to lactation consultants is critical to augment the effectiveness of peer counseling programs and to provide professional lactation services in more complex situations.[5] Agencies with better initiation and duration rates typically offer breastfeeding classes, one-on-one prenatal counseling, telephone contacts, on-call services, and hospital visits.[6] There is a direct link between resources committed to breastfeeding and breastfeeding outcomes.

Hospital-based bedside support has been shown to be an effective intervention for increasing breastfeeding initiation.[7] Exclusive breastfeeding during the hospital stay is one of the most important influences on how long babies are breastfed exclusively after discharge.[8] Babies who are fed breast milk exclusively in the hospital are more likely to receive only breast milk at home and to continue breastfeeding for a longer period of time. Not all mothers have an equal opportunity to breastfeed their infants, as many WIC infants are born in hospitals with low scores on maternity care practices that are supportive of breastfeeding.[9] All breastfeeding WIC mothers and infants deserve access to optimal lactation care and services. International Board Certified Lactation Consultants (IBCLCs) should be allowed to recertify breastfeeding mothers and babies in the hospital and be designated as a "competent professional authority" for the breastfeeding dyad to assure continuity of care for the entire breastfeeding experience.

Many mothers lack access to this care as not all WIC agencies have peer counselors, lactation consultants, or breastfeeding coordinators whose position is dedicated to providing breastfeeding services. If WIC mothers cannot afford this care from community resources then they often abandon breastfeeding. WIC currently provides entitlements for formula feeding that far outweigh those for breastfeeding, the results of which are reflected in the association of WIC participation with lower breastfeeding initiation and duration rates.[10] While some mothers may find WIC breastfeeding education and support effective, many others may be more influenced by the offer of free formula.[11] WIC should expend what is necessary to meet the Healthy People 2010 breastfeeding goals for the nation.

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[4] Bronner Y, Barber T, Vogelhut J, Resnik AK. Breastfeeding peer counseling: results from the National WIC Survey. *J Hum Lact.* 2001. 7:119-25.

[5] Grummer-Strawn LM, Rice SP, Dugas K, et al. An evaluation of breastfeeding promotion through peer counseling in Mississippi WIC clinics. *Matern Child Health J.* 1997 Mar;1(1):35-42.

[6] Food Assistance: Activities and use of nonprogram resources at six WIC agencies. GAO/RCED-00-202, September 2000.

[7] Ahluwalia IB, Tessaro I, Grummer-Strawn LM, et al. Georgia's breastfeeding promotion program for low-income women. *Pediatr* 2000; 105:e85.

[8] Kramer MS, Chalmers B, Hodnett ED, et al. Promotion of Breastfeeding Intervention Trial (PROBIT): a randomized trial in the Republic of Belarus. *JAMA*. 2001;285:413-420. Murray EK, Ricketts S, Dellaport J. Hospital practices that increase breastfeeding duration: results from a population-based study. *Birth* 2007;34:202-211. Semenic S, Loiselle C, Gottlieb L. Predictors of the duration of exclusive breastfeeding among first-time mothers. *Research in Nursing & Health* (published online). Mar 6 2008. Szajewska H, Horvath A, Koletzko B, Kalisz M. Effects of brief exposure to water, breast-milk substitutes, or other liquids on the success and duration of breastfeeding: a systematic review. *Acta Paediatr*. 2006;95:145-152.

[9] Morbidity and Mortality Weekly Report. Breastfeeding-Related Maternity Practices at Hospitals and Birth Centers—United States, 2007. June 13, 2008 / Vol. 57 / No. 23 http://www.cdc.gov/mmwr/PDF/wk/mm5723.pdf

[10] Racine EF, Frick K, Guthrie JF, Strobino D. Individual net-benefit maximization: a model for understanding breastfeeding cessation among low-income women. *Matern Child Health J.* DOI 10.1007/s10995-008-0337-1, 2008.

[11] Chatterji P, Bonuck K, Dhawan S, Deb N. WIC participation and the initiation and duration of breastfeeding. Discussion paper No. 1246-02, Institute for Research on Poverty, Madison WI: February 2002. http://www.irp.wisc.edu/publications/dps/pdfs/dp124602.pdf

USBC requests that all WIC agencies be required to make lactation care and services available through International Board Certified Lactation Consultants (IBCLCs), peer counselors, and breastfeeding support groups such as La Leche League; and have the breastfeeding coordinator position be restricted to activities associated with creating and providing breastfeeding education and support.

USBC requests that $100 million be appropriated for the WIC peer counseling program.

USBC requests that a new definition be added under Sec 17 (b) Definitions:
The term "breastfeeding education" shall mean individual and group sessions and the provision of materials that are designed to provide information on breastfeeding initiation techniques and describe breastfeeding as the normal and preferred infant feeding method so that women may make informed feeding decisions; the term "support" shall mean face-to-face counseling, technical breastfeeding assistance, demonstration of breastfeeding aids, and encouragement to assure the meeting of the mother's breastfeeding goals; breastfeeding protection shall mean the conducting of programs and activities, including promotion of environmental supports in the community, and the development of agency policies that enable mothers to breastfeed.

USBC requests that lactation consultants with the IBCLC credential be designated as and added to the definition of a "competent professional authority" for the breastfeeding dyad under Sec 17 (b) (3).

USBC requests that standards be established for staff-to-participant ratios of breastfeeding peer counselors and lactation consultants for *all* WIC agencies.

USBC requests that there be minimum education requirements for all staff delivering lactation care and services and provisions for continuing education.

USBC requests that Sec 17 (e) be amended to state:
For each fiscal year, the national minimum breastfeeding promotion expenditure means an amount that is—(i) equal to $100 multiplied by the number of pregnant women and breastfeeding women participating in the program nationwide, based on the average number of pregnant women and breastfeeding women so participating during the last 3 months for which the Secretary has final data; and (ii) adjusted for inflation on October 1, 1996, and each October 1 thereafter, in accordance with paragraph (1)(B)(ii).

USBC requests that all funds allocated for breastfeeding education and support be earmarked as such and distributed locally to direct service providers.

USBC requests that the word "benefits" be removed from Sec 17 (f) (25) INFANT FORMULA BENEFITS-to avoid the appearance of providing more entitlements for formula feeding than breastfeeding.

Many mothers who are served by WIC must return to employment or school soon after the birth of their infant. The opportunity to express milk while separated from their infants is of prime importance in preserving breastfeeding. Mothers who wish to exclusively breastfeed should be provided with a high quality breast pump to assure a continued supply of milk for their infants. Breast pumps should be part of the food package for those mothers exclusively breastfeeding their infants. Those who are provided with a pump are significantly less likely to request infant formula from WIC.[12]

USBC requests that WIC provide a high quality breast pump to all mothers who wish to exclusively breastfeed and must return to employment or school.

USBC requests that contingency funds cease excluding breast pumps.

Formula companies use the WIC trademark to market infant formula. This may give the impression that FNS promotes formula feeding. Formula manufacturers may need to be reminded that use of the WIC acronym on their marketing materials could interfere with the granting of state contracts.

USBC requests that all formula companies be instructed to comply with FNS restrictions on the use of the WIC acronym and logo in formula advertisements.[13]

The "WIC Eligible in All 50 States" statement is frequently seen in formula advertisements to physicians for specialty formulas that are more expensive than standard contract types. Parents ask for many of these "designer" formulas since they think it will cure fussiness or other normal infant behavior. Physicians will often write a prescription for one of these formulas even though there is no medical indication to do so.[14] Infant formula companies entice physicians to prescribe the higher priced formulas[15] by providing them with "prescription" pads containing tear off sheets that list all of the company's formulas but not which ones are more expensive to WIC.[16] Physicians should be educated regarding the use of WIC contracted formulas.

USBC requests that WIC formula purchasing contracts prohibit vendors from using the term "WIC eligible" on formula marketing materials and physician formula prescription sheets to reduce the use of non-contract and exempt infant formulas.

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[12] Meehan K, Harrison GG, Afifi AA, et al. The association between an electric pump loan program and the timing of requests for formula by working mothers in WIC. *J Hum Lact* 2008; 24:150-158.
[13] Report to Congressional Addressees. Breastfeeding: Some strategies used to market infant formula may discourage breastfeeding; state contracts should better protect against the misuse of WIC name. GAO-06-282, February 2006.
[14] Food Assistance: Potential to serve more WIC infants by reducing formula cost. GAO-03-331, February 2003; Food Assistance: FNS could take additional steps to contain WIC infant formula costs. GAO-06-380, March 2006.
[15] http://www.rosspediatrics.com/asp/newsletter.asp?ItemType=2&ItemSubType=4
[16] http://www.rosspediatrics.com/library/WIC%20Exception%20Form.pdf and http://apps.meadjohnson.com/hcp/pdf/LA3126REV11_04pad.pdf

Approximately 86% of WIC mothers receive commercial formula discharge bags when they leave the hospital.[17] This practice has been shown to reduce exclusive breastfeeding at all points measured between 0-6 months[18] and contribute to early weaning.[19] If the formula contained in this gift bag is not the contracted formula, mothers may request that their baby be changed to this brand, costing WIC additional money for a non-contracted brand of formula. WIC should include in state contracts that WIC participants are not to receive formula company discharge bags as they directly serve to neutralize the time investment that is necessary to assure exclusive breastfeeding for the first month. WIC should request that hospitals refrain from distributing these bags to WIC participants. Much of the formula in these bags is powdered, increasing the risk of an infant being fed a contaminated product, as powdered infant formula is not sterile. Infants have been sickened from the use of this "gift."[20] These samples are also subject to recall if the formula is defective in some manner, as evidenced by the September 15, 2006 recall of defective liquid formula in hospital distributed discharge bags.[21]

USBC requests that the elimination of commercial formula bag distribution to WIC mothers be a condition of state formula purchasing contracts.

WIC currently restricts the issuance of ready-to-feed (RTF) liquid formulas to conditions where the household water supply is unsanitary or restricted or if people using the formula cannot properly dilute concentrated or powdered forms. WIC should also issue RTF forms of formula to households with well water that has been tested and shown to contain high levels of lead, arsenic, cadmium, or atrazine (or other agricultural contaminants). Powdered infant formulas are not sterile, with some found to be contaminated with *Enterobacter sakazakii, Salmonella,* and endotoxins. Infections and death have been associated with use of powdered formulas contaminated with *E sakazakii* bacteria CDC.[22] The presence of endotoxins increase the risk of bacteria penetrating the gut and blood-brain barrier, placing formula-fed infants at higher risk for bacterial diseases such as necrotizing enterocolitis.[23] WIC should consider a restriction on issuing powdered infant formula to any infant under 4 weeks of age, as full term infants are also

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[17] Baydar N, McCann M, Williams R, Vesper E. Final report: WIC infant feeding practices study. Alexandria, VA: USDA, Office of Analysis and Evaluation, Food and Consumer Service, November 1997.

[18] Donnelly A, Snowden HM, Renfrew MJ, Woolridge MW. Commercial hospital discharge packs for breastfeeding women. Cochrane Database Syst Rev. 2000; (2):CD002075.

[19] Caulfield LE, Gross SM, Bentley ME, et al. WIC-based interventions to promote breastfeeding among African-American women in Baltimore: effects on breastfeeding initiation and continuation. *J Hum Lact* 1998; 14:15-22. Rosenberg KD et al. Marketing infant formula through hospitals: the impact of commercial hospital discharge packs on breastfeeding. *Am J Pub Health* 2008; 98:290-295.

[20] www.wave3.com/global/story.asp?s=2531323&ClientType=Printable

[21] http://www.fda.gov/oc/po/firmrecalls/abbott09_06.html

[22] Drudy D, Mullane NR, Quinn T, et al. Enterobacter sakazakii: an emerging pathogen in powdered infant formula. *Clin Infect Dis* 2006; 42:996-1002. Forsythe S. Enterobacter sakazakii and other bacteria in powdered infant milk formula. *Maternal Child Nutr* 2005; 1:44-50. Centers for Disease Control and Prevention. Enterobacter sakazakii infections associated with the use of powdered infant formula-Tennessee, 2001. MMWR 2002; 51:297-300. Food and Drug Administration. Health professionals letter on Enterobacter sakazakii infections associated with the use of powdered (dry) infant formulas in neonatal intensive care units. October 2002; www.cfsan.fda.gov/~dms/inf-ltr3.html

[23] Townsend S, Barron JC, Loc-Carrillo C, Forsythe S. The presence of endotoxin in powdered infant formula milk and the influence of endotoxin and Enterobacter sakazakii on bacterial translocation in the infant rat. *Food Microbiol* 2007; 24:67-74.

at risk.[24] Only two manufacturers have placed a warning on some of their labels of standard powdered infant formula that it is not sterile. Preparation instructions on the labels are incorrect. WIC needs to make sure that participants receive the current preparation instructions which recommend that water be brought to a rolling boil, cooled to 70°C to 90°C (158°F to 194°F) and added to the powdered formula, then cooled to body temperature before feeding.[20]

USBC requests that WIC issue only ready-to-feed or concentrated formula to infants less than 4 weeks of age.

All infant formulas marketed in the United States must meet the nutrient specifications listed in FDA regulations. These nutrient specifications include minimum amounts for 29 nutrients and maximum amounts for 9 of those nutrients. Infant formula manufacturers may have their own proprietary formulations but they must contain at least the minimum levels of all nutrients specified in FDA regulations without going over the maximum levels, when maximum levels are specified. Store brand formulas are much less expensive than premium brands of formula but still meet the FDA nutrient specifications for formula consumed in the US. Use of these formulas may reduce the cost of infant formula—a major expense for the WIC program. Not all of the infant formula issued is necessarily used by those infants for whom it is issued. Some formula issued by WIC is stolen, sold on the internet or at flea markets or other outlets, contributing to the increasing amounts of formula WIC needs to purchase.[25]

USBC requests that the opportunity to bid for a WIC contracted formula be extended to all manufacturers of infant formula in the US, including the manufacturers of generic or store brand products. Compliance with FDA nutrient specifications should govern the suitability of a formula for use by WIC participants.

USBC requests that there be a national or individual state label for formula used by WIC. One company would supply WIC with formula that carried a generic WIC label.

While all infant formulas must meet FDA nutrient specifications, infant formula manufacturers have their own proprietary formulations. Those that contain sucrose as a carbohydrate have the potential to induce higher risk for dental caries.[26] Concern over the potential for inducing a preference for sweetened foods as well as the potential for causing overeating and subsequent obesity has led the European Union to eliminate the use of sucrose in infant formulas. Lactose is the principal carbohydrate in human milk and is important for appropriate infant development and gastrointestinal function. Removal of lactose from an infant’s diet, and therefore substitution of a lactose-free infant formula, should occur only for a specific medical reason.

USBC requests that infant formulas containing sucrose not be permitted for inclusion in WIC formula contract bidding.

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[24] Bowen AB, Braden CR. Invasive Enterobacter sakazakii disease in infants. *Emerg Infect Dis* 2006; 12(8), Centers for Disease Control and Prevention (CDC). www.medscape.com/viewarticle/542396

[25] http://www.fda.gov/ohrms/DOCKETS/dailys/03/Jun03/062503/95n-0309-c000015-01-vol9.pdf; http://www.jsonline.com/story/index.aspx?id=689626;

[26] Bhat SS, Dubey A. Acidogenic potential of soya infant formula in comparison with regular infant formula and bovine milk: a plaque pH study. *J Indian Soc Pedod Prev Dent.* 2003 Mar;21(1):30-4.

The rate of premature birth in the US increased almost 35% between 1981 and 2005, rising from 9.4% to 12.7% of all births. The fastest growing portion of preterm births is that of late preterm infants born between 34 0/7 and 36 6/7 weeks, who represented 72% of preterm births in 2005.[27] Preterm infants are especially vulnerable to diseases known to be prevented by the use of human milk. WIC pays for exempt and specialty formulas for formula-fed infants whose medical condition warrants them, but will not pay for banked donor human milk, a substance known to improve health and cognitive outcomes in preterm infants. This inequity reduces the access of WIC infants to a health promoting, disease preventing, and lifesaving intervention that non-WIC infants may receive.

USBC requests that WIC reimburse for the use of banked donor human milk from milk banks that are part of the Human Milk Banking Association of North America.

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[27] Hamilton BE, Martin JA, Ventura SJ. Births: Preliminary data for 2006. National vital statistics reports; vol 56 no 7. Hyattsville, MD: National Center for Health Statistics. 2007.