

Ban the Bags Tool Kit

Anticipating Formula Industry Strategies and Countering Them

Health professionals should prepare talking points for interview situations, contact with the press, or meeting with legislators or public health officials and avoid being drawn into debates that make them appear to be zealots. The following are common industry assertions and claims by opponents followed by useful responses.

Industry Assertion:

Attempts to ban free formula gift packs are “anti-business”; formula companies have a responsibility to communicate their product innovations

Counter: Permitting the practice undermines the public health, which is costly, unethical, and, ultimately, bad for business. Marketing to mothers through the health care system exploits women’s fears and insecurities during the transition to motherhood

Industry Assertion: The Ban the Bags movement is anti-choice.

Counter: We avoid engaging in *any* exchange that borrows the language of the abortion debate. If necessary, identify your refusal to engage in a discussion using this language *precisely* because it co-opts the emotional language of the other, totally unrelated issue.

Appropriate response: Regulating advertising that negatively affects the health of vulnerable women and children has little to do with personal choice. It is about prohibiting unethical marketing practices to vulnerable populations.

Industry Assertion: Creating government regulations to control marketing practices is intrusive and unnecessary.

Counter: Market forces cannot be depended upon to protect vulnerable populations. Because the infant is most affected when breastfeeding is undermined, regulation is a sensible measure to protect the public health. This issue is similar to the regulations concerning exposure to passive smoke.

Industry Assertion: Ban the Bags makes women feel guilty.

Counter: Health professionals work hard to help women breastfeed, and are well aware of the problems that can occur to prevent success. What we seek to prevent is the deliberate undermining of breastfeeding by an industry that profits when breastfeeding fails. Industry would not provide the bags if they did not subvert breastfeeding. The “guilt” argument is used to dodge the issue of failure to fully inform women of the risks of formula feeding.

Industry Assertion: Ban the Bags is elitist because it deprives poor women of a free present they look forward to receiving.

Counter: Undermining breastfeeding and depriving low-income families of the numerous health and economic protections that breastfeeding provides is profoundly exploitative, especially to non-Hispanic black women, who have the lowest breastfeeding rates in the US. The increased health care costs incurred by the uninsured burden the whole country. These bags are NOT free! We are all paying for their hidden costs in terms of a seriously strained health care system.

Industry Assertion: Maternal employment, not formula gift bags, is the major barrier to breastfeeding, especially for working class women with few workplace accommodations.

Counter: Society needs to work harder to ensure that employed mothers and their babies have equal rights with regard to the opportunity to breastfeed. Women planning to return to jobs deserve the right to establish a full milk supply. Early formula supplementation interferes with the establishment of a full milk supply and can compromise their ability to continue breastfeeding when they return to work.

Industry Assertion: Formula is safe and healthy, and many US citizens were raised on it.

Counter: An epidemic of childhood obesity demands that we re-examine the foods and feeding methods that currently predominate.

Breastfeeding is one of the stated “pillars” of the US Public Health system’s childhood anti-obesity campaign. The US healthcare system spends an additional \$3 billion on diseases and conditions that are increased due to not breastfeeding

Hospital Assertion: We need to give out these bags to obtain discounted materials and supplies when purchasing items from pharmaceutical companies.

Counter: This practice may violate OIG, Anti-Kickback and FTC gifts and advertising prohibitions.

Hospital Assertion: We have a contract with formula companies. Under the contracts clause of the US Constitution, a government agency is barred from impeding that contract

Counter: Allow the contract to run out and do not renew it. It is unethical to place commercial interests above patient interest.

Hospital Assertion: The Department of Public Health should not be regulating commercial endeavors as long as they are consistent with hospital operations and not related to harming the health or safety of a patient

Counter: Patient health and safety can be compromised by failure to exclusively breastfeed or from contaminated powdered infant formula that is not sterile

Hospital Assertion: Removal of the bags interferes with the doctor patient relationship and restricts physicians from counseling patients with whatever type of information on infant feeding options that they believe is necessary

Counter: The bags in no way interfere with the communication between health care providers and patients. Discharge bags are a marketing tool to cause mothers to purchase expensive brands of infant formula under the guise of a medically sanctioned and recommended action

Hospital Assertion: Discharge bags are given when women leave the hospital, therefore they cannot negatively influence breastfeeding behavior while in the hospital.

Counter: While some progress has been made increasing breastfeeding initiation rates, few women are exclusively breastfeeding by the end of the 2nd week postpartum. Formula samples in the discharge bags may undermine mothers decision to

exclusively during the vulnerable time when they are transitioning home. Exclusive breastfeeding confers the greatest benefits to mothers and babies.

Conclusion:

Promotional items are inappropriate in a medical environment and should not be used as patient education materials.

Formula reps have unparalleled access to maternity staff in hospitals. Reps are vendors. They should not be treated as part of the healthcare team. They have succeeded in getting hospital staff to market for them. Hospital staff and health care providers should not be acting as formula marketers, nor should they lend their prestige to a product that undermines the health of our nation’s infants and mothers.

Supportive references:

According to the American Academy of Pediatrics, “Prevention is one of the hallmarks of pediatric practice. Documented trends in increasing prevalence of overweight...mean pediatricians must focus preventive efforts on childhood obesity.” Preventive recommendations include: “Encourage, support and protect breastfeeding.” American Academy of Pediatrics, Committee on Nutrition: Prevention of Pediatric Overweight and Obesity, *Pediatrics* 2003; 112(2):424-429.

A minimum of \$3.6 billion annually in health care costs would be saved if the prevalence of exclusive breastfeeding increased from current rates to the Surgeon General’s target goals. Weimer J: The economic benefits of breastfeeding: A review and analysis. *USDA, Nutrition Research Report No. 13*. 1800 M St. NW, Washington DC, 2001.

It is a stated goal of US Public Health Policy to achieve exclusive breastfeeding rates of 75% at hospital discharge and 50% at 6 months. *US Department of Health and Human Services, Healthy People 2010*. Conference Edition – Vols I and II. Washington, DC. Public Health Service. Office of the Assistant Sec. for Health, Jan 2000, pp 2, 47-48.

“The new multimedia public advertising campaigns may increase the cost of infant formula to the general public...” Greer F, Apple R: Physicians, Formula Companies, and Advertising, *AJDC* 1991; 145:282-286.

“Gifts cost patients money, and they may change society’s perception of the [medical] profession as serving the best interest of patients.” Chren M, LandefeldS, Murray T: *JAMA* 1989; 262(24):3448-3451.

“Pharmaceutical companies are not charitable foundations. They do what they do to make money for their stockholders...As a result, they can act in ways that are not in the best interest of patients as a whole.” Kramer, T: Practitioners and the Pharmaceutical Industry, *Medscape*

Psychiatry & Mental Health eJournal 2002; 7(3).
<http://www.medscape.com/viewarticle/433017>

“...companies are responsible...for sales agents ... who
”engage in improper marketing and promotional
activities”...for example, under new proposed guidelines, a
drug maker cannot give golf balls emblazoned with the
company’s name to doctors because the products do not
provide a benefit to patients.” Pear R: Drug Industry is Told
to Stop Gifts to Doctors. NY Times Oct 1, 2002
<http://nytimes.com/2002/10/01/national/01DRUG.html>

“Conflict of interest has been defined as “a set of conditions in
which professional judgment concerning a primary interest
(such as patients’ welfare) tends to be unduly influenced by a
secondary interest (such as financial gain”Smith R: Beyond
Conflict of Interest, *BMJ* 1998; 317:291-292.

Nader R. Consumer born every minute. San Francisco Bay
Guardian, August 24, 1999. www.sfbg.com/nader/68.html

The US National Immunization Survey (NIS) tracks
breastfeeding data. While initiation rates indicate that
approximately 65% of US children have ever been breastfed,
only 60% have ever been *exclusively* breastfed. By 7 days
breastfeeding rates are 59.3%, indicating an early drop off in
exclusivity, a trend that continues over the period of the the first
6 months. Only 8% are exclusively breastfed by 6 months.
Non-Hispanic blacks have the lowest rates of breastfeeding
initiation and continuation. The authors state: “The health care
system has an important role to play in the promotion and
support of breastfeeding. Maternity care and newborn facilities
should follow practices that are conducive to proper lactation,
and all health care providers who interact with women or infants
should be knowledgeable...about breastfeeding and lactation
and in providing medical care to breastfeeding women [in order
to] identify the social, cultural, economic, and psychological
barriers to breastfeeding that all women face, especially black
women.” Ruowei L, Zhao Z, Mokdad A, et al. Prevalence of
breastfeeding in the United States: The 2001 National
Immunization Survey, *Pediatrics* 2003; 111(5):1198-1201.

Ban the Bags

Action Ideas

Government

Legislation

☞ State legislation is one route to use for mandating the elimination of commercial discharge bags from the hospital. Write to your state legislators asking that such a bill be introduced

☞ California's Senate Bill 1275 (Ortiz) in 2004 contains model language for state legislation:

http://www.leginfo.ca.gov/cgi-bin/postquery?bill_number=sb_1275&sess=PREV&house=B&author=ortiz

The Right to Informed Infant Feeding Choices

1. Inclusion of Disclaimer Notice.
Requires infant formula companies that market and distribute infant formula in a hospital to include a single, prominent notice on their marketing discharge bags that will state that "the distribution of formula or the marketing materials in a hospital setting does not necessarily mean that the hospital or health care providers endorse the company or the product that is being distributed."
2. A hospital's maternity unit or nursery may not be used for display of products (promotional items), or placards or posters concerning these products, provided by a manufacturer or distributor of infant formula.

www.breastfeedingtaskforla.org

Policy

☞ State perinatal regulations are operating mandates to hospitals that can be used to specify the elimination of commercial discharge bags. Both New York and Massachusetts have state perinatal regulations that contain statements to curb the hospital distribution of commercial bags. These state that breastfeeding mothers should

not be given commercial discharge bags unless prescribed by the physicians or

requested by the mother

<http://www.massbfc.org/news/perinatalRegs.html>

☞ Contact your state department of public health for a copy of your own state's perinatal regulations and work with that agency to change hospital policy

State Breastfeeding Coalitions and Task Forces

☞ The Massachusetts Breastfeeding Coalition worked closely with the state department of public health to revise the state perinatal regulations. While not able to strengthen the prohibition on commercial discharge bags due to interference from the Governor, the regulations have considerably improved what hospitals must provide to breastfeeding mothers
<http://www.massbfc.org/news/perinatalRegs.html>

☞ The New Mexico Breastfeeding Taskforce has a project called The Discharge Pack Initiative that trades a free T-shirt for baby for a commercial discharge bag. The bags are sent back to the formula manufacturer.
www.breastfeedingnewmexico.org

Maternity Hospitals

☞ Check your institution or agency's policy on selling or marketing products to patients. Since discharge packs are forms of marketing, employees may be unknowingly violating institutional policy.

☞ Check your job description. Does it mention marketing of products as a requirement of the job? If not, do not do it. Does your job description or any document you signed as a condition of employment prohibit marketing of

products? If not, you may wish to add this to it for patient protection. If it does, then avoid giving out discharge packs from commercial interests

☞ Most hospitals have provisions for conscientious objection to performing care that violates your ethical or moral principles. Check your hospital's policy and record your objection to this practice *Waller-Wise R. Conscientious objection: do nurses have the right to refuse to provide care? AWHONN Lifelines 2005; 9:283-286*

☞ HIPAA regulations consider formula discharge bags as a form of marketing. Remind your hospital that distribution of these bags facilitates a marketing opportunity for corporations
www.hhs.gov/ocr/hipaa/guidelines.pdf

☞ Obtain the mission statement of the hospital, agency, or program where you work. Does it mention promotion of health as a goal? If so, ask how marketing formula promotes a health goal. Does it mention marketing commercial products as a means to this goal? If not, avoid using formula company items

☞ If you are a nurse, contact your state nurse's association regarding the marketing of products to patients. Does this fall within the scope of practice of a nurse? Does it fit in with the ethical practice of the nursing profession? If not, ask them for a statement to this effect for your use

☞ The federal anti-kickback statute (The Medicare and Medicaid Patient Protection Act of 1987 as amended, 42 U.S.C. 1320a-7b) is a criminal statute that applies to health care providers, hospitals, clinics, etc. Several common practices may violate this law – giving formula discharge bags to patients, accepting free formula for use in the hospital, soliciting or receiving gifts from formula companies, accepting cash

from vendors. Check with your hospital's attorney to see if your institution is in violation of this statute. If so, report this to the Inspector General's Office of the Department of Health and Human Services at:
esec@os.dhhs.gov

☞ Ask your purchasing department if your hospital has a contract with a formula company. Request a written copy of this. Ask if any other units have a contract with a supplier to accept free goods in return for marketing their products. Ask what the cash is used for and who is accountable for it. All other units pass on the cost of food to the insurer. Food trays are part of the room and board charge. Why doesn't the nursery?

☞ Ask your purchasing department if the hospital has an agreement with a service that purchases supplies in bulk quantities for many hospitals. Formula companies often require hospitals to give out formula-containing discharge bags to breastfeeding mothers as a condition of the discount received on other supplies

☞ Has your unit been approached to change its breastfeeding policy to allow distribution of formula-containing discharge packs? Formula companies have offered cash to maternity units for "educational" purposes in return for changing established unit policy to require giving breastfeeding mothers commercial discharge packs. This type of bribe can set a dangerous precedent whereby formula companies may pressure cash-strapped maternity units to change breastfeeding **management** guidelines to increase the chances that a mother would need or want to supplement her baby with formula

☞ Contact both the ethics committee and your hospital's attorney and ask for a statement on the legality and ethical

principles behind the issue of the hospital endorsing products for financial gain, either directly by accepting infant formula at no cost and distributing commercial discharge bags, or indirectly by accepting cash grants and additional services

☞ Form a hospital task force or contact your Quality Improvement department to begin the process of eliminating the distribution of commercial discharge bags from your hospital

FREE COMMERCIAL FORMULA DISCHARGE BAGS AND THEIR ASSOCIATION WITH DECREASED BREASTFEEDING

Many studies show an association between distribution of free commercial formula discharge bags and decreased breastfeeding:

Title: Do infant formula samples shorten the duration of breastfeeding?

Source: Lancet

- Breastfeeding mothers who received free formula samples at discharge were less likely to still be breastfeeding at one month (78% vs. 84%, $p=0.07$)
- Breastfeeding mothers who received free formula samples at discharge were more likely to introduce solid foods by 2 months (18% vs. 10%, $p=0.01$)
- The above trends were more significant among less educated mothers, first time mothers, and mothers who had been ill post partum.

Bergevin et al., Do infant formula samples shorten the duration of breast-feeding? Lancet. 1983 May 21;1(8334):1148-51

Title: Commercial hospital discharge packs for breastfeeding women

Source: Cochrane Database Systematic Review

- Meta-Analysis shows that giving breastfeeding women a commercial formula discharge pack decreased exclusive rates of breastfeeding at any point in time, from 0–6 months postpartum

Donnelly et al., Commercial hospital discharge packs for breastfeeding women. Cochrane Database Syst Rev. 2000;(2):CD002075

Title: Infant formula marketing through hospitals: The impact of discharge bags containing formula on breastfeeding.

Source: American Public Health Association Meeting and Conference

- Women who did not receive discharge packs containing formula were more likely to be exclusively breastfeeding at 3 weeks postpartum (OR 1.52, 95% CI 1.12-2.05).

Eastham et al., Differential effect of formula discharge packs on breastfeeding by maternal race/ethnicity. APHA 133rd annual meeting and exposition 2005, Philadelphia.

Title: Commercial discharge packs and breast-feeding counseling: effects in infant-feeding practices in a randomized trial

Source: Pediatrics

- Mothers who received a discharge pack that did not contain formula breastfed exclusively for longer ($p=.04$), and were more likely to be breastfeeding at 4 months postpartum ($p=.04$)

Frank et al., Commercial discharge packs and breast-feeding counseling: Effects on infant-feeding practices in a randomized trial. Pediatrics, 1987 Dec;80(6):845-54

Title: Effect of discharge samples on duration of breast-feeding

Source: Pediatrics

- Women who received a discharge pack with a manual breast pump but no formula breastfed longer (mean = 4.18 weeks) than women who received infant formula in their discharge package (mean=2.78 weeks) $p < 0.05$

Dungy et al., Effect of discharge samples on duration of breast-feeding. Pediatrics, 1992 Aug;90(2 Pt 1):233-7.

Title: Infant feeding policies in maternity wards and their effect on breast-feeding success: An analytical overview

Source: American Journal of Public Health

- Meta-Analysis found that free commercial discharge bags had an adverse effect on lactation performance

Perez-Escamilla et al., Infant feeding policies in maternity wards and their effect on breast-feeding success: An analytical overview. Am J Public Health. 1994 Jan;84(1):89-97.

Title: Changing hospital practices to increase the duration of breastfeeding

Source: Pediatrics

- Meta-analysis indicated that commercial discharge packs had an adverse effect on lactation performance

Wright et al Changing hospital practices to increase the duration of breastfeeding. Pediatr 1996 May;97(5):669-675

Title: The association of formula samples given at hospital discharge with the early duration of breastfeeding

Source: Journal of Human Lactation

- Fewer Hispanic women were breastfeeding at 3 weeks in the presence of gift packs

Snell et al. The association of formula samples given at hospital discharge with the early duration of breastfeeding. J Hum Lact 1992 Jun;8(2):67-72

The effects of free commercial formula discharge bags on WIC-participants

Title: WIC-based interventions to promote breastfeeding among African-American women in Baltimore: Effects on breastfeeding initiation and continuation

Source: Journal of Human Lactation

- Women who received free commercial formula were less likely to begin breastfeeding and less likely to still be breastfeeding at 7-10 days

Caulfield et al., WIC-based interventions to promote breastfeeding among African-American women in Baltimore: Effects on breastfeeding initiation and continuation. J Human Lactation 1998:15-22

Title: Breast-feeding patterns among Indochinese Immigrants in Northern California


Source: American Journal of Diseases of Children


- Mothers who received free formula samples at discharge were 2 times more likely to formula-feed their infants


Romero-Gwynn E. Breast-feeding pattern among Indochinese immigrants in northern California. Am J of Diseases of Children 1989 July;143:804-808.


FACT SHEET ON ON FORMULA MARKETING IN HOSPITALS


 80% of baby formula sold in the United States comes from major pharmaceutical companies.


 Pharmaceutical companies use hospitals to market formula because the practice implies that doctors and hospitals endorse not only formula-feeding in general, but their brand in particular. They use hospital-distributed commercial discharge bags to advertise their product directly to new mothers as they leave the hospital.


 Research shows that mothers who receive commercial discharge bags are more likely to start using formula. The effect is so dramatic that it is seen even when the bags do not contain formula samples.


 The commercial discharge bags market the most expensive brands of formula, which hurts formula-feeding families as well. There is evidence that the marketing fosters brand loyalty: families continue to use the brand they were given in the hospital. Each of these bags costs the companies less than \$7, but a year of name-brand formula costs parents up to \$2,000, a significant portion of which pays for marketing. As a result, families pay at least an extra \$700 per year for name-brand formula as compared to store brands.

 The American Academy of Pediatrics (AAP), the American College of Obstetrics and Gynecology (ACOG), the American Academy of Family Physicians (AAFP), and the World Health Organization (WHO), along with many other public health organizations, recommend that mothers breastfeed their babies exclusively for six months and continue to breastfeed with the addition of complementary foods for at least the first year.

 Mothers who use formula instead of breastfeeding face increased risks of breast cancer, ovarian cancer, and type 2 diabetes. Children who are formula-fed have higher rates of many infant infections, as well as chronic diseases such as type 1 diabetes, leukemia and lymphoma, and obesity. The benefits of breastfeeding are dose-related; the more breastmilk a baby receives, the greater the protection for both mother and baby.

 Studies suggest that infants who are not breastfed have significantly higher health care costs, something which the national cannot afford in this era of rising health care costs. Formula feeding costs tax payers by increasing expenses for Medicaid and WIC food benefits. A 2001 report from the US Department of Agriculture estimates that the US could save at least \$3.6 billion in annual health care costs if breastfeeding rates rose to the levels recommended by the Surgeon General.

 Research shows that mothers who formula-feed have three times as many one-day absences from work to care for sick children as do breastfeeding mothers. Other research estimates that one year of sick time could be saved for every thousand babies breastfed instead of formula-fed.

 Many organizations oppose hospital distribution of commercial discharge bags, including the AAP; the AAFP; District I of ACOG; the Centers for Disease Control; the WHO; the Massachusetts Medical Society; and the Massachusetts Public Health Association. The federal Government Accountability Office (GAO) recently spoke out against this specific practice, defining it as marketing, and the 2000 Surgeon General's report also condemned it.

HOSPITALS SHOULD MARKET HEALTH, AND NOTHING ELSE.



State of Massachusetts: Breastfeeding Report Card

Published May, 2006

Name of licensed maternity facility* N=52	Breastfeeding on discharge*	Total births*	Baby-Friendly Award or Certificate of Intent	Distributes commercial discharge bags
Cambridge Birth Center	100%	108	Certificate of Intent+	No **
North Shore Birth Center	100%	80	No	No **
BirthPlace at Wellesley	100%	110	No	Yes
Mount Auburn Hospital	93%	1797	No	Yes
Cambridge Hospital Campus	92%	1205	Certificate of Intent+	No **
Metro West Medical Center	90%	1991	No	Yes
Cooley Dickinson Hospital	87%	859	No	Yes
BI Deaconess Medical Center	85%	4980	No	Yes
Boston Medical Center	85%	2271	Award (1999)	No **
Emerson Hospital	85%	1317	No	Yes
Martha's Vineyard Hospital	85%	131	No	Yes
Brigham and Women's Hosp	84%	8632	No	No **
Nantucket Cottage Hospital	84%	97	No	Yes
Cape Cod Hospital	82%	922	No	Yes
Anna Jacques Hospital	81%	766	No	Yes
Newton-Wellesley Hospital	79%	2944	No	No **
Beverly Hospital	78%	2230	No	Yes
Caritas Norwood Hospital	77%	597	No	Yes
Mass General Hospital	77%	3425	No	No **
Franklin Medical Center	76%	443	No	No **
<i>----Healthy People 2010 goal--75%-----</i>				
St. Elizabeth Medical Center	74%	1362	No	Yes
Saint Vincent Hospital	73%	1877	No	Yes
Holy Family Hospital	71%	1315	No	Yes
Berkshire Medical Center	69%	803	No	Yes
Brockton Hospital	69%	1269	No	Yes
Mercy Medical Center	69%	1380	No	Yes
South Shore Hospital	69%	4119	No	Yes
UMass Memorial Leominster	69%	1100	No	Yes
Baystate Medical Center	68%	4067	No	Yes
Jordon Hospital	68%	624	No	Yes
North Shore Med Ctr (Salem)	68%	1828	No	Yes
Tobey Hospital	68%	509	No	Yes
Tufts NEMC	67%	1248	No	Yes
Lowell General Hospital	66%	1874	No	No **
Falmouth Hospital	65%	641	No	Yes
Melrose-Wakefield Hospital	65%	1549	No	No (2/06)
UMass Memorial Worcester	65%	4373	No	Yes
Good Samaritan Medical Ctr	63%	997	No	Yes

Milford Regional Med Center	63%	856	No	Yes
North Adams Regional Hosp	63%	296	No	Yes
Sturdy Memorial Hospital	60%	1038	No	Yes
Saints Memorial Med Center	59%	688	No	Yes
Mary Lane Hospital	58%	130	No	Yes
Harrington Memorial Hospital	57%	470	No	Yes
Holyoke Medical Center	54%	586	No	Yes
Charlton Memorial Hospital	52%	1708	No	Yes
St. Luke's Hospital	47%	1499	No	Yes
Morton Hospital	45%	525	No	Yes
Fairview Hospital	no data	174	No	No
Heywood Hospital	no data	539	No	Yes
Lawrence General Hospital	no data	1765	No	Yes
Winchester Hospital	no data	<u>2137</u>	No	Yes
		78,251		

*mass.gov data for 2004 (breastfeeding information obtained from birth certificate data)

+active Certificate of Intent per Baby-Friendly USA (5/06)

**Information obtained from study conducted for 2005: BMC, Cambridge Birth Center, Franklin, Lowell, MGH, Newton-Wellesley, North Shore Birth Center

**B & W (2/06)

**Cambridge Hospital Campus (Health Alliance) (4/06)

National Rank

<u>2004 Breastfeeding Initiation Rates by State (%)</u>	
1. Alaska	88.0
2. Idaho	86.0
3. Oregon	86.0
4. Washington	85.9
5. Utah	84.8
18. Mass.	74.0
51. Mississippi	46.1
www.cdc.gov/breastfeeding	

<u>2004 6-Month Breastfeeding Rates by State (%)</u>	
1. Oregon	53.0
2. Utah	52.4
3. Idaho	50.3
4. Alaska	48.1
5. Nevada	47.0
18. Mass.	38.8
51. Mississippi	16.2
www.cdc.gov/breastfeeding	



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta, GA 30333

April 26, 2006

Phyllis V. Cudmore
Consumer Advocate
Massachusetts Public Health Council
61 Morton Street
Canton, MA 02021

Dear Ms. Cudmore:

On March 15, 2006, you contacted the Centers for Disease Control and Prevention regarding the proposed regulation of infant formula sample distribution in Massachusetts' hospitals. You asked that we comment on the Massachusetts Public Health Council's recommendation to ban commercial formula company discharge bags from being distributed by all hospitals in the state of Massachusetts.

The health benefits of breastfeeding for both the mother and baby are well-established. The U.S. Surgeon General has declared that the relatively low rates of breastfeeding in the U.S. are a major public health issue¹. Further, ongoing significant disparities in breastfeeding rates between both whites and blacks and different economic groups² represent a complex public health challenge. The Department of Health and Human Services has included objectives for increasing breastfeeding initiation, duration and exclusivity and decreasing disparities in these rates across all populations in the United States as part of *Healthy People 2010 Objectives*³. Health institutions, particularly hospitals, have a responsibility to ensure that that choice is well-informed and is not impeded by commercial interests.

There is clear evidence that the distribution of free samples of infant formula and promotional materials to new mothers encourages use of infant formula by significantly reducing breastfeeding continuation and exclusivity. A systematic Cochrane library review published in 2004 included nine randomized controlled trials involving a total of 3,730 women in North America⁴. These studies evaluated the impact of both distributing free samples of infant formula and giving out promotional materials on infant formula to new mothers who were already breastfeeding. The review found that when compared with not giving a discharge pack or providing a non-commercial discharge pack, distributing samples of infant formula reduced rates of exclusive breastfeeding at both 3 and 6 months postpartum. Further, this negative impact of distributing formula samples is disproportionately stronger on mothers who are

particularly vulnerable, which includes those who are primiparous (first-time mothers), have less formal education, are nonwhite, or are ill postpartum.

The DHHS Blueprint for Action has identified the hospital experience as a critical period in the establishment of lactation¹. The Blueprint lists distribution of infant formula kits to mothers as strongly discouraging of breastfeeding. This statement is in line with international guidelines on the appropriate role of maternity services⁵. Free distribution of formula samples or coupons is interpreted by mothers as tacit endorsement of formula. Furthermore, mothers who have formula samples on hand are more likely to supplement their infants earlier, thus shorten the duration of both exclusive and any breastfeeding

It has been suggested by some that the Massachusetts regulation would deny a mother her right to choose how to feed her infant. However, the evidence points out that distribution of free samples of infant formula in fact inhibits a new mother's ability to carry out her infant feeding choice. While it is of course each mother's right and responsibility to make a choice about how she feeds her infant, the maternity care hospital stay is a time when new mothers seek expert information on infant feeding. Items new mothers receive in this environment should clearly model and support established healthy choices and behaviors. As such, it is inappropriate for hospitals to assist in the marketing of the less healthy choice.

While a clear negative impact of distribution of infant formula samples to new mothers exists, particularly for high-risk women, no detrimental health impact has been found with discontinuation of distribution of sample packs. Instead, discontinuing this practice improves health outcomes for both mothers and infants.

CDC applauds the Massachusetts Public Health Council for proposing this regulation in the interest of infant and maternal health. The regulation appears to be quite appropriate and in line with national and international recommendations. Thank you for your attention.

Sincerely,

Laurence M. Grummer-Strawn

Laurence M. Grummer-Strawn, PhD
Chief, Maternal and Child Nutrition Branch
Division of Nutrition and Physical Activity
Centers for Disease Control and Prevention

p.s. References cited:

¹ HHS Office on Women's Health. *Blueprint for Action on Breastfeeding*.

² Grummer-Strawn L, Scanlon KS, Darling N, Conrey E. Racial and socioeconomic disparities in breastfeeding – United States, 2004. *MMWR* March 31, 2006;55(12);335-339.

³ U.S. Department of Health and Human Services. *Healthy People 2010*. 2nd ed. 2 vols. Washington, DC: U.S. Government Printing Office, November 2000. (<http://www.healthypeople.gov/Publications>).

⁴ Donnelly A, Snowden HM, Renfew MJ, Woolridge MW. Commercial hospital discharge packs for breastfeeding women (Cochrane review). In: *The Cochrane Library*, Issue 2, 2004. Chichester, UK: John Wiley & Sons, Ltd.

⁵ World Health Organization/UNICEF. *Protecting, Promoting and Supporting Breastfeeding: The Special Role of Maternity Services*. A joint WHO/UNICEF statement. Geneva: World Health Organization, 1989.



American Public Health Association

Working for a Healthier World

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May 16, 2006

Governor Mitt Romney
State House, Room 360
Boston, MA 02133

Dear Governor Romney:

On behalf of the American Public Health Association (APHA), the oldest, largest and most diverse organization of public health professionals in the world, dedicated to protecting all Americans and their communities from preventable, serious health threats and assuring community-based health promotion and disease prevention activities and preventive health services are universally accessible in the United States, I am writing to urge you to reconsider your position on formula marketing in hospitals. Contrary to your public comments, the Public Health Council Regulation does not affect a woman's right to choose formula feeding. It simply removes marketing campaigns that target new mothers from our state's hospitals.

The science to support breastfeeding is clear, as is the science to support the negative impact of marketing to new mothers. A scientific analysis in 2000 of previously published studies found that women who got gift bags were less likely to exclusively breast-feed. Since the early 1970's APHA has been on record, consistently supporting international promotion of breastfeeding and the WHO/UNICEF Code of Marketing of Breastmilk Substitutes. Pharmaceutical companies sell about 80% of the baby formula in the US, and they rely on doctors and nurses to endorse their brand by distributing discharge "diaper bags" in hospitals. Multiple studies show that breastfeeding mothers are more likely to start using formula if they take home a bag-- even if the bag doesn't contain formula.

Formula feeding is linked to myriad health problems, from breast cancer in mothers to childhood obesity. Obesity rates in Massachusetts have increased 80 percent in the last 15 years – our state's hospitals should not promote a product that may make it worse. Research shows that children who are not breastfed have higher health care costs, resulting in increased Medicaid expenditures. Research also shows their parents miss more time from work to care for sick children, resulting in decreased economic productivity.

We see this as also a consumer protection issue. This marketing strategy starts babies on a product that costs formula-feeding families more than \$700 a year above store brands. Formula marketing in hospitals targets young consumers and aims to establish brand and product loyalty at the expense of public health. The U.S. Government Accountability Office has

condemned this practice of hospital-based marketing. The Massachusetts Public Health Association, American Academy of Pediatrics, the Centers for Disease Control and Prevention, and the Massachusetts Medical Society, among others, all oppose hospital-based formula marketing. We join with our colleagues in urging you to protect the public health and reverse your position on formula marketing in hospitals.

Sincerely,

A handwritten signature in black ink, appearing to read "Georges Benjamin". The signature is written in a cursive, flowing style.

Georges Benjamin, MD, FACP
Executive Director



District I ACOG
Office of the Chair
Michael R Tesoro MD
152 East Street
Sharon, CT, 06069
860-364-5615
Drmtesoro@aol.com

May 15, 2006

Dear Public Health Council Members,

The Advisory Council of District I of the American College of Obstetricians and Gynecologists (ACOG) geographically contains all the New England states, Quebec and the Atlantic Provinces of Canada) has formally approved a motion position on the marketing of infant formula in hospitals. The following is the position as passed on April 8, 2006 at our meeting in Boston Ma.

“Post-partum care is a collaborative interdisciplinary process that involves obstetricians, pediatricians, nurses and hospital staff. The obstetrician-gynecologists of ACOG District I strongly discourage hospitals from marketing branded infant formula products and/or gifts on hospital premises”

Organizations which discourage the distribution of the bags include: the American Academy of Pediatrics, Centers for Disease Control, Massachusetts Medical Society, World Health Organization and Massachusetts Public Health Association.

The national ACOG states the following in Education Bulletin #258 from July, 2000: "Formula companies try to attract the interest of pregnant women with gift packs. Care providers should be aware that the giving of gift packs with formula to breastfeeding women is commonly a deterrent to continuation of breastfeeding. A professional recommendation of the care and feeding products in the gift pack is implied. Physicians may conclude that noncommercial educational alternatives or gift packs without health related items are preferable."

As health care providers, we would appreciate the support of the Public Health Council that health care decisions should be between a patient and her health care provider, without pharmaceutical advertising and marketing intervening while the patient is in the hospital.

I urge you to support the proposal that these gift bags and branded formula should not be marketed or distributed on hospital premises.

Sincerely,

Michael R. Tesoro, MD



Your Voice for Public Health

434 Jamaicaway • Jamaica Plain, MA 02130 • TEL: (617) 524-6696 • FAX: (617) 524-5225 • www.mphaweb.org

Judith Kurland, *President*

Geoffrey W. Wilkinson, *Executive Director*

April 10, 2006

Governor Mitt Romney
State House, Room 360
Boston, MA 02133

Dear Governor Romney,

We are writing to urge you to reconsider your position on formula marketing in hospitals. Contrary to your public comments, the Public Health Council Regulation does not affect a woman's right to choose formula-feeding. It simply removes marketing campaigns targeting new mothers from our state's hospitals.

Pharmaceutical companies sell about 80% of the baby formula in the US, and they rely on doctors and nurses to endorse their brand by distributing discharge "diaper bags" in hospitals. Multiple studies show that breastfeeding mothers are more likely to start using formula if they take home a bag-- even if the bag doesn't contain formula. All major medical authorities recommend that children get no other food or drink besides breastmilk for the first six months of life.

Formula feeding is linked to myriad health problems, from breast cancer in mothers to childhood obesity. Obesity rates in Massachusetts have increased 80 percent in the last 15 years – our state's hospitals should not promote a product that may make it worse. Research shows that children who are not breastfed have higher health care costs, resulting in increased Medicaid expenditures. Research also shows their parents miss more time from work to care for sick children, resulting in decreased economic productivity.

This is a consumer issue as well as a public health issue. This marketing strategy starts babies on a product that costs formula-feeding families more than \$700 a year above store brands. Formula marketing in hospitals aims to establish brand loyalty at the expense of public health. This practice of hospital-based marketing has been defined and condemned as such by the Government Accountability Office at the federal level The American Academy of Pediatrics, the Centers for Disease Control and Prevention, and the Massachusetts Medical Society, among others, all oppose hospital-based formula marketing.

PARTNERS IN PUBLIC HEALTH

Alexander Aronson Finning • Blue Cross Blue Shield of Massachusetts • Boston Public Health Commission
Boston University School of Public Health • Cambridge Health Alliance • Harvard University School of Public Health
The Health Foundation of Central Mass • Massachusetts Medical Society • Partners HealthCare System
Tufts University School of Medicine, Graduate Programs in Public Health • University of Massachusetts Medical Center

Formula companies can, and will, continue to market their product in commercial settings. They should stay out of our state's maternity wards. Please reconsider your position on this issue. Hospitals should market health, and nothing else.

Sincerely,

A handwritten signature in black ink, appearing to read "G. Wilkinson", with a long horizontal flourish extending to the right.

Geoffrey Wilkinson
Executive Director

A handwritten signature in black ink, appearing to read "G. Wilkinson", with a long horizontal flourish extending to the right.

This “free” bag comes with a \$700 price tag. So why does your hospital want to hand it out?



This “free” bag comes courtesy of big drug companies. They want to start babies on their expensive brands of infant formula.

- \$\$\$** ▶ If a mom chooses to formula-feed, that “gift” starts her baby on a brand that costs \$700 more a year than store brands.*
- \$\$\$** ▶ If a mom chooses to breastfeed, research shows she is more likely to start using formula if she takes home a bag.**
- \$\$\$** ▶ Health professionals want hospitals to stop marketing formula to new mothers. This practice is opposed by the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the CDC, the American Public Health Association, and the World Health Organization.

Visit www.BantheBags.org for more information. Tell your hospital that you don't want drug companies to profit at the expense of mothers and babies.

Hospitals should market health, and nothing else.



Massachusetts
Breastfeeding
Coalition

www.BantheBags.org

Just Say No



This Bag is Not Free

- ☞ if you are breastfeeding, this bag leads to supplementation and buying formula
- ☞ this is the most expensive kind of formula and will cost you 66% (\$700 a year) more than store brand formula
- ☞ you don't need what's in this bag, but your baby needs what's in your breasts

Protect Yourself and Your Baby

- ☞ Your hospital is used by formula companies to market their products
- ☞ Your hospital receives goods and services in exchange for giving you this bag. It is not designed to help you breastfeed
- ☞ Information found in the bags can be biased, since formula companies make money when you decide to supplement or not to breastfeed

☞ If you are given one of these bags, give it back and ask not to be used as a marketing target

☞ If you need help with breastfeeding contact La Leche League at www.lalecheleague.org or the International Lactation Consultant Association at www.ilca.org

From: www.banthebags.org
Contact us to learn more

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From: www.banthebags.org
Contact us to learn more

Commercial Discharge Bags

Healthcare Laws, Regulations, Guidelines, and Compliance

Increasing attention is being directed towards compliance requirements in the healthcare and pharmaceutical industries. Some of these regulations have implications for those who purchase, recommend, receive, and/or distribute infant formula. Healthcare recommendations and decisions should be made without financial conflicts of interest or commercial bias. Infant formula is viewed very much like pharmaceuticals for the purpose of compliance with healthcare laws, regulations, and guidelines. As with pharmaceuticals, infant formula is marketed to and through health care professionals, mothers often purchase infant formula based on health provider recommendations, and infant formula is paid for by federally funded programs such as Medicaid and WIC. Therefore, there are a number of laws, regulations, and guidelines that may be helpful to use in your work to eliminate hospital distribution of commercial discharge bags.

The Federal Anti-Kickback Statute is a federal law that makes it a felony to give or receive a “kickback” to induce or reward the purchase of items covered by a federal health care program. Specifically, it prohibits offering, paying, soliciting, or receiving:

.... any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person.... to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program....

[42

U.S.C. § 1320a-7b(b)(2).

This statute may apply to discharge bags because mothers can perceive that they are a recommendation to purchase the product. Mothers may wish to use the product after discharge and such usage may be funded by Federal programs. Thus the statute applies to hospitals and health providers who treat infants eligible for the Medicaid or WIC program. Almost half of the infants in the US are serviced by WIC.

Certain purchasing agreements between hospitals and formula companies also violate this statute, such as offering free samples of one product (infant formula for the nursery) on the condition that the hospital distribute samples (discharge bags) of other products from the same manufacturer. Compensation given to healthcare providers for

recommending products violates this statute. Mothers may perceive that the distribution of formula discharge bags is a recommendation to purchase the product.

The courts have identified a number of considerations that help identify arrangements at greatest risk of prosecution:

- Does the arrangement have a potential to interfere with or skew clinical decision-making? The bags are often part of a hospital culture that requires provider neutrality on infant feeding, preventing providers from unequivocal support of breastfeeding. Bags could be given in lieu of expert lactation care and services
- Does the arrangement have the potential to increase costs to Federal health care programs or enrollees? Discharge bags market the most expensive brands of infant formula. When only these are provided to Federal programs the costs of the formula are increased. Mothers who purchase the formula incur increased costs over store brand formulas
- Does the arrangement raise patient safety concerns? Powdered infant formula in discharge bags is not sterile and can and has resulted in infant infections with *Enterobacter sakazakii*. Lot numbers of formula in the bags are not routinely recorded so parents cannot be informed of formula

recalls in a timely manner. Mothers are not asked if they have a history of allergies or diabetes in the family prior to the distribution of the formula bags. Sensitization of breastfed infants from susceptible families can occur with just one bottle made from this formula

Suspected violations of this statute should be reported to the Inspector General of the Department of Health and Human Services at: esec@os.dhhs.gov

Federal Antitrust Laws are a group of laws insuring fair competition in the marketplace. Some purchasing arrangements between hospitals and infant formula manufacturers may violate antitrust laws. These usually involve agreements (bundling, tie-in) where the hospital receives discounts on one item if it agrees to use that same manufacturer's products from another category

PhRMA Code is a voluntary guide for the pharmaceutical industry regarding relationships with physicians and other health care providers.¹ It was adopted in 2002 in response to closer scrutiny by the federal government of questionable and excessive promotional activities by the pharmaceutical industry. Because it is voluntary and written by an industry that should receive oversight from objective sources, this code remains broad with no penalties or recourse for violations

¹ www.phrma.org/files/PhRMA%20Code.pdf

OIG Compliance Program Guidance

The Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) issued *Publication of the OIG Compliance Program Guidance for Hospitals*,² and *OIG Supplemental Compliance Program Guidance for Hospitals*³ which recommend and model internal compliance programs in hospitals. Other guidance documents were issued for pharmaceutical manufacturers and small-group physician practices. None of these are mandatory. Infant formula companies are specifically mentioned

Health Insurance Portability and Accountability Act (HIPAA)⁴

The privacy rule with HIPAA defines marketing as “making a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.” If the communication is “marketing” then the communication can occur only if the covered entity first obtains an individual’s “authorization.” HIPAA however goes on to exempt certain situations from the requirement of prior authorization, even if it is marketing, if it is in the form of a face-to-face communication made by a covered entity to an individual, or a promotional gift of nominal value provided by the covered entity. No prior authorization is necessary “when a hospital provides a free package of formula and other baby

products to new mothers as they leave the maternity ward.” This means that even though discharge bags are a form of marketing, mothers do not have to be informed that the “gift” is actually an inducement to purchase the formula following discharge. Mothers may think that it is a health provider recommendation rather than a sales pitch.

² www.oig.hhs.gov/authorities/docs/cpghosp.pdf

³ www.oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf

⁴ www.hhs.gov/ocr/hipaa/guidelines/marketing.pdf