

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 nothing 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 second hand 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’s suboptimal breastfeeding rates cost our economy \$13 billion a year in excess costs, and 911 excess preventable deaths, nearly all of which are in infants and children.

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 hospital Corporate Compliance policy, as well as Office of Inspector General, 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: Our mothers want these bags, and they should be allowed to have them if they want.

Counter: Research from the CDC shows that 60% of women do not meet their own breastfeeding goals. The bags undermine women’s ability to meet their breastfeeding goals because they negatively impact breastfeeding. For mothers who choose to formula feed, the bags encourage brand loyalty to the pricey name-brand that is advertised, costing families over \$700 more a year than store brand formula. Mothers can easily get the samples directly by contacting the formula companies, with contact information on the can. The hospital should not be distributing marketing materials.

Hospital Assertion: Our nurses feel good about giving free gifts to our patients.

Counter: Formula companies take advantage of the good will of health professionals. In fact, health care professionals are being consciously co-opted by formula companies. The text of an old employee manual for Ross’ Similac (Abbott) was revealed in a Texas lawsuit:

“Never underestimate the importance of nurses. If they are sold and serviced properly, they can be strong allies. A nurse who supports Ross is like an extra salesperson.” (Abbott v. Segura, 1995)
Health care professionals do not want be manipulated.

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 second week postpartum. Formula samples in the discharge bags may undermine mothers decision to exclusively breastfeed during the vulnerable time when they are transitioning home. Exclusive breastfeeding confers the greatest benefits to mothers and babies.

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Conclusion:

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

The Centers for Disease Control and Prevention and the American Academy of Pediatrics both note that distribution of commercial discharge packs negatively impacts breastfeeding. The AAP acknowledges the health effects of breastfeeding on prevention of multiple diseases and conditions, including type 1 diabetes, obesity, infections, and necrotizing enterocolitis.

American Academy of Pediatrics, Section on Breastfeeding. Breastfeeding and Use of Human Milk, Pediatrics; originally published online February 27, 2012.

Centers for Disease Control and Prevention. Breastfeeding-related maternity practices at hospitals and birth centers— United States, 2007. MMWR Morb Mortal Wkly Rep. 2008;57(23):621–625

According to the Infant Feeding Practices Survey II from the Centers for Disease Control and Prevention, 60% of women do not meet their own breastfeeding goals.
http://www.cdc.gov/breastfeeding/data/infant_feeding.htm

The US's suboptimal breastfeeding rates costs the US economy \$13 billion per year (2007 dollars), \$2.2 billion of which are direct health costs. Bartick M, Reinhold A. The Burden of Suboptimal Breastfeeding in the United States: A Pediatric Cost Analysis. Pediatrics 2010; 125:5 e1048-e1056; published ahead of print April 5, 2010, doi:10.1542/peds.2009-1616

It is a stated goal of US Public Health Policy to achieve breastfeeding initiation rates of 81.9%, with 46.2% exclusively breastfeeding at 3 months. U.S. Dept. of Health and Human Services, Healthy People 2020 Breastfeeding Objectives.

The CDC now monitors the percentage of breastfed infants receiving formula before 2 days of age. CDC Breastfeeding Report Card 2012.

“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, Landefeld S, 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>

Brand name formula costs a family an average of \$700 more a year compared to store brand. Oliveira V. et al, WIC and the retail price of infant formula. U.S. Dept. of Agriculture. Food Assistance and Nutrition Research Report Number 39, 2004.

Discharge bags undermine breastfeeding. Donnelly et al. Commercial hospital discharge packs for breastfeeding women, 2000. Cochrane Database Systematic Review.

The U.S. Surgeon General states that “marketing of infant formula should be conducted in a way that minimizes its impact on exclusive breastfeeding.” As part of this, an action items states, “Ensure that health care clinicians do not serve as advertisers for infant formula.” U.S. Dept of Health and Human Services. The Surgeon General's Call to Action to Support Breastfeeding, 2011.

Ban the Bags Action Ideas

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 below 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 physician or requested by the mother. 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 facilitated a project called The Discharge Pack Initiative that traded 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
<http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/marketing.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 esec@os.dhhs.gov

Ask your purchasing department if your hospital has a contract or agreement 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 and Risk Management departments 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

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.

More and more research articles continue to confirm the deleterious effects that industry sponsored discharge bags have on breastfeeding.

Improving Maternity Care Practices in New York: Answering the Surgeon General's Call to Action. Hisgen S, Dennison BA, Fitzpatrick E, Waniewski PA. *Breastfeed Med.* 2012 Oct;7:337-42.

Removal of industry-sponsored formula sample packs from the hospital: does it make a difference? Feldman-Winter L, Grossman X, Palaniappan A, Kadokura E, Hunter K, Milcarek B, Merewood A. *J Hum Lact.* 2012 Aug;28(3):380-8

Distribution of industry-sponsored diaper bags from maternity facilities in Massachusetts. Philipp BL, Frank DA, Humphreys RJ, Jean-Marie S. *Breastfeed Med.* 2007 Dec;2(4):255-60.

Marketing infant formula through hospitals: the impact of commercial hospital discharge packs on breastfeeding. Rosenberg KD, Eastham CA, Kasehagen LJ, Sandoval AP. *Am J Public Health.* 2008 Feb;98(2):290-5.

Trends in US hospital distribution of industry-sponsored infant formula sample packs. Sadacharan R, Grossman X, Sanchez E, Merewood A. *Pediatrics.* 2011 Oct;128(4):702-5

US hospitals violate WHO policy on the distribution of formula sample packs: results of a national survey. Merewood A, Grossman X, Cook J, Sadacharan R, Singleton M, Peters K, Navidi T. *J Hum Lact.* 2010 Nov;26(4):363-7.

FACT SHEET ON FORMULA MARKETING IN HOSPITALS

\$\$\$ 80 % of infant formula in the United States comes from big pharmaceutical companies. When hospitals hand out discharge bags 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 2010 study shows that the US's poor breastfeeding rates cost our economy \$13 billion a year, and 911 in preventable excess deaths.

\$\$\$ 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.

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



\$700

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.

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Massachusetts
Breastfeeding
Coalition

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* Oliveira et al. *WIC and the Retail Price of Infant Formula*. *Food Assistance and Nutrition Research Report No. (FANRR39-1)*. June 2004.

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

Suggested strategies to help rid hospitals of industry discharge bags

1. Many hospitals are not influenced by appeals that formula bag distribution will adversely affect breastfeeding. Therefore, more success has been obtained when using the approach that such relationships with pharmaceutical or other industries is unethical, especially in light of the increased scrutiny being seen between pharmaceutical companies and healthcare providers. Also helpful has been the approach that hospitals are actually acting as a marketing conduit and agent for infant formula manufacturers and should be marketing their own services rather than a potentially harmful product.
2. Contact the Corporate Compliance Department of the hospital and ask if the relationship between the hospital and the formula company is in compliance with the rules that all other departments and units must follow. Ask if employees are permitted to accept gifts from vendors in exchange for recommending the use of their product.
3. Contact the Risk Management Department and inform them that there are no stock control measures for the distribution of formula gift bags. If there is a recall, the hospital has no way of informing their patients that they were given a defective or dangerous product. Hospitals do not record the lot number of the gift bag and the contact information of the mother to whom it was given. This could make the hospital liable for damages to the infant if he is sickened by a defective product. Also, nurses do not teach mothers how to prepare and use the product in the gift bag, presenting a danger that the product will be misused.
4. The maternity unit is the only unit in the hospital that gives patients potentially harmful gifts. Contact the hospital chief executive officer (CEO) and inform him/her that this is a potentially hazardous practice

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 *Cronbacter sakazakii* (formerly known as *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