



UNITED STATES  
 CONSUMER PRODUCT SAFETY COMMISSION  
 4330 EAST WEST HIGHWAY  
 BETHESDA, MD 20814

**VOTE SHEET**

Date: **JAN 24 2008**

TO : The Commission  
 Todd A. Stevenson, Secretary

THROUGH: Patricia Semple, Executive Director *P.S.*  
 Lowell F. Martin, Acting General Counsel *L.F. Martin*  
 Jeffrey R. Williams, Assistant General Counsel *J.R. Williams*

FROM : Hyun S Kim, Attorney *HSK*

SUBJECT : Regulatory Alternatives to Address Boston Billows' Request for Exemption from Ban on Infant Cushions/Pillows and Other Aspects of the Open Rulemaking on Infant Cushions/Pillows Ballot Vote Due January 29, 2008

Attached is a briefing package from the staff discussing options to address Boston Billows' request for an exemption from the ban on infant cushions/pillows and to address the remaining aspects of the open rulemaking on infant cushions/pillows. The Commission could direct the Office of General Counsel ("OGC") to prepare Federal Register notices based on one of the alternatives presented by the staff.

Please indicate your votes.

I. Boston Billows Exemption

1. Direct OGC to prepare an NPR proposing an exemption for the Boston Billow nursing pillow and substantially similar nursing pillows.

\_\_\_\_\_  
 Signature

\_\_\_\_\_  
 Date

2. Do not proceed with the Boston Billows exemption proceeding and instruct OGC to prepare a Federal Register notice accordingly.

\_\_\_\_\_  
 Signature

\_\_\_\_\_  
 Date

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*1/24/08*  
*[Signature]*

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II. General infant cushion/pillow rulemaking other than Boston Billows issue.

1. Direct OGC to prepare a Federal Register notice terminating the rulemaking.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

2. Take other action (please specify):

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date



# INFANT CUSHION BRIEFING PACKAGE

For further information contact:

Suad Wanna-Nakamura, Ph.D.  
Project Manager  
Directorate for Health Sciences  
Consumer Product Safety Commission  
(301) 504-7252

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## EXECUTIVE SUMMARY

On September 1, 2004, the U.S. Consumer Product Safety Commission (CPSC) announced a recall of the Boston Billow Nursing Pillow because at the time, CPSC staff determined that it met the legal definition of an infant cushion and was subject to the ban on infant pillows. Currently, the rule bans any article known as an "infant cushion" or "infant pillow" which has the following characteristics: (1) a flexible fabric covering; (2) loosely filled with a granular material such as polystyrene beads or pellets; (3) easily flattened; (4) capable of conforming to the body or face of an infant; and (5) intended or promoted for use by children under one year of age.

On September 15, 2005, the Commission docketed a petition from Boston Billows, Inc. (HP 05-1) asking the Commission to amend 16 CFR § 1500.18(a)(16)(i)(A)-(E) to provide an exception to the ban when the product is specifically designed, intended and promoted for mothers to use when breastfeeding and when the product is requested by a pediatrician or a Board Certified Lactation Consultant (BCLC). On July 10, 2006, the Commission voted to grant the petition and directed the staff to begin rulemaking to examine all aspects of these types of products.

The Commission published an advance notice of proposed rulemaking (ANPR) and initiated a rulemaking proceeding. The ANPR requested comments on the following regulatory alternatives: 1) amend the regulation to allow exemption for certain infant cushions/pillows and pillow-like products; 2) amend the regulation to delete, revise, or add criteria to the ban; 3) leave the existing regulation unchanged, or; 4) repeal the existing regulation. The ANPR also requested comments on other possible ways to address the issues. The public comment period closed on November 27, 2006.

Staff reviewed the human factors of nursing pillow use and evaluated the incident data related to infant deaths associated with all pillows (including nursing pillows). According to Human Factors staff, nursing pillows perform a related but different function than infant cushions. They are also generally a different shape from the banned infant cushion. The nursing pillow gives a moldable but firm support surface to enhance comfort for the nursing mother and to help position the infant during nursing. While the nursing pillow's tubular shape does not lend itself to being used as a small mattress as the banned infant cushions were used, it is foreseeable, however, that caregivers may use/misuse the nursing pillow to prop babies or place an infant to sleep on the products. This increases the likelihood that these products will be in an infant's sleep environment. While the malleability of a nursing pillow may make it more adjustable for the nursing mother, it simultaneously makes the pillow more hazardous for the infant if used in the infant sleep environment (it can easily conform to an infant's face).

Health Sciences staff review of the CPSC data from January 1992 through June 2007 identified 484 infant deaths associated with cushions or pillows. One death

in 2001 involved a polyester filled nursing pillow (not within the definition of a banned infant cushion) and occurred when the infant was placed to sleep on his stomach in a playpen with his head resting on the nursing pillow. In the vast majority of the 484 deaths, the infants were found in the prone position, face down on a pillow/cushion. The data are insufficient to determine if there is any increased risk of infant death due to a specific type of pillow or filling, however staff notes that it is the softness and malleability of the pillows that are the primary risk factors of infant suffocation. Health Sciences staff believes that when a nursing pillow is used for its intended purpose (nursing), the likelihood of infant suffocation on a nursing pillow is very low. However, the comparative risk of the petitioner's nursing pillow and alternative nursing pillows, if used in the infant sleep environment, is not known (e.g., if the product was to be used as a pillow for propping infants up during sleep or when an infant accidentally falls asleep on the pillow during activities such as "tummy time").

Health Sciences staff notes that the number of infant suffocation deaths on pillows and cushions is high and has not decreased since 1992, unlike the decline in the number of SIDS deaths. As a result, staff discusses focusing on information for caregivers to increase awareness about the dangers of all types of pillows and cushions in an infant's sleep environment and the need to place infants to sleep on their backs. In addition, Human Factors staff discusses the use of nursing pillow warning labels and possible future work with ASTM on a product warning label for nursing pillows. Staff will consider pursuing these activities during the FY 2008 mid-year review or for future operating plans.

In light of the ongoing risks posed by infant pillows/cushions when used in the sleep environment, staff believes that there is no justification for repealing the ban on infant pillows/cushions at this time. Moreover, after review of the comments, incident reports and other available information, staff concluded that there was insufficient data or product information on other infant cushions or pillow-like products, other than the Boston Billow Nursing Pillow, to proceed with further rulemaking on those products at this time. Accordingly, because staff has product information related to Boston Billows' specific request for an exemption from the ban, staff's proposed options in this briefing package are limited to either exempting the Boston Billow Nursing Pillow and substantially similar nursing pillows, or not exempting these products.



United States  
CONSUMER PRODUCT SAFETY COMMISSION  
Washington, D.C. 20207

JAN 24 2008

MEMORANDUM

To : The Commission  
Todd A. Stevenson, Secretary

Through : Lowell Martin, Acting General Counsel  
Patricia Semple, Executive Director

From : Jay Howell, Acting Assistant Executive Director,  
Office of Hazard Identification and Reduction  
Suad Wanna-Nakamura, PhD, Project Manager for Infant Cushion  
Project, Directorate for Health Sciences

Subject : Staff Response to Advance Notice of Proposed Rulemaking on  
Infant Pillows

This briefing package presents the staff's analysis of comments received in response to the advance notice of proposed rulemaking (ANPR)<sup>1</sup> on infant pillows published in 2006 and provides the following options for consideration by the Commission: (1) exempt Boston Billow Nursing Pillow and substantially similar nursing pillows from the infant cushion rule and otherwise terminate the rulemaking and (2) do not exempt Boston Billow Nursing Pillow from the infant cushion rule and terminate the rulemaking.

I. Background:

On September 1, 2004, the U.S. Consumer Product Safety Commission (CPSC) announced a recall of the Boston Billow Nursing Pillow because at the time, CPSC staff determined that it met the legal definition of an infant cushion and was subject to the ban on infant pillows. Currently, the rule bans any article known as an "infant cushion" or "infant pillow" which has the following characteristics: (1) a flexible fabric covering; (2) loosely filled with a granular material such as polystyrene beads or pellets; (3) easily flattened; (4) capable of conforming to the body or face of an infant; and (5) intended or promoted for use by children under one year of age<sup>2</sup>. However, because of the beneficial uses for the Boston Billow Nursing Pillow in hospitals and the supervision under which it would be used, the CPSC's Office of Compliance exercised enforcement

<sup>1</sup> 71 FR 56418 (Sept.27, 2006).

<sup>2</sup> 16 C.F.R. 1500.18 (a) (16) (i).

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discretion to allow nursing pillows with a wipeable cover, if sales were limited to hospitals for use only in a supervised setting<sup>3</sup>.

On September 15, 2005, the Commission docketed a petition from Boston Billows, Inc. (HP 05-1) asking the Commission to amend 16 CFR § 1500.18(a)(16)(i)(A)-(E) to provide an exception to the ban when the product is specifically designed, intended and promoted for mothers to use when breastfeeding and when the product is requested by a pediatrician or a Board Certified Lactation Consultant<sup>4</sup> (BCLC). On July 10, 2006, the Commission voted to grant the petition and directed the staff to begin rulemaking to examine all aspects of these types of products.

On September 27, 2006, the Commission published an advance notice of proposed rulemaking (ANPR)<sup>5</sup> and initiated a rulemaking proceeding. The ANPR requested comments on the following regulatory alternatives: 1) amend the regulation to allow exemption for certain infant cushions/pillows and pillow-like products; 2) amend the regulation to delete, revise, or add criteria to the ban; 3) leave the existing regulation unchanged; or: 4) repeal the existing regulation. The ANPR also requested comments on other possible ways to address the issues. The public comment period closed on November 27, 2006.

In light of the ongoing risks posed by infant pillows/cushions when used in the sleep environment, staff believes that there is no justification for repealing the ban on infant pillows/cushions at this time. Moreover, after review of the comments, incident reports and other available information, staff concluded that there was insufficient data or product information on infant cushions or pillow-like products, other than the Boston Billow Nursing Pillow, to proceed with further rulemaking on those products at this time. Accordingly, because staff has product information related to Boston Billows' specific request for an exemption from the ban, staff's proposed options in this briefing package are limited to either exempting the Boston Billow Nursing Pillow and substantially similar nursing pillows, or not exempting these products.

## **II. Staff Evaluation:**

### **A. Product Description and Market Information (Tab A)**

Nursing pillows come in a variety of shapes and fillings including crescent (C-shaped), rectangular, and kidney shaped, with the C-shape pillow being the most common. The fillings of nursing pillows currently in the marketplace include: polyester, memory foam, and air. Most have removable/washable zipper-closed covers that are made of either cotton or a polyester/cotton blend. Some nursing pillows have additional features such as adjustable back straps for the mother, back support for the infant, and side pockets. While the petitioner's nursing pillow is similar to the other nursing pillows in the marketplace, it differs from those products because of its granular bead filling.

<sup>3</sup> On February 27, 2004, the staff of the Office of Compliance allowed the firm to sell their product for use in a supervised hospital setting.

<sup>4</sup> Petition HP 05-1. The petition was docketed on September 15, 2005 under the Federal Hazard Substances Act (FHSA). 16 C.F.R. 1500.18 (a)(16)(i)(A)-(E).

<sup>5</sup> 71 FR 56418 (Sept.27, 2006).



Nursing pillows are widely available. They are sold in department stores, specialty stores, on the internet, and on the secondary market. Based on an internet search for various nursing pillow brands and manufacturers, it appears that there are over 15 firms that manufacture nursing pillows and a few of these firms account for the majority of nursing pillow sales.

Nursing pillows are typically sold as individual items. For pillows with removable covers, customers typically purchase at least one additional replacement/back-up cover. Prices for nursing pillows vary depending on brand and additional features, but generally range from about \$20 to \$45 each.

Some substitutes are available. For example, a nursing sling can be used when nursing and its pricing point is similar to that of a nursing pillow. Before nursing pillows were sold, mothers used quilts, blankets, standard pillows, rocking chairs, or nothing at all to support their arms and the baby when breastfeeding.

As described in Tab A, nursing pillows may be used by about 1.8 million mothers every year. Typically, they may be used with a child for about 6 months. Assuming that each pillow is used for about two children before they are discarded, annual sales may amount to about 900,000 nursing pillows annually.

## **B. Human Factors Assessment (Tab B)**

The Human Factors staff memorandum (Tab B) describes the human factors of infant cushion and nursing pillow use.

According to the Human Factors staff, the infant beanbag cushions which are currently banned were designed in the 1980's to elevate infants in car seats or strollers to enhance fit and comfort. They looked like small, rectangular mattresses. A foreseeable use of infant cushions was as a sleeping surface for infants. The size and shape of infant cushions, essentially bead-filled pillows or miniature mattresses, readily allowed this. The recommended sleep position for infants at the time these products were sold was the prone position (on the stomach). The infant beanbag cushions presented a suffocation hazard when infants were placed to sleep on them in the prone position.

Nursing pillows perform a related but different function than infant cushions. Learning how to breastfeed can be a difficult experience. The often exhausted, nervous nursing mother manipulates and coaxes the sometimes uncooperative infant to the right position to get a proper "latch", the seal that lets the infant drink easily without hurting the mother. Mothers sometimes find that training their child to nurse is an emotionally frustrating and physically painful experience. Given the difficulties, physical and social support of the mother are extremely important for successful breastfeeding. Nursing pillows help position the infant for achieving a good latch and provide a place for the mother to rest her arms while breastfeeding. Having a malleable and supportive pillow, blanket, or other item helps this process every time a mother nurses, which is 8 to 12 times a day, around the clock. The nursing pillow gives a moldable but firm support

surface to enhance comfort during extended periods when changing position is difficult because the mother is still in pain from giving birth or just afraid to disturb the infant's latch.

It is foreseeable that caregivers may use/misuse the nursing pillow to prop babies or place an infant to sleep on the product. This increases the likelihood that these products will be in an infant's sleep environment. Highly malleable products that can easily conform to an infant's face are suffocation hazards. While the malleability of a nursing pillow may make it more adjustable for the nursing mother, it simultaneously makes the pillow more hazardous for an infant if used in the infant sleep environment.

### **C. Summary of Incident Data/Health Sciences Evaluation (Tabs C and D)**

Since the Commission's infant cushion ban, there have been no reported deaths associated with infant cushions. This is not surprising since these products are no longer on the market. However, there continues to be a significant number of infant deaths associated with a variety of pillow types (Figure 2, Tab D). The data retrieved from the CPSC databases for the period from January 1992 through June 2007 (DTHS<sup>6</sup> and INDP<sup>7</sup> files) identified a total of 484 infant deaths associated with pillows or cushions. One death in 2001, associated with a polyester filled nursing pillow, (not within the definition of banned infant cushion) occurred when the infant was placed to sleep on his stomach in a playpen with his head resting on the nursing pillow. The infant was found face down on the nursing pillow.

In the vast majority of the 484 deaths, the infants were found in the prone position, face down on a pillow/cushion. A variety of pillow types and cushions with different types of filling including foam, feathers, and polyester were involved in the incidents. The majority of incidents involved adult pillows and sofa cushions, which possess many of the same characteristics as the bean bag cushions. These products have soft covers and flexible fillings that can conform to the face. These are two intrinsic properties of pillows. A quarter of the deaths occurred in infant cribs, bassinets, cradles, and playpens, while the rest occurred outside the normal infant sleep areas, such as on adult beds, on sofas, or on the floor. As with the infant bean bag cushion, these pillows and cushions can cause death by suffocation/asphyxiation when an infant is face down on them.

Unlike the decrease in Sudden Infant Death Syndrome<sup>8</sup> (SIDS) deaths, there has not been a consistent decrease in the infant deaths associated with pillows and cushions (Figure 2, Tab D). The data are insufficient to determine if there is any increased risk of infant death due to any specific type of pillow or cushion filling, but rather, staff notes

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<sup>6</sup> The DTHS file includes information from death certificates purchased by CPSC from all 50 states and the District of Columbia. The information provided in this database is anecdotal, but is useful in describing features of a pattern of injury.

<sup>7</sup> The INDP file contains data from follow-back investigations reported by CPSC staff. These investigations are done in an effort to gather detailed information on a death or injury associated with a particular consumer product.

<sup>8</sup> SIDS is defined as the sudden death of an infant under one year of age, whose cause remains unexplained after a thorough case investigation, including performance of a complete autopsy, examination of the death scene, and review of the clinical history, i.e., it is a diagnosis based on exclusions (*Willinger et al, 1991*).

that it is the softness and malleability which are inherent properties of pillows that are the primary risk factors. Most significantly, the greatest common risk factor comes from the observation that the infants were found in the prone position in the majority of the 484 deaths. Unlike adults, the limited physical and developmental capabilities of infants render them susceptible to danger from suffocation in certain sleeping environments. Physiological abnormalities and delays in the development of vital systems can further hamper an infant's ability to react to a hazardous condition. Infants who are not placed to sleep according to the Back to Sleep recommendation, in the supine position, are especially at risk for suffocation on any type of pillow, regardless of the type of filling.

Based on the CPSC epidemiological data (Tab C), Health Sciences staff believes that infants placed to sleep prone on any pillows including nursing pillows are at risk for suffocation, regardless of size, type, shape of pillow or filling. However, it is not possible to compare the risk of suffocation among different types of pillow fillings. It is not known if some are more hazardous than others.

Thus, despite the proven effectiveness of the recommendation to place infants to sleep on their backs in reducing the incidence of SIDS, there remain a significant number of caregivers who continue to place infants to sleep on their stomachs, (i.e., in the prone position). Increased compliance with the recommendation from the Back to Sleep campaign for placing infants to sleep on their backs (i.e., in the supine position), as well as continued vigilance in ensuring a safe sleeping environment, could potentially have significant benefits in reducing the risk of infant suffocation deaths caused by adult pillows, sofa cushions, and nursing pillows, as well as further reducing SIDS.

#### **D. Labeling and Information and Education Campaign (discussed in Tabs B and D)**

CPSC staff supports the development of a warning label and continuing information and education messages as strategies to reduce the risk of suffocation associated with nursing pillows.

Human Factors staff considered the use of warning labels on nursing pillows and determined the use of warning labels may result in some benefits by reducing the risk of suffocation hazards.

Currently there are ASTM product warning label requirements for infant bedding and related accessories including bumper pads, decorator pillows, diaper stackers, and fitted sheets.<sup>9</sup> However, nursing pillows fall outside of the scope of that standard. If warning labels are considered for use as an injury prevention strategy, Human Factors staff recommends the following text:

**WARNING: SUFFOCATION HAZARD**  
This product can suffocate your infant by molding to the face.  
Remove all pillows from infant sleeping areas.

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<sup>9</sup> ASTM F 1917 Standard Consumer Safety Specification for Infant Bedding and Related Accessories Product/Package Marking 7.2, 7.23-7.3.1

In addition to the use of warning labels on nursing pillows, CPSC staff also considered the benefits of continuing CPSC's ongoing messaging on a safe infant sleep environment, with an emphasis on the hazards associated with soft pillows. CPSC staff believes that a comprehensive safety campaign to increase awareness of the dangers of all types of pillows and cushions in an infant's sleep environment could be beneficial to infant caregivers. The campaign's key message would be that "Babies and Pillows are a Dangerous Mix" and that placing babies to sleep with such products, especially in the prone position, puts them at greater risk of suffocation and death. An added benefit of these messages could be an increase in the number of infants placed to sleep in a supine position (on the back), and could therefore also result in further decreases in SIDS deaths.

Staff will consider recommending these activities (pursuing labeling and an information and education campaign) during mid year review or when developing future operating plans.

## **F. Economic Analysis (Tab A)**

In addition to analyzing market information, the Directorate for Economic Analysis staff memorandum (Tab A) evaluated the costs and benefits of exempting the petitioner's nursing pillow from the ban on infant cushions.

### **1. Costs of an Exemption**

The cost of granting an exemption for the petitioner's nursing pillow would be the potential increase in the relative risk of suffocation, when compared to the risk associated with nursing pillows already in use. When used for its intended purpose – nursing – the risk associated with any nursing pillow, including the Boston Billow Nursing Pillow, is very low.

The main risk associated with nursing pillows arises if the pillows enter the sleeping environment; suffocation can occur if children fall asleep on them in the prone position with their head on the pillow. CPSC staff is aware of one death involving a nursing pillow. That death, which occurred in 2001, involved a nursing pillow, which is not a banned hazardous product subject to the CPSC's infant cushion rule. Since 2002, based on our estimates of about 900,000 nursing pillows sold annually, more than 5 million nursing pillows have been purchased by consumers without any additional known suffocation incidents.<sup>10</sup>

According to Health Sciences staff, all soft pillows present a suffocation hazard when used in an infant's sleeping environment. The available suffocation data do not reveal any increased risk of infant death due to any specific type of pillow or cushion filling although highly malleable and soft products can easily conform to an infant's face and

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<sup>10</sup> Prior to the 2004 Boston Billows recall, the Boston Billow Nursing Pillow had reportedly been produced and sold in the U.S. for about five years. With the exception of the Boston Billow Nursing Pillow, the staff is unaware of any other nursing pillows filled with granular material.

pose a suffocation hazard. Since the comparative risk based on filling materials is unknown, it is not possible to quantify the difference in risk, if any, between the petitioner's nursing pillow and nursing pillows now in the marketplace. If we assume the risks are similar, there would be no reason to expect that exempting the petitioner's nursing pillow and substantially similar nursing pillows would materially affect the risk of infant suffocation. This is because purchases of the petitioner's nursing pillow would, for the most part, be substituted for other types of nursing pillows, which would pose a similar risk. If the risks associated with the petitioner's nursing pillow are higher or lower than the risks for other nursing pillows currently available, then exempting that petitioner's nursing pillow would increase or decrease the risk of infant suffocation.

If the petitioner's nursing pillow proves popular with consumers because they find it more useful than other nursing pillows or nursing alternatives, it is possible that aggregate sales of nursing pillows could increase above current levels. Any potential increase in risk associated with increased nursing pillow use would in part be offset by a decrease in risk that results from a decrease in the use of alternative and possibly less safe nursing products. However, as described at Tab A, the potential for a measurable increase in aggregate nursing pillow sales is limited.

## **2. Benefits of an Exemption**

Exempting the petitioner's nursing pillow from the infant cushion rule would increase consumer choice by allowing consumers an alternative to the nursing pillows already in the marketplace. The primary benefits would be the increase in the functional value of the pillows that some consumers might obtain from the use of the petitioner's nursing pillow, rather than an alternative.

According to the petitioner, because of its granular filling, the Boston Billow Nursing Pillow is flexible and moldable, which allows for proper infant positioning and enables mothers to nurse immediately after a C-section birth with no discomfort.<sup>11</sup> This and other assertions of quality differences are supported by comments from lactation consultants and other medical professionals received in response to the petition docketed in September 2005 and the September 2006 ANPR.

## **III. Public Comments (Tab E) and Staff Response:**

The comment period closed on November 27, 2006 during which time the Commission received nine comments. All nine comments were in favor of exempting the Boston Billow Nursing Pillow from the regulation. Copies of all comments are provided in Tab E and are also available from the Office of the Secretary.

**Comments:** A comment was received from Mr. Erik Skoug, President of Boston Billows, Inc. (original petitioner) reiterating his rationale behind the requested exemption to Criteria #5 of the federal regulation to ban infant cushions or infant pillows; arguing

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<sup>11</sup> According to Human Factors staff, these characteristics can also make a pillow *more* of a suffocation risk if used in an infant's sleep environment.

that the product is specifically designed, intended, and promoted for use by mothers when breastfeeding.

There were also seven letters/e-mails of support submitted by registered nurses (RN) who are also BCLC's. The letters/e-mails supporting an exemption for the Boston Billow Nursing Pillow related to the significant benefits of the granular filled pillow because of its ability to conform to the mother's body regardless of her weight or size. They also restated previous comments to CPSC that premature babies have poor muscle tone and are unable to hold their heads upright. They opined that the nursing pillow design helps support the mother's arm and raises the infant's head to breast level during nursing. The nursing pillow is also beneficial, in their view, especially to mothers who delivered by Caesarian-section, had post-delivery surgery, or were nursing premature infants. The group of BCLC's asserts that the product is a nursing aid for breastfeeding mothers and is not intended, and is unlikely to be used, as a sleeping surface.

Another commenter, Dr. J. Bruce Beckwith, a pediatric pathologist, restated his opinion that the product has been "shown to be a popular means of encouraging and facilitating breast feeding" and that the product is not a device intended for use during prone sleeping. He suggested that because of the design it would be difficult, if not impossible, for an infant to assume a sleeping position on the product.

**Response:** Human Factors (HF) staff (Tab B) agrees that all types of nursing pillows are beneficial in positioning the infant during breastfeeding and at the same time provide a place for the mother to rest her arms while breastfeeding. Because of the recognized beneficial uses for the Boston Billow Nursing Pillow, the Office of Compliance allowed sale and use of this product, but only in a supervised hospital setting.

HF staff states that nursing pillows, in general, perform a related, but different function than infant cushions. They are also generally a different shape from the banned infant cushions. Nursing pillows are designed to encircle the waist of a nursing mother to support her arms and the infant's body and head. Usually filled with soft fibers like a pillow, the common design is a crescent C-shape. HF staff agrees that a nursing pillow's tubular shape does not lend itself to being used as a small mattress, as the banned infant cushions were used. However, they can serve as a pillow or a nest, supporting a child's head and/or torso while they play. It is not uncommon for firms to advertise that a nursing pillow can also be used for additional activities including propping babies up and providing an elevated surface for "tummy time"<sup>12</sup> (when infants are awake).

When used as a nursing pillow, the likelihood of infant suffocation is very low (HS memo, Tab D). At this time, the comparative risk of the petitioner's nursing pillow and alternative nursing pillows is not known if the product was to be used as a pillow for

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<sup>12</sup> Human Factors of Infant Cushion and Nursing Pillow Use, staff memo Midgett, Jonathan D. 2008 (Tab B)

propping infants up during sleep or when an infant accidentally falls asleep on the pillow during activities such as “tummy time”.

#### **IV. Options:**

The CPSC staff considered several alternatives to address the issues identified with infant cushions/pillows and pillow-like products. After consideration of technical information, the staff believes that the following options best address the issues presented.

##### **1. Exempt Boston Billow Nursing Pillow and substantially similar nursing pillows from the infant cushion rule, and otherwise terminate the rulemaking.**

If the Commission believes that the Boston Billow Nursing Pillow and substantially similar nursing pillows differ in design and primary use from the infant cushions that are banned, and the foregoing analysis supports an exemption, it could instruct the staff to prepare a notice of proposed rulemaking (NPR) proposing an exemption and otherwise terminate the rulemaking.

##### **2. Do not exempt Boston Billow Nursing Pillow from the infant cushion rule, and terminate the rulemaking.**

If the Commission believes that the Boston Billow Nursing Pillow does not differ in design and primary use from the infant cushions that are banned, and the foregoing analysis does not support an exemption, the Commission can vote to deny the exemption and terminate the rulemaking.

**TAB A**





UNITED STATES  
CONSUMER PRODUCT SAFETY COMMISSION  
WASHINGTON, DC 20207

**Memorandum**

Date: 21 JAN 2006

TO : Suad Wanna-Nakamura, Ph.D., Infant Cushions Project Manager

THROUGH: Gregory B. Rodgers, Ph.D., Associate Executive Director, Directorate for  
Economic Analysis *GBR*  
Deborah V. Aiken, Ph.D., Senior Staff Coordinator, *DVA*  
Directorate for Economic Analysis

FROM : John W. Peternel, Economist, Directorate for Economic Analysis *JWP*

SUBJECT : Preliminary Economic Analysis; Nursing Pillows

Attached is a preliminary economic analysis of the nursing pillow industry. The analysis contains background information on the nursing pillow market in general and an evaluation of the costs and benefits of exempting the Boston Billow Nursing Pillow from the ban on infant cushions. The analysis also considers regulatory alternatives including an industry-wide labeling requirement.

**Preliminary Economic Analysis: Nursing Pillows**

**January 2008**

**John William Peternel  
Directorate for Economic Analysis**

## Preliminary Economic Analysis: Nursing Pillows

### I. Introduction

In 1992, CPSC staff investigated 37 incidents, occurring between 1985 and 1992 that were associated with the use of infant bean bag cushions; 35 were fatal, one resulted in brain damage, and one did not result in injury. In all incidents where the infant's position could be determined, the infant was found sleeping in the prone position. In all but two of the incidents, the infant was less than four months of age. Subsequently, the Commission banned any article designed as an "infant cushion" or "infant pillow" having the following characteristics: (1) a flexible fabric covering, (2) loosely filled with granular material, including but not limited to polystyrene beads or pellets, (3) easily flattened, (4) capable of conforming to the body or face of an infant, and (5) intended for use by children under one year of age.

On January 23, 2004, the Office of Compliance determined that the infant nursing pillow product, the Boston Billow Nursing Pillow, met the definition of an infant cushion and was subject to the ban on infant pillows.<sup>1</sup> While the CPSC's compliance staff notified Boston Billows, Inc. that the staff would not stop the firm from selling the Boston Billow Nursing Pillow for use in a supervised hospital setting, the pillows distributed to the public were subsequently recalled and removed from the marketplace.<sup>2</sup>

In 2005, Boston Billows, Inc. petitioned (HP 05-1) the Commission to exempt its product from the ban on infant cushions, arguing that its product is specifically designed, intended, and promoted for use by mothers when breastfeeding.<sup>3</sup> Subsequently, the Commission initiated a rulemaking proceeding by issuing an Advanced Notice of Proposed Rulemaking (ANPR) that could result in an amendment to the ban on infant cushions/pillows.<sup>4</sup>

The purpose of this memo is to provide background information on the market for nursing pillows, evaluate the costs and benefits of exempting the Boston Billow Nursing Pillow from the ban on infant cushions, and to examine regulatory alternatives.

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<sup>1</sup> Federal Hazard Substances Act (FHSA). 16 C.F.R. 1500.18(a) (16) (i) (A) – (E).

<sup>2</sup> For exposition purposes, the term Boston Billow Nursing Pillow refers to all nursing pillows that Boston Billows, Inc. produces, including the Boston Billow Nursing Pillow as well as similar granularly filled nursing pillows.

<sup>3</sup> Petition HP 05-1: The petition was docketed on September 15, 2005 under the Federal Hazard Substances Act (FHSA). 16 C.F.R. 1500.18(a) (16) (i) (A) – (E)

<sup>4</sup> Federal Register: September 27, 2006 (Volume 71, Number 187) Page 56418-56420.

## II. Product and Market Information

A nursing pillow is a pillow whose primary function is to assist in breastfeeding. According to Human Factors staff, a nursing pillow help position infants for achieving a good latch and provide a place for mothers to rest their arms while breastfeeding. Some nursing pillows are marketed as having additional functional uses including propping babies and tummy time.<sup>5</sup>

Nursing pillows are widely available. They are sold in department stores, specialty stores, on the internet, and on the secondary market. Nursing pillows come in a variety of shapes including crescent (C-shaped), rectangular, kidney shaped, and two-sided (dual), with the C-shape pillow being the most common. Most nursing pillows have removable and washable zipper-closed covers that are typically made of either cotton or a polyester/cotton blend. Some nursing pillows come with additional features including an adjustable back strap that goes around the mother's waist, a back support for the infant, and side pockets. The filling of nursing pillows currently in the marketplace include: polyester, memory foam, and air. While the Boston Billow Nursing Pillow is similar to the other nursing pillows in the marketplace, it is banned because of its granular filling. Prior to the 2004 Boston Billows recall, the Boston Billow Nursing Pillow had reportedly been produced and sold in the U.S. for about five years. As previously mentioned, it is still available for use in hospitals.

Most nursing pillows sold in the United States are produced abroad. After conducting an internet search for various nursing pillow brands and manufacturers, it appears that there are over 15 firms that manufacture nursing pillows and a few of these firms account for the majority of nursing pillow sales. Additionally, make-your-own nursing pillow craft kits and home-based craft nursing pillow makers exist, but comprise a very small percentage of the nursing pillow market.

Nursing pillows are typically sold as individual items. For pillows with removable covers, customers typically purchase at least one additional replacement/back-up cover. Prices for nursing pillows vary depending on brand name and additional features. A casual inspection of price engine websites indicates that retail prices for nursing pillows typically range from \$20 to \$45, while some high end pillows exceed \$75.<sup>6</sup>

Some substitute products are available. For example, a nursing sling can be used when nursing and its pricing point is similar to that of a nursing pillow. Before nursing pillows were sold, mothers used quilts, blankets, standard pillows, rocking chairs, or nothing at all to support their arms and the baby when breastfeeding.

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<sup>5</sup> "Human Factors of Infant Cushion and Nursing Pillow Use" Midgett, Jonathan D. (2007)

<sup>6</sup> Price engine websites allow individuals to see lists of prices for specific products. Most price comparison services do not sell products themselves, but source prices from retailers from whom users can buy. ([http://en.wikipedia.org/wiki/Price\\_comparison\\_service](http://en.wikipedia.org/wiki/Price_comparison_service))

### III. Estimate of Potential Market for Nursing Pillows

The potential market demand for nursing pillows can be estimated using the number of live births and the percentage of mothers who begin breastfeeding in early postpartum (i.e., at initiation).<sup>7</sup> Table 1 provides estimates for annual nursing pillow usage and annual nursing pillow sales for the years 1999 to 2007. In 2004, for example, live births totaled approximately 4.1 million and the early postpartum breastfeeding rate was 74%, which results in a potential demand of about 3.0 million nursing pillows (4.1 million  $\cdot$  0.74 = 3 million).<sup>8,9</sup> However, not all breastfeeding mothers use a nursing pillow. In order to estimate the number of mothers who used a nursing pillow in 2004, the results of the Baby Products Tracking Study were applied. In both the 2002 and 2005 survey years, 61% of mothers who breastfed said that they use a nursing pillow. Thus, assuming that a similar percentage of nursing mothers used nursing pillows in 2004 as they did in 2002 and 2005, nursing pillows were used by 1.8 million mothers in 2004 (3.0 million  $\cdot$  0.61 = 1.8 million).<sup>10</sup>

Nursing pillow sales can be estimated by assuming that a nursing pillow is like an infant cushion in that it is used for a period of six months per infant and that each pillow is used for two time periods, on average.<sup>11</sup> Applying the annual nursing pillow usage of 1.8 million and dividing by the two product life use periods, yields an estimate of approximately 900,000 new nursing pillows sold in 2004 (1.8 million  $\div$  2 = 900,000).

### IV. Cost and Benefits of an Exemption

#### *Cost of an Exemption*

The cost of granting an exempting the Boston Billow Nursing Pillow would be the potential increase in the relative risk of suffocation, when compared to the risk associated with pillows already in use. When used for its intended purpose – nursing – the risk associated with nursing pillow use, including the Boston Billow Nursing Pillow, is very low.<sup>12</sup>

The main risk associated with nursing pillows arises if nursing pillows enter the sleeping environment: suffocation can occur if children fall asleep on them in the prone position with their head on the pillow. CPSC staff is aware of one death involving a

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<sup>7</sup> Early postpartum breastfeeding (i.e., initiation of breastfeeding) was defined by a positive response to the question, "Was [child's name] ever breastfed or fed breast milk?"

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mmm5630a2.htm> (Published August 3, 2007)

<sup>8</sup> Source for 1979-2005 data: National Vital Statistics Reports, National Center for Health Statistics (2005 data is preliminary) "Statistics on Breastfeeding Practices in the U.S. — Results from the National Immunization Survey (NIS)" Center for Disease Control. (August 2007)

<sup>9</sup> National Center for Health Statistics (<http://www.cdc.gov/nchs/births.htm>) (Visited September 8, 2007)

<sup>10</sup> 2006 Baby Products Tracking Study: Feeding Baby. Includes Breastfeeding and Bottle Feeding. American Baby Group. Conducted by Zeldis Research Associates. (Survey occurred in 1999, 2002, and 2005).

<sup>11</sup> Memorandum from William Zamula, ECSS and Anthony C. Homan, ECPA to Frank Brauer, EXPB: PSA #5352, Infant Pillows.

<sup>12</sup> "Suffocation hazards of infants when placed to sleep on cushions and pillows," Suad Wanna-Nakamura, 2007.

nursing pillow. That death, which occurred in 2001, involved a polyester-filled nursing pillow that was not a banned hazardous product subject to the CPSC's infant cushion rule. Since 2002, based on estimates of about 900,000 nursing pillows sold annually, more than 5 million nursing pillows have been purchased by consumers without any additional known suffocation incidents.<sup>13</sup>

According to Health Sciences staff, all soft pillows present a suffocation hazard when used in an infant's sleeping environment. The available suffocation data do not reveal any increased risk of infant death due to any specific type of pillow or cushion filling; rather it is the softness and the malleability of the pillow that leads to the risk of death. Since the comparative risk based on filling materials is unknown, it is not possible to quantify the difference in risk, if any, between the Boston Billow Nursing Pillow and nursing pillows now in the marketplace. If we assume the risks are similar, there would be no reason to expect that exempting the Boston Billow Nursing Pillow would materially affect the risk of infant suffocation. This is because purchases of Boston Billows' nursing pillow would, for the most part, be substituted for other types of nursing pillows, which would pose a similar risk. If the risks are higher or lower than the risks for other nursing pillows currently available, then exempting the Boston Billow Nursing Pillow would increase or decrease the risk of infant suffocation.

If Boston Billows' nursing pillow proves very popular with consumers because they find the pillow substantially more useful than other nursing pillows or nursing pillow alternatives, it is possible that aggregate sales of nursing pillows could increase above current levels. This would affect risk exposure in that more infants would potentially be subject to the risk, if any, posed by the use of nursing pillows in general. However, the potential for a market expansion is bounded by birth rates, breastfeeding rates, and the percentage of breastfeeding mothers who also use nursing pillows. Birth rates have and are expected to remain relatively stable, and breastfeeding rates are nearing the upper bound of the Healthy People 2010 goal breastfeeding targets. Out of the mothers who breastfeed, more than one-half already use nursing pillows. Thus, the potential for a measurable increase in aggregate nursing pillow use and risk is limited.<sup>14</sup> Moreover, even if more nursing pillows were sold, the possible added risk, if any, would have to be weighed against (1) the risk associated with the nursing pillow alternatives that would have otherwise been used and (2) the benefits of nursing pillows as an aid to breastfeeding, as described in the memorandum from the Division of Human Factors.<sup>15</sup>

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<sup>13</sup> Prior to the 2004 Boston Billows recall, the Boston Billow nursing pillow had reportedly been produced and sold in the U.S. for about five years. With the exception of Boston Billows' nursing pillows, the staff is unaware of any other domestically sold nursing pillow filled with granular material.

<sup>14</sup> In 2004, the Center for Disease Control estimated early postpartum breastfeeding rates at 73.8% and the U.S. Department for Health and Human Services Healthy People 2010 goal is 75%.

<sup>15</sup> If the market expansion were achieved through an increase in the number of new mothers who breastfeed, the possible added risks, if any, associated with an increase in nursing pillow use would also have to be weighed against the known benefits of breastfeeding that were noted in the memorandum from the Division of Human Factors. However, such an expansion resulting from the availability of a nursing pillow is unlikely.

### *Benefits of an Exemption*

Exempting Boston Billows' nursing pillow from the infant cushion rule would increase consumer choice by allowing consumers an alternative to the nursing pillows already in the marketplace. The primary benefits would be the marginal increase in the functional value of the pillows that some consumers might obtain from the use of Boston Billows' nursing pillow, rather than an alternative.

According to Boston Billows', because of its granular filling, the Boston Billow Nursing Pillow is flexible and moldable, which allows for proper infant positioning and enables mothers to nurse immediately after a C-section birth with no discomfort.<sup>16</sup> This and other assertions of quality differences are supported by comments from lactation consultants and other medical professionals received in response to the petition docketed in September 2005, and the September 2006 ANPR.<sup>17</sup>

### V. Alternatives Considered by Staff

#### 1. *Exempt the Boston Billows Nursing Pillow and substantially similar nursing pillows from the infant cushion rule.*

When used for its intended purpose – nursing – the risk associated with nursing pillows, including the Boston Billow Nursing Pillow, is very low. The primary risk associated with any nursing pillow arises if it enters the sleep environment since suffocation can occur if children fall asleep on them in a prone position with their head on the pillow.

If the Commission concludes that the risks associated with Boston Billows Nursing Pillow are generally comparable to the risks associated with other nursing pillows already in the marketplace, or that the additional risks, if any, are balanced by the additional benefits of Boston Billows' pillow, the Commission could exempt the Boston Billows Nursing Pillow from the infant cushion rule. If the risks are generally comparable to those of other nursing pillows, an exemption would have little, if any, effect on the risk of infant suffocation as the Boston Billows Nursing Pillow is substituted for other brands of nursing pillows with a similar risk. At the same time, Boston Billows, Inc. and some lactation consultants suggest that the Boston Billow Nursing Pillow has unique attributes that may enhance the use value of nursing pillows for some consumers.

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<sup>16</sup> Infant Cushion/Pillows: Advanced Notice of Proposed Rulemaking. Public Comments (November 27, 2006), and <http://bostonbillows.com/> (Visited September 15, 2007). According to Human Factors staff, these characteristics can also make a pillow more of a suffocation risk if used in an infant's sleep environment.

<sup>17</sup> Petition HP 05-1. Petition Requesting Amendment to Ban on Infant Pillows (December 13, 2005) and Infant Cushion/Pillows; Advanced Notice of Proposed Rulemaking (November 27, 2006).

2. *Do not exempt the Boston Billow Nursing Pillow from the infant cushion rule.*

The Commission could decide not to exempt the Boston Billow Nursing Pillow if it believes the pillow meets the legal definition of an infant cushion that is subject to the ban on infant cushions.

3. *Repeal the infant cushion rule.*

As noted in the ANPR, the Commission could repeal the existing regulation for infant cushions. However, in light of the ongoing risk posed by pillows as described in Health Sciences memo, and the fact that a sizable proportion of the infants still sleep in the prone position, there is little justification for repealing the infant cushion rule. The ban on infant cushions was promulgated to remove soft granularly filled infant cushions on which infants were placed to sleep in the prone position. Repealing the infant cushion rule would allow for sale of such soft infant pillows and cushions, which would result in an increased risk of infant suffocation.



**Table 1: Nursing Pillow Sales and Number in Use Estimates**

	1999	2000	2001	2002	2003	2004	2005	2006	2007
Live births (in millions) (1)	3.96	4.06	4.02	4.02	4.08	4.11	4.14	4.13	4.17
Proportion that breastfeed at initiation (2)	0.68	0.71	0.65	0.71	0.71	0.74	0.75	0.75	0.75
Potential demand (in millions) (3)	2.69	2.87	2.62	2.87	2.89	3.03	3.11	3.10	3.13
Proportion of new mothers who breastfeed that also use a nursing pillow (4)	0.23	0.35	0.49	0.61	0.61	0.61	0.61	0.61	0.61
Annual nursing pillow usage (in millions) (5)	0.62	1.01	1.28	1.75	1.76	1.85	1.89	1.89	1.91
Estimated sales of new nursing Pillows (in millions) (6)	0.31	0.50	0.64	0.88	0.88	0.93	0.95	0.94	0.95

(1) For 2000 to 2005, National Vital Statistics actual birth data (2005 is preliminary).

For 2006 and 2007 data is based on Department of Census estimates.

(2) For 2000 to 2004, data from Center for Disease Control, National Immunization Surveys (2000-2004).

For 2005 to 2007 data is based on United States Department for Health and Human Services 2010 Health People Goal estimates.

(3) Potential demand is simply the estimate of the number of breastfeeding mothers. (1) multiplied by (2)

(4) For 1999, 2002, and 2005, data from 2006 Baby Products Tracking Study: Feeding Baby. Includes Breastfeeding and Bottle Feeding. Conducted by Zeldis Research Associates for American Baby Group.

Data for other years were estimated by CPSC Directorate of Economics.

(5) Potential Demand times Proportion of new mothers who breastfeed that also use a nursing pillow. (3) multiplied by (4)

(6) Annual Nursing Pillow Usage divided by number of life use periods (two period estimates). (5) divided by two.

**TAB B**



UNITED STATES  
CONSUMER PRODUCT SAFETY COMMISSION  
WASHINGTON, DC 20207

**Memorandum**

Date: 21 JAN 2008

TO : Suad Wanna-Nakamura, Ph.D., Infant Cushions Project Manager

THROUGH: Hugh McLaurin, Associate Executive Director *HMM*  
Directorate for Engineering Sciences  
Robert B. Ochsman, Ph.D. *RBO*  
Director, Division of Human Factors (ESHF)

FROM : Jonathan D. Midgett, Ph.D. *JDM*  
Engineering Psychologist, ESHF

SUBJECT : Human Factors of Infant Cushion and Nursing Pillow Use

The Commission granted the petition (HP 05-1) of Boston Billows, Inc. to evaluate whether pellet-filled nursing pillows should be exempt from the ban on infant cushions. This memo describes the human factors of infant cushion and nursing pillow use and the effectiveness of warning labels.

**The Uses of Infant Cushions**

Infant beanbag cushions were designed in the 1980's to elevate infants in car seats or strollers to enhance fit and comfort. They looked like small, rectangular mattresses.

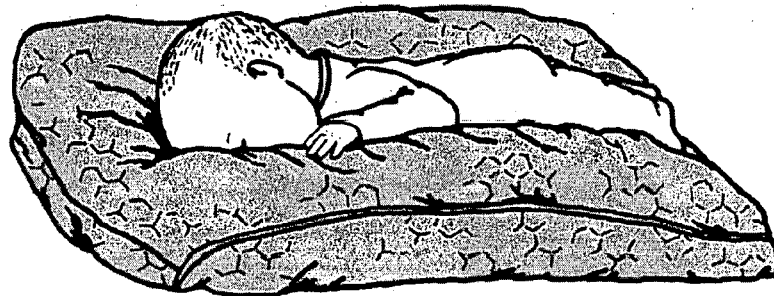


Figure 1: Infant cushion illustration from CPSC Doc. # 5090

One use of infant cushions was to allow children to sleep on them. The size and shape of infant cushions, essentially bead-filled pillows or miniature mattresses, readily allowed infants to sleep on them. The current practice of laying children to sleep on their backs was not established yet, so some children were placed prone on infant cushions. When infants were placed on the cushions face down, the granular filling inside could easily conform to their faces and suffocate them. The Commission learned of 35 deaths (U.S. CPSC, Federal Register, Volume 57(121), June 1992) associated with infant beanbag cushions and banned them and similar products.

## **The Uses of Nursing Pillows**

The well-known benefits of breastfeeding make it a worthwhile endeavor, but learning how to breastfeed can be a difficult experience. The often exhausted and sometimes nervous nursing mother manipulates and coaxes the sometimes-uncooperative infant into the right position to get a proper “latch,” the seal that lets the infant nurse easily without hurting the mother. Mothers sometimes find that training their child to nurse is an emotionally frustrating and physically painful experience. Given the difficulties, physical and social support of the mother are extremely important for successful breastfeeding. Nursing pillows help position infants for achieving a good latch and provide a place for mothers to rest their arms. Having a malleable and supportive pillow, blanket, or other item helps this process every time a mother nurses, which can be 8 to 12 times a day, around the clock.

Nursing pillows are generally a different shape from the banned infant cushions. They are designed to encircle the waist of a nursing mother to support her arms and the infant’s body and head. Usually filled with soft fibers like a pillow, the common design is a C-shaped fabric tube with a washable cover. Some have foam inside. The nursing pillow gives a moldable, but firm support surface to enhance comfort during extended periods when changing position is difficult because the mother is still in pain from giving birth or just afraid to disturb the infant’s latch.

Since some nursing inevitably occurs at night and at other times during the day when the mother is sleepy, pillows and blankets commonly pervade the nursing environment. Additionally, nursing frequently occurs in an adult bed and mothers may fall asleep while nursing or soon after finishing. Consequently, any nursing product has a high likelihood of being found in or near a family’s sleeping environment, including infant sleeping environments.

Although nursing pillows’ primarily perform a different function than infant cushions, they can be used in a similar way. While a nursing pillow’s tubular shape does not lend itself to being used as a small mattress, as the banned infant cushions were used, it can serve as a pillow or a nest, supporting a child’s head and/or torso while they sleep or play. Online images of babies sleeping in nursing pillows are plentiful. In fact, caregivers frequently prop infants in pillows and bedding of all kinds and surround infants with pillows to prevent them from rolling off beds, even though this is not a recommended practice. During “tummy time,” they lay children over pillows and on blankets to facilitate infants holding their heads up. “Tummy time” entails laying an alert, active infant on his/her stomach to play. This exercise is promoted for infants (beginning at birth) to alleviate the upper shoulder girdle weaknesses and skull flattening seen after widespread acceptance of the SIDS prevention practice of always placing infants on their backs to sleep (Persing, James, Swanson, & Kattwinkel, 2003). A nursing pillow’s encircling shape readily affords propping babies during “tummy time.” Images of propped babies and “tummy time” uses are common in the nursing pillow industry’s advertisements. Even without the images in a product’s advertising, this use is reasonably foreseeable because the nursing pillow’s shape lends itself to propping. Using pillows for propping babies increases the likelihood that caregivers may use nursing pillows in or near an infant’s sleeping environment because an infant’s play environment can turn into a sleeping environment at any time. Highly malleable products that can easily conform to an infant’s face are suffocation hazards. Unfortunately, while increasing a nursing pillow’s malleability makes it more adjustable for the caregiver, it simultaneously makes the pillow more hazardous for a sleeping infant. Any products

used in or near an infant's play and/or sleeping environment should be as *firm* and *non-conforming* as is practical.

### **Warning Labels**

Besides making nursing products as firm and non-conforming as is practical, warning labels are a secondary option for preventing suffocations on nursing pillows. The ASTM (F 1917) standard for infant bedding requires a warning, but nursing pillows fall outside of the scope of that standard. In general, warning labels for consumer products are not universally read or heeded. Additionally, a tired nursing mother who is on the verge of falling asleep is not as likely to recall product warnings, as she would be if she were well rested. However, if warning labels are considered for use as a secondary injury prevention strategy, the following text may suffice:

**WARNING: SUFFOCATION HAZARD**

This product can suffocate your infant by molding to the face.  
Remove all pillows from infant sleeping areas.

Human Factors staff generally accepts that warnings on juvenile products can be a critical part of preventing deaths and injuries, even though they are not the first choice for injury prevention.

### **References**

Persing, J., James, H., Swanson, J. & Kattwinkel, J. (2003). Prevention and management of positional skull deformities in infants. Pediatrics, 112, 1, 199-202.

**TAB C**



UNITED STATES  
CONSUMER PRODUCT SAFETY COMMISSION  
WASHINGTON, DC 20207

**Memorandum**

Date: **21** JAN 2008

TO : Suad Wanna-Nakamura, Ph.D., Infant Cushions Project Manager  
Physiologist, Directorate for Health Sciences

THROUGH: Russ Roegner, Ph.D., Associate Executive Director  
Directorate for Epidemiology  
Kathleen Stralka, Director  
Division of Hazard Analysis

RTL

FROM : Craig Andres, Mathematical Statistician  
Division of Hazard Analysis

CA

SUBJECT : Pillow related infant deaths

The request to exempt a pellet filled infant nursing pillow from the ban on infant cushions related to bean-bag infant pillows generated discussion concerning pillow related deaths in general. Five data files were created from the DTHS<sup>1</sup>, INDP<sup>2</sup>, and NEISS<sup>3</sup> databases to provide records of any cases involving pillows or cushions from January 1992 through June 2007 that involved an infant 12 months old or under. Health Sciences' evaluated each incident to identify those within scope of this project, see memo (Tab C). An additional request to discover if there were any incidents involving nursing and infant pillows for the same age group and the same time period in the NEISS database is addressed in the notes below.

**Methods**

The approach taken was first to perform a general text search within the DTHS and INDP databases for the dates and the age of victim as described. The text search is referred to as the first search method. We looked for any record that contained the text "PILLO" or "CUSHI" in the narrative, "PILLO" for pillow and "CUSHI" for cushion. This produced one EXCEL file from each database. The second method was to search DTHS and INDP within the NEISS product code for pillows (which is 4050) under the dates and ages mentioned. This generated another EXCEL file for each database. To avoid duplicate incidents, a filter was then applied to these last two files to display incidents where the above two text strings were not in the narrative.

<sup>1</sup> The DTHS file includes information from death certificates purchased by CPSC from all 50 states and the District of Columbia. The information provided in these databases with exception of the INDP database is anecdotal, but is useful in describing features of a pattern of injury.

<sup>2</sup> The INDP file contains data from follow-back investigations reported by CPSC staff. These investigations are done in an effort to gather detailed information on a death or injury associated with a particular consumer product.

<sup>3</sup> The NEISS database is a statistically based CPSC injury file that contains patient information collected from NEISS hospitals for every patient treated in the emergency department for an injury associated with a consumer product. The NEISS database file is a probability sample of hospitals in the U.S. and its territories that have at least six beds and an emergency department. National estimates are made of the total number of product-related injuries treated in U.S. hospital emergency departments based on the NEISS data collected from these hospitals. The NEISS is a stratified sample based on emergency department size and geographic location.

### ***Results***

A total of 397 incidents were found in the DTHS database (395 using the first search method). A total of 169 incidents were found in the INDP database (152 using the first search method). The second search methods found some incidents that may not be related to the project and others where “pillow” or “cushion” were misspelled. Health Sciences staff examined each case to determine if it was in the scope of the study. This resulted in 373 in scope cases from DTHS, and 111 in INDP, for a total of 484 fatalities (duplicates between the two databases were accounted for). Further categorical breakdowns of DTHS and INDP results were performed by Health Sciences staff.

### ***Notes***

It is speculated that it would be uncommon for NEISS to capture suffocation related incidents since, for many, the victim would either be taken out of danger before it was serious enough to take the victim to an emergency room, or the victim would have been deceased when discovered. Thus we see many more cases in DTHS as opposed to NEISS.

The search performed in NEISS in the codes “4050 1542 4074” for text “pillo” or “cush” using EPISEARCH was to look for incidents involving nursing and infant pillows. The NEISS results were insufficient in size to produce a national estimate. Of the 19 cases discovered, Health Sciences staff identified 14 incidents that were in scope. Four of the other five incidents involved falls.

There were three out of scope cases in NEISS that involved the use of a nursing pillow for an infant to sit, or lay, that resulted in a fall related incident. These particular incidents establish that this type of products is sometimes intentionally used by the consumer for purposes other than as an aid for mothers to nurse their infants.

Each file was sorted by date of incident. Each file had four narrative fields which were combined into a single column labeled “narrative” and the text was ‘wrapped’ so that it would be easier to read.



**TAB D**



UNITED STATES  
CONSUMER PRODUCT SAFETY COMMISSION  
WASHINGTON, DC 20207

**Memorandum**

Date: 21 JAN 2008

TO : Mary Ann Danello, Ph.D., Associate Executive Director

THROUGH: Lori E. Saltzman, M.S., Division Director, Division of Health Sciences *mad for LES*

FROM : Suad Wanna-Nakamura, Ph.D., Physiologist  
Directorate for Health Sciences *W*

SUBJECT : Suffocation hazards to infants when placed to sleep on cushions and pillows

This memorandum discusses the comparative risk of suffocation on pillows with different types of fillings and provides updated information about initiatives that may have reduced risk factors associated with infant suffocation deaths on pillows.

**Background**

In 1990, following the association of 35 infant deaths with bean bag cushions, the Commission banned infant cushions from the market place pursuant to its authority under the Federal Hazardous Substances Act 16 C.F.R. 1500.18(a) (16) (i), (US CPSC, 1992). The evidence indicated that bean bag cushions posed a suffocation hazard because of their capacity to conform to an infant's face, and potentially block the nose and mouth. In addition, in all reported incidents where the infant's position was determined, the infant was found sleeping in a prone (on the stomach) position, suggesting that this position posed an increased risk of suffocation to infants on such products. At the time, the normal practice and general advice given to parents by health care providers was to place infants to sleep on their stomachs (prone position).

During the same time, a large number of epidemiological studies indicated that the incidence of Sudden Infant Death Syndrome<sup>1</sup> (SIDS) dropped markedly in countries when the caregivers began placing infants to sleep on their backs rather than in a prone position (Dwyer et al., 1995), although the precise mechanism that links prone sleeping and SIDS remains unknown. It was in light of this evidence linking SIDS and the prone sleeping position that the recommendation was made to put infants to sleep on their backs, rather than their stomachs. In 1992, the American Academy of Pediatrics, in a measure to reduce the risk of SIDS, recommended that babies always be placed on their backs when put to sleep (supine position). In 1994, the American Academy of Pediatrics and the U.S. Department of Health and Human Services launched a nation-wide "Back to Sleep" campaign in the United States to increase compliance and awareness of this recommendation. The Commission joined the campaign to encourage parents

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<sup>1</sup> SIDS is defined as the sudden death of an infant under one year of age, whose cause remains unexplained after a thorough case investigation, including performance of a complete autopsy, examination of the death scene, and review of the clinical history, i.e., it is a diagnosis based on exclusions (*Willinger et al, 1991*).

to put their infants to sleep in a supine rather than prone position since the prone position was a high risk factor for suffocation on infant bedding.

### **Infant Suffocation Deaths**

Unlike adults, the limited physical and developmental capabilities of infants render them susceptible to danger from suffocation in certain sleeping environments. Studies have indicated that, in addition to the normal problems with infants extricating themselves from a compromised situation, some infants may have delayed development of arousal and cardiovascular control mechanisms. Because these systems are compromised, a sleeping infant may be unable to arouse him/herself sufficiently to react to a life threatening event.

Mechanical asphyxia can occur when an infant is placed to sleep in a prone position on top of a pillow or cushion made of a flexible fabric covering with loosely filled granular material, or other filling that can be easily flattened and is capable of conforming to the body or face of an infant. The face may become pressed against a pillow such that the mouth and nose are physically blocked, resulting in suffocation. The infant's inability to extricate him/herself due to the characteristics of the pillow or cushion and the infant's developmental stage result in infant deaths.

### **Incident Data**

Four CPSC data files covering the period from January 1992 through June 2007 were searched for infant (under one year of age) deaths associated with pillows or cushions. The databases used for this purpose were: Injury and Potential Injury Incidents (IPII)<sup>2</sup>; In-Depth Investigations (INDP)<sup>3</sup>; National Electronic Injury Surveillance System (NEISS)<sup>4</sup>; and Death Certificates (DTHS)<sup>5</sup> (Andres, 2008, Tab C).

Since the Commission infant cushion ban, there have been no reported deaths associated with bean bag cushions since they are no longer on the market (Federal Register, 2006). However, there continue to be a significant number of deaths associated with a variety of pillows (Figure 1). The data retrieved from the CPSC databases (INDP and DTHS) for the period from January 1992 through June 2007 (Andres, 2008) were reviewed for in scope cases which totaled 484 deaths of infants associated with pillows or cushions, The figure indicates that the number of deaths has remained relatively constant from 1992 to 2005, (2006 data is only 40% complete).

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<sup>2</sup> The IPII file contains data on consumer product-related incidents extracted from consumer complaints, as reported to CPSC through letters and telephone calls. The database also includes media articles, medical examiner reports, reports from fire and police departments nationwide, and referrals from other federal agencies.

<sup>3</sup> The INDP file contains data from follow-back investigations reported by CPSC staff. These investigations are done in an effort to gather detailed information on a death or injury associated with a particular consumer product.

<sup>4</sup> The NEISS database is a statistically based CPSC injury file that contains patient information collected from NEISS hospitals for every patient treated in the emergency department for an injury associated with a consumer product. The NEISS database file is a probability sample of hospitals in the U.S. and its territories that have at least six beds and an emergency department. National estimates are made of the total number of product-related injuries treated in U.S. hospital emergency departments based on the NEISS data collected from these hospitals. The NEISS is a stratified sample based on emergency department size and geographic location.

<sup>5</sup> The DTHS file includes information from death certificates purchased by CPSC from all 50 states and the District of Columbia. The information provided in these databases with exception of the INDP database is anecdotal, but is useful in describing features of a pattern of injury.

Data show that infants who are 3 months of age or younger are at greatest risk, with almost 69% (336/484) of the deaths occurring in this age range (Figure 2).

Most significantly, in the vast majority of the 484 deaths, the infants were found in the prone position. Of the deaths, 263 (54%) of the infants were discovered face down on a pillow with their airways obstructed. The remaining 221 (46%) deaths occurred by suffocation and positional asphyxia of infants found face down in a crowded sleeping setting where bedding materials such as pillows, quilts, and cushions were found. About 24% of the deaths, (118/484) occurred in infant cribs, bassinets, cradles, and playpens, while over 42% (205/484) occurred outside the infant sleep areas, such as on adult beds, or sofas, or on the floor. The locations of the remaining deaths were not reported.

A variety of pillow types and cushions were involved in these 484 deaths. Almost 70% involved adult pillows and sofa cushions and one death involved a polyester filled nursing pillow (Table 1). Based on what we know about the types of pillows involved in these incidents they most likely are filled with foam, feathers, or polyester and possess many of the same characteristics as the bean bag cushions. They have flexible fabric covers and can conform to the face. As with the infant bean bag cushions, they can cause death by suffocation when infants are placed to sleep face down on them. Based on CPSC staff epidemiological data, Health Sciences staff believes that infants placed to sleep prone on any pillows including nursing pillows are at risk for suffocation, regardless of size, type, shape or filling. However, it is not possible to compare risk of suffocation among different types of pillows or different types of fillings. It is not known if some are more hazardous than others. When the nursing pillow is used for its intended purpose (nursing), staff believes the infant suffocation risk is very low. The comparative risk of the petitioner's nursing pillow and alternative nursing pillows is not known when infants are intentionally placed to sleep on the product, when the product is used as a pillow for propping an infant's head during sleep, or if an infant accidentally falls asleep on the pillow during activities such as tummy time.<sup>6</sup>

### **Prone Sleeping**

Prone sleeping is a high risk factor for infant suffocation on pillows. Additionally a large number of epidemiological studies throughout the world have identified prone sleeping as a high risk factor for SIDS. In 1992 the American Academy of Pediatrics, in a measure to reduce that risk, recommended that babies always be placed on their backs when put to sleep (supine position). As a result, SIDS deaths between 1992 and 2004 in the United States decreased from 5,000 per year to 2,246 per year. These numbers are based on vital statistics data of the United States (United States Centers for Disease Control and Prevention, National Center for Health Statistics). The most dramatic decrease in the number of deaths and the number of prone sleeping infants occurred in the period between 1992 and 1999. There has not been a significant additional drop in the number of SIDS deaths or the number of infants placed to sleep in the prone position since 1999. Although the SIDS rates have decreased in all racial and ethnic minority groups, the reductions have not been as dramatic in certain racial and ethnic groups. When compared with Whites, the SIDS rate is more than twice that rate among African Americans and three times that rate among American Indians (Iyasu 2002). A recent study in Chicago found that there was a significantly lower level of adoption of the infant supine sleep

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<sup>6</sup> Human Factors of Infant Cushion and Nursing Pillow Use, staff memo, Midgett, Jonathan D. 2008 (Tab B)

recommendation among African Americans compared with Whites, and concluded that this was a primary factor in the higher SIDS rates in this community (Hauck, 2003). Similar results have been reported in other studies in different communities confirming that SIDS rates remain higher in communities where there is a lower level of compliance with the Back to Sleep recommendation. Since prone sleeping is also a high risk factor for infant suffocation deaths on pillows, this lower compliance also puts this vulnerable population at greater risk of infant suffocation on pillows. Figure 1 indicates that deaths on pillows have remained relatively constant from 1992 to 2006. In the majority of the deaths associated with pillows, the infants were found in the prone position. This confirms that even though the recommendation to place infants to sleep on their backs is being promoted, there is still a significant group of people who continue to place infants to sleep in the prone position. It is for this reason that information targeted at the population of caregivers whose infants are not placed to sleep in the supine position, according to the Back to Sleep recommendation, would be helpful.

### **Safety Campaign:**

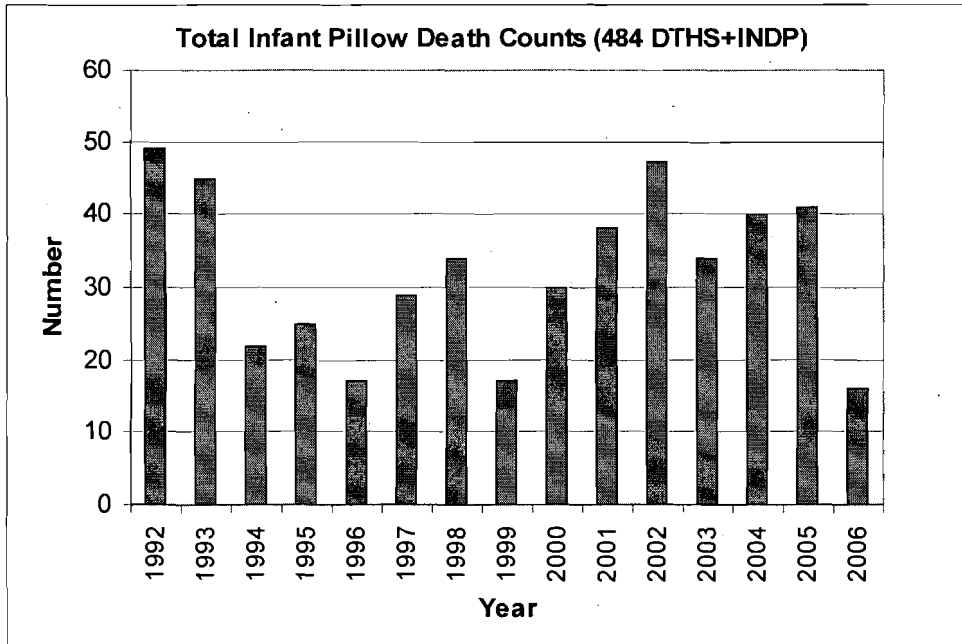
HS staff believes that continuing CPSC's ongoing messaging on the benefits of a safe infant sleep environment with an emphasis on the hazards associated with soft pillows would increase awareness among new parents and infant caregivers of the dangers of all types of pillows, soft bedding, and quilts in an infant's sleep environment. The campaign's key message should be that "Babies and Pillows are a Dangerous Mix" and that placing babies to sleep with such products, especially in the prone position, puts them at great risk of suffocation and death. A side benefit of these messages could be to increase the number of infants placed to sleep in a supine position and could, therefore, also result in further decreases in SIDS deaths.

### **Conclusions**

Since the Commission's 1992 infant cushion ban, there have been no reported incidents of infant deaths on infant bean bag cushions (CPSC, 1992). However, unlike the trend in SIDS deaths, there has not been a consistent decrease in the infant deaths associated with pillows and cushions (Figure 1). The CPSC data from 1992 to 2006, reported above, show that a wide variety of pillows and cushions, regardless of shape, size or type of filling, have been involved in the deaths. At least 70% of the infant deaths involved adult pillows or sofa cushions, few if any of which are likely to be filled with polystyrene beads. The analysis of the data does not reveal an increased risk due to any specific type of pillow or cushion filling, but rather it is the softness and malleability which are inherent properties of pillows that is the primary risk factor that leads to the risk of death. The comparative risk of suffocation based upon filling is unknown. Most significantly, the greatest common risk factor is that infants were found in the prone position in the majority of the 484 deaths. Unlike adults, the limited physical and developmental capabilities of infants render them susceptible to danger from suffocation in certain sleeping environments. Physiological abnormalities and delays in the development of vital systems can further hamper an infant's ability to react to a hazardous condition. Vulnerable populations not placed to sleep in the supine position according to the Back to Sleep recommendation are especially at risk for suffocation on any type of soft pillow, regardless of the type of filling.

Thus, despite the proven effectiveness of the recommendation to place infants to sleep on their backs in reducing the incidence of SIDS, there remain a significant number of caregivers who continue to place infants to sleep in the prone position. Since this is the case, staff believes that

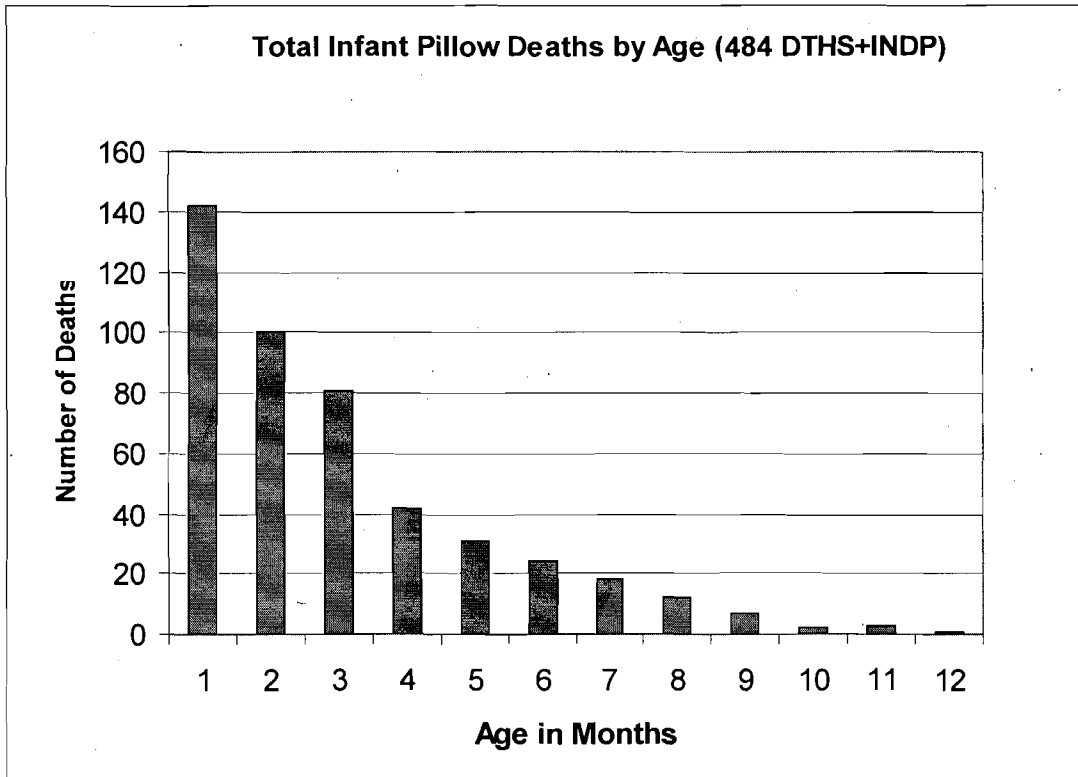
messaging focused on “Babies and Pillows are a Dangerous Mix” is of vital importance. Increased compliance with the recommendation for supine sleep, as well as continued vigilance in ensuring a safe sleeping environment could have benefits in reducing the risk of infant suffocation deaths caused by adult pillows, sofa cushions, and nursing pillows as well as further reducing SIDS.



**Figure 1.** Total number of Infant Deaths associated with pillows from 1992 through June 2007

% complete\* 2003 is 98%; 2004 is 97%; 2005 is 85%; and 2006 is 40% complete. (Data Source DTHS and INDP)

\*Where % completed is a measure of state-months in which CPSC has received 1 or more death certificates (Schroeder, 2007).



**Figure 2.** Deaths Associated with Pillows by Age in Months. (Data Source DTHS and INDP)



Pillow Type	Adult Pillows	Sofa Cushions	Nursing Pillow	Small Pillows	Unknown	Total
Number of Deaths	213	128	1	5	137	484

**Table 1.** Pillow related deaths from 1992 through June 2007 by pillow type. (*Data Source DTHS and INDP*)

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# T A B L E



United States  
CONSUMER PRODUCT SAFETY COMMISSION  
4330 East-West Highway  
Bethesda, Maryland, 20814

MEMORANDUM

DATE: November 27, 2006

TO : HS

Through: Todd A. Stevenson, Secretary, OS *TAS*

FROM : Martha A. Kosh, OS *MAK*

SUBJECT: Infant Cushion/Pillows; Advance Notice of Proposed Rulemaking

ATTACHED ARE COMMENTS ON THE CF 07-1

<u>COMMENT</u>	<u>DATE</u>	<u>SIGNED BY</u>	<u>AFFILIATION</u>
CF 07-1-1	11/02/06	Bonnie Cable RN, IBCLC	Mt Carmel Health Outpatient Lactation 5965 E Broad St, Suite 100B Columbus, OH. 43212
CF 07-1-2	11/06/06	C. M-Street RN, IBCLC	Lakeland Lactation Center W3985 County Rd NN Elkhorn, WI 53121
CF 07-1-3	11/20/06	M. Truesdale Director	Baby Matters <a href="mailto:mtruesdale@baby-matters.com">mtruesdale@baby-matters.com</a>
CF 07-1-4	11/20/06	Jane Kershaw	<a href="mailto:Jane.Kershaw@HCAHealthcare.com">Jane.Kershaw@HCAHealthcare.com</a>
CF 07-1-5	11/21/06	Peggy Andrews	<a href="mailto:AndrewPK@ah.org">AndrewPK@ah.org</a>
CF 07-1-6	11/22/06	Sally Wodicka RN, IBCLC	Community Memorial Hospital W180 N8085 Town Hall Rd. Menomonee Falls, WI 53051
CF 07-1-7	11/22/06	J.B. Beckwith	<a href="mailto:beckwithbrowning@earthlink.net">beckwithbrowning@earthlink.net</a>
CF 07-1-8	11/23/06	Nancy Engle	<a href="mailto:gengle1@twcnny.rr.com">gengle1@twcnny.rr.com</a>
CF 07-1-9	11/25/06	S.E. Skoug	<a href="mailto:gaapaa@yahoo.com">gaapaa@yahoo.com</a>

Stevenson, Todd A.

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*Boston  
Billow 1*

From: Cable, Bonnie [bcable@mchs.com]  
Sent: Thursday, November 02, 2006 3:47 PM  
To: Stevenson, Todd A.  
Cc: gaapaa@yahoo.com  
Subject: infant cushions/pillows ANPR

Hello,

I have been working with breastfeeding mothers for over 20 years. I am a board certified lactation consultant and a registered nurse. I am writing to express my support for the Boston Billow nursing pillow product. We have sold and used the pillow for 5 years and have never had any negative feedback or experiences with the pillow. I use the pillow daily in my practice, and mothers love it. I love it also. It is the best nursing pillow I have ever found, and I think we have tried them all.

I find it hard to imagine what the problem is. I cannot see how the product could pose any danger. It supports the baby when the baby is nursing. It is not used for sleep, or any other purpose. The Billow is a super product. It's flexibility allows it to fit around women of all shapes and sizes. It is washable, durable, and light weight. I find the phrase "much ado about nothing" coming to mind when I try to understand all the hoopla about the possibility of injury from this product. How is the world is that possible?

I love the Billow. I have used it for years and continue to love it. Nursing support type billows are widely available in stores, through catalogs, and through online sources. They have been available for years. Products of this typed are helpful. The Billow is the best of the bunch. I cannot imagine why in the world anyone would need a prescription for any product of this type.

Please know that I would never use or recommend any product that could be dangerous to any mother or baby. The billow is in no way a dangerous product. I think it is a wonderful, unique product that is tremendously helpful to nursing mothers.

Thanks you.

Bonnie Cable RN,IBCLC

Mt. Carmel Health Outpatient Lactation

5965 E. Broad St., Suite 100B

Columbus, OH 43213

11/9/2006

614-234-8130

bcable@mchs.com

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"This electronic message transmission contains confidential or privileged informati  
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Kosh, Martha A.

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From: Stevenson, Todd A.  
Sent: Monday, November 06, 2006 11:03 AM  
To: [REDACTED]  
Subject: FW: Nursing Pillows  
Importance: High

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From: carol.mcshane-street@aurora.org [mailto:carol.mcshane-street@aurora.org]  
Sent: Sun 11/5/2006 2:52 PM  
To: Stevenson, Todd A.  
Subject: Nursing Pillows

To Whom It May Concern,

I am writing in regard to the CPSC request for public comment on the use and purchase of nursing pillows.

I am a board certified Lactation Consultant working in a hospital in the state of Wisconsin. I have been working in Obstetrics for over 20 years and specialized in the field of lactation for over 10 years. It is common knowledge for those of us working with nursing mothers that comfortable positioning of the mothers' arms and shoulders is a crucial aspect of successful breastfeeding. I have seen mother's using several different types and brands of pillows over the years and in my opinion the Boston Billow Pillow is superior to the others on the market for ease of positioning of the mother.

I have never recommended to a mother that she use a pillow as something to position the baby on. Babies at the breast are cradled in the mother's arms and the support of a pillow is *under* the mother's arm. This is true of any pillow - even a common bed pillow. I am aware of one nursing pillow on the market that includes in its marketing use as a support pillow for the infant. To my knowledge, the Boston Billow company has never advertised in this way and Lactation Consultants don't condone the propping of babies on any pillow. Evidently this is where the concern of the CPSC has been directed and I believe the concerns should be focused on any company that advertises propping babies on a pillow rather than focusing on a product that is to be expressly used by mothers. I understand you have described the Boston Billow nursing pillow as an "infant cushion". If you look at the major competitor's advertising I think you will find they are the ones that describe their own product for use by the infant and not Boston Billow.

Not all Lactation Consultants are working in a practice with retail sales of products. It would greatly diminish our ability to advise the mother on what may provide the best support for her if the sale of certain nursing pillows is restricted to a medical sales facility or by prescription. Convenience of obtaining any product as well as cost are huge factors for most new parents. As professionals, you would be restricting the way we advise our patients if we cannot reasonably assure them that the product is available in their area for purchase at a reasonable cost. Physicians have little interest in the process to become successful at breastfeeding, let alone taking time for prescribing a nursing pillow. Insurance providers will probably not cover the cost of an item of this nature. This seems like an unreasonable request.

11/6/2006



The current wording of the proposed amendment would eliminate board certified Lactation Consultants to recommend a particular nursing pillow. At the very least, you should add to the proposed amendment request, "and other qualified professionals".

Just because one company in the United States has become very well-known and popular for producing a nursing pillow does not mean they produce the best nursing pillow. It is certainly not in the best interest of the consumer - new mothers - for one company to have a monopoly on the market. The company that I suspect brought forward the concerns due to competition in the first place is one that I would never recommend to a new mother for breastfeeding. It simply doesn't work well for the mothers and then they resort to using it to place the baby on (as indicated in the photos with the product at purchase) rather than for their own arm support. Below is a link to the specific use indicated by the largest seller of nursing pillows in the U.S. I have never seen this indication for use from any other nursing pillow manufacturer and never from Boston Billow.

<http://www.boppy.com/howitwork.asp?sts=11%2F5%2F2006+12%3A44%3A17+PM&mscssid=QBH6TT3P5WA29GRHMG2S3J4JL2ME6QL2>

I believe in this particular issue the CPSC has been misled in their concerns for safety regarding the Boston Billow Nursing Pillow. Nursing pillows should not be for use by the infant, but for use by the mother. ALL pillows on the market, regardless of the shape or content, should be labeled "Not for use by infants". Unless you are planning to restrict the sale of every pillow on the market used by adults, I believe your energies would be better spent on this focus.

Sincerely,  
Carol A. McShane-Street, RN, IBCLC  
Lakeland Lactation Center  
W3985 County Road NN  
Elkhorn, WI 53121-1002  
(262) 741-2814  
carol.mcshane-street@aurora.org

Stevenson, Todd A.

*Handwritten notes:*  
infant cushion  
pillow  
ANPR

**From:** Marguerite Truesdale [mtruesdale@baby-matters.com]  
**Sent:** Monday, November 20, 2006 2:31 PM  
**To:** Stevenson, Todd A.  
**Cc:** gaapaa@yahoo.com  
**Subject:** infant cushion/pillows ANPR

I am a certified parent educator and I teach breastfeeding classes. I have been a big fan of the Billow Nursing pillow. It is a flexible nursing pillow and as such serves tall, medium, and short women very well as opposed to the more set height of most nursing pillows. I would very much like to have this nursing accessory back in circulation so I could recommend it to my clients.

Thank you for your attention to this matter.

Marguerite Truesdale, RN,BS,CCE

Director: Baby Matters- Birthing Basics and Beyond

Stevenson, Todd A.

Infant  
Cushions  
ANPR 4

From: Kershaw Jane [Jane.Kershaw@HCAHealthcare.com]

Sent: Monday, November 20, 2006 2:49 PM

To: Stevenson, Todd A.

Subject: Infant cushions/pillows ANPR

I believe infant support pillows should be marketed appropriately. Let the marketplace decide on their effectiveness, as long as they do not harm. Infant pillows are still sold, pillows of all types are still sold and adults will sometimes use them inappropriately. Do we ban all pillows because some adults use them incorrectly with babies? As a lactation consultant and the manager of a support service that markets breastfeeding aids, I have used several different types of support pillows with babies. Our mothers and babies seem to like the Boston Billow the best because of its ability to be conformed to the shape of the mother and adjusted to provide firm support to the baby, regardless of its weight or size. I don't want to restrain free trade of other brands of pillows, but I don't think it's so much a health and safety jeopardy issue as it a preference issue. If we were discussing breast pumps, I would be much more stringent on requirements! The Boston Billow is an important adjunct to helping mothers, but it is not a medical device and causes no harm. The only thing I would think that would drive others to ban it would be a wish to restrain free trade and reduce competition.

Jane Kershaw, RN, BA, IBCLC  
Coordinator, Lactation Support Services  
Centennial Medical Center

Infant  
Cushion  
5

Stevenson, Todd A.

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**From:** Peggy Andrews [AndrewPK@ah.org]  
**Sent:** Tuesday, November 21, 2006 1:39 PM  
**To:** Stevenson, Todd A.  
**Subject:** infant cushions/pillow

I am a lactation consultant, labor, delivery and nursery RN. I recommend the Boston Billow for positioning breastfeeding infants especially in situations where latch is difficult. and infants are frail. This is the best positioning tool I have found in 39 years of helping new moms. Please look at the logic of laws and do not include this product in your "infant sleeping pillow" legislation.

Stevenson, Todd A.

*John  
C. Stevenson*

From: Sally Wodicka [swodicka@communitymemorial.com]

Sent: Wednesday, November 22, 2006 1:45 PM

To: Stevenson, Todd A.

"Infant cushions/pillows ANPR"

11/22/06

I am responding to an email I received regarding the use of the Boston Billow Nursing Pillow and all of the legal brick walls it has had to contend with. I am so sick of the bureaucracy surrounding this issue I could scream. Is this America, or not? The Boston Billow is a superior product for use as a nursing pillow. It is flexible, light weight, easily transportable, washable, and affordable. With all of the 'Back to Sleep' campaign promotion going on, I believe it is clear to new parents NOT to use this or any item similar to it (Boppy, My Breast Friend, etc.) as a head supporting pillow in the crib or anywhere near where baby sleeps. Not only do I not recommend or endorse in any way any pillow competitor, I now boycott the Boppy based on their business ethics. If your product cannot stand alone on it's own merit, than it should swim with the fishes and take its chances like all other fair market products! The nonsense that a Physician or LC must order the Pillow is outrageous! It is not a durable medical equipment item, and should not be treated as such. There are many physicians that are not even up to date on breastfeeding much less, breastfeeding accessories. Many LC's do not or cannot carry retail items so may run into trouble ordering that a mom get a billow. These should be available wherever infant products are sold. What's next? Must we have every new mom obtain a doctors' order to purchase a nursing bra? Let's leave the educated choice up to the moms, and take it out of the hands of the government. Aren't there more important issues to be dealing with? Please let's move along on this issue and get us back the best nursing pillow on the market, the Boston Billow Nursing Pillow!!!!

Sincerely,

*Sally Wodicka, RN, IBCLC*  
Lactation Services  
Community Memorial Hospital  
W180 N8085 Town Hall Rd.  
Menomonee Falls, WI 53051  
(262)257-5030

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11/24/2006

Stevenson, Todd A.

*mt put* 7

From: Bruce Beckwith and Nancy Browning [beckwithbrowning@earthlink.net]  
Sent: Wednesday, November 22, 2006 11:21 AM  
To: Stevenson, Todd A.  
Subject: Boston Billows

I am writing to add my voice to those asking you to cease delaying tactics and remove your ban on the sale and use of the Boston Billows nursing pillow. I am a pediatric pathologist with extensive experience with Sudden Infant Death Syndrome (SIDS) and other natural and unnatural causes of sudden death in infants. For 20 years I was responsible for the autopsy and investigation of every case of sudden unexpected infant death in King County, Washington. During that period not a single infant expired unexpectedly during breast feeding. SIDS is a phenomenon that occurs during sleep, and this product has no relationship to infant sleep-its design would make it difficult if not impossible for an infant to assume a sleeping position. Its surface characteristics make it impossible to mold to the infant face. It is not surprising that no case of infant death has been documented during use of this product.

The Boston Billows pillow has been shown to be a popular and effective means of encouraging and facilitating breast feeding. Breast feeding has been consistently shown to be associated with a reduced risk of SIDS. By preventing access to this product you are in fact doing the opposite of protecting infants.

Lest you suspect that my reaction is motivated by any pecuniary or other interest in this product, I assure you I have never received compensation of any sort, nor have I any expectation of such compensation in the future. I was given an example of the product to examine and keep, but that is the only thing I have ever received, or intend ever to receive, from the manufacturers of this product. My only interest and motivation in this matter is the protection and welfare of infants through the encouragement of breast feeding.

Respectfully,  
J. Bruce Beckwith MD

Stevenson, Todd A.

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*infant cushions*

From: Nancy Engle [gengle1@twcny.rr.com]

Sent: Thursday, November 23, 2006 4:08 PM

To: Stevenson, Todd A.

Subject: [Possibly SPAM (k): ] - Infant.cushions/pillows ANPR - Found word(s) drugs in the Text body

I have been following the decisions related to the Boston Billow nursing pillow over the past few years. Prior to the ban and recall of this pillow, I carried this pillow in my inventory, and found it to be very helpful to nursing mothers.

I am confused over the controversy with these pillows, as they were designed and marketed for use while mothers were breastfeeding their babies. This means that they are only used when the mother and the baby are together, not when the baby is by itself (unlike some of the other nursing pillows which are advertised for use to prop baby other than in the parent's arms). Because of this, I would not define it as an infant cushion, but a nursing pillow, .

If there is still concern about the use of this pillow, I would think that written cautions on the tag as well as other packaging regarding not using it without competent adult supervision (similar to safe sleep recommendations as far as adult not under the influence of alcohol or drugs, etc.). In addition to this, education and recommendation for use by a healthcare professional would, I believe, reduce the risk of injury or death.

Although as a Maternity Nurse and Lactation Consultant, I would love to be able to direct every new mother to purchase only what she really needs to care for her baby, and the safest products to accomplish that, I'm not sure that it would be practical to require that there be a written recommendation or prescription for such products. Perhaps limiting the distribution and sale of infant cushions/pillows to healthcare product companies or medical professionals would add to the safety of this product. In a specialty company as opposed to mass marketing, the employees should theoretically have a greater knowledge of the product and recommendations for use. This would provide another opportunity to educate the purchaser individually regarding safety issues.

In conclusion, I look forward to hearing that an ammendment has been made to the 1992 Federal Regulations to allow an exception to the ban on infant cushions/pillows when the product is specifically designed, intended and promoted for mothers to use when breastfeeding. If these items were available when recommended by a physician, a board certified lactation consultant, or other qualified medical personnel as mentioned above, this would allow pillows such as the Boston Billow nursing pillow to be safely used to help breastfeeding mothers and babies.

Sincerely, Nancy M. Engle, RN, IBCLC, RLC  
Owner, Feedernright (Breastfeeding help and supplies)  
Lowville, NY

11/27/2006

Stevenson, Todd A.

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*Infant  
Cushions 9*

From: S. Erik Skoug [gaapaa@yahoo.com]  
Sent: Saturday, November 25, 2006 12:49 PM  
To: Stevenson, Todd A.  
Subject: Infant cushions/pillows ANPR

Sirs:

There are numerous types of nursing pillows available in the market. Strangely enough the CPSC has not taken action against nursing pillows filled with polyester fiber. Healthcare research has long established that such fibers may cause infant allergies and be a cause of asthma development. This will be so especially when wet, something that will be the case with babies breastfeeding and urinating etc. Under such circumstances, and otherwise, polyesterfiber and similar fillings may harbor dust mites and other microscopic insects where feces will build up over time and cause these allergies or induce asthma developments. The sale of such infant cushions/pillows should therefore be restricted. (See comments below.) Nursing pillows filled with beads that are not water permeable can be washed. Washing pillows filled with polyester fiber is difficult and inefficient, at best.

Limiting the sale of infant cushions/pillows:

Health issues with infant cushions is best countered by limiting the sale to stores in, or directly associated with, hospitals and to sales by medical professionals like pediatric offices, lactation consultants etc. Single unit Internet purchases should be permitted provided a purchase is recommended by a named lactation consultant.

Recommendations by medical professionals:

Medical professionals are the only ones with the background to determine if an infant cushion/pillow is needed for a mother with a newborn baby and which type of infant cushion/pillow will be best for the mother and her baby. Requiring a written recommendation will be accepted by the medical community and will work although we question whether it will be practical or even effective.

Sincerely,

S.E.Skoug.

"Injury or death" in connection with nursing pillows

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Everyone is raving about the all-new Yahoo! Mail beta.

11/27/2006



**TAB F**

agent). You are required to assure the product is airworthy before it is returned to service.

(3) **Reporting Requirements:** For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120-0056.

#### Related Information

(h) This AD is related to EASA EAD No: 2006-0243-E, which references Allstar PZL Glider Sp. z o.o. Mandatory Bulletin No. BE-058/SZD-50-3/2006 "PUCHACZ", dated August 10, 2006.

Issued in Kansas City, Missouri, on September 20, 2006.

David R. Showers,

Acting Manager, Small Airplane Directorate,  
Aircraft Certification Service.

[FR Doc. E6-15905 Filed 9-26-06; 8:45 am]

BILLING CODE 4910-13-P

## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Part 1500

#### Infant Cushions/Pillows; Advance Notice of Proposed Rulemaking; Request for Comments and Information

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Advance notice of proposed rulemaking.

**SUMMARY:** Under the Commission's regulations, any infant cushion/pillow that meets the criteria set forth in the Commission's regulations at 16 CFR 1500.18(a)(16)(i), is currently a banned hazardous substance. In July 2005, the Commission received a petition from Boston Billows, Inc. asking the Commission to amend 16 CFR 1500.18(a)(16)(i)(A)-(E) to provide an exception to the ban when the product is specifically designed, intended and promoted for mothers to use when breastfeeding and requested by a Pediatrician or a Board Certified Lactation Consultant. On July 10, 2006, the Commission voted to grant the petition to the extent it requests the Commission to commence a rulemaking process to evaluate whether the Boston Billow nursing pillow and other infant cushions/pillows or pillow-like products<sup>1</sup> could result in an amendment to the existing ban.

<sup>1</sup> The term "infant cushions/pillows or pillow-like products" used throughout this ANPR means infant cushions/pillows or pillow-like products intended for use by infants less than one year of age, including, but not limited to, nursing pillows, infant beanbag seats or carriers, infant sleep aid pillows or similar products.

Accordingly, this advance notice of proposed rulemaking (ANPR) initiates a rulemaking proceeding that could result in an amendment to the existing ban on infant cushions/pillows. This proceeding is commenced under the Federal Hazardous Substances Act (FHSA).

By this notice, the Commission solicits written comments from interested persons concerning, in general, the risk of injury associated with infant cushions/pillows or pillow-like products. The Commission requests written comments on the regulatory alternatives discussed in this notice and other possible ways to address these risks. The Commission also invites interested persons to submit an existing standard, or a statement of intent to modify or develop a voluntary standard, to address the risk of injury identified in the notice.

**DATES:** Written comments and submissions in response to this notice must be received by November 27, 2006.

**ADDRESSES:** Comments should be submitted to the Office of the Secretary by e-mail at [cpssc-os@cpssc.gov](mailto:cpssc-os@cpssc.gov), or mailed or delivered, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814. Comments may also be filed by facsimile to (301) 504-0127. Comments should be captioned "Infant Cushions/Pillows ANPR."

**FOR FURTHER INFORMATION CONTACT:** Suad Wanna-Nakamura, Directorate for Health Sciences, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; telephone (301) 504-7252; e-mail [snakamura@cpssc.gov](mailto:snakamura@cpssc.gov).

#### SUPPLEMENTARY INFORMATION:

##### A. Background

Between 1985 and 1992, there were 35 infant deaths associated with the use of infant cushions/pillows (also known, among other names, as "baby beanbag pillows" and "beanbag cushions"). The Commission initiated a rulemaking proceeding to determine whether a ban was necessary to address the unreasonable risks of injury and deaths associated with these types of infant cushions/pillows. 55 FR 42202. Due to the number of infant deaths associated with these products, the Commission proposed a rule to ban infant cushions/pillows with certain characteristics. 56 FR 32352. On June 23, 1992, the Commission issued a rule codified under 16 CFR 1500.18(a)(16)(i), banning infant cushions/pillows that: (1) Have a flexible fabric covering; (2) are loosely filled with a granular material,

including but not limited to, polystyrene beads or pellets; (3) are easily flattened; (4) are capable of conforming to the body or face of an infant; and (5) are intended or promoted for use by children under one year of age. 57 FR 27912.

On July 17, 2005, Boston Billows submitted a petition requesting an amendment to 16 CFR 1500.18(a)(16)(i)(A)-(E) to allow an exception to the ban when the product is specifically designed, intended and promoted for mothers to use when breastfeeding and requested by a Pediatrician or a Board Certified Lactation Consultant. The petitioner is the manufacturer of the Boston Billow nursing pillow, which is purportedly designed and promoted to aid mothers when breastfeeding.

The Commission published a notice in the Federal Register on October 13, 2005, requesting comments on the petition. 70 FR 59726. The Commission received a total of 5 comments on the petition. The Commission staff reviewed the petition, the comments, and available information and prepared a briefing package for the Commission (available at <http://www.cpsc.gov>). On July 10, 2006, the Commission voted 3-0 to grant the petition to commence an ANPR.

##### B. The Product

There has been a proliferation of infant cushions/pillows or pillow-like products in the marketplace in all different shapes and sizes that meet some or all of the criteria set forth in the ban. For example, an infant cushion may have a flexible fabric covering, which conforms to the body or face of an infant, and is used by a child under one year of age, but contains a filling that is made of cotton or polyfill, instead of being filled with a granular material, such as polystyrene beads or pellets. The Commission believes that an examination of these different types of infant cushions/pillows or pillow-like products may now be warranted, given the proliferation of these products in the marketplace and their varying characteristics, including sizes, shapes and uses.

##### C. The Risk of Injury

Between 1985 and 1992, there were 35 infant deaths associated with the use of infant cushions/pillows. The Commission is unaware of any deaths or injuries associated with infant cushions/pillows since the ban on infant cushions and pillows went into effect in 1992. At the time of the ban, the recommendation from pediatricians was to place infants to sleep in the prone position (on the

stomach). In all infant cushion/pillow related deaths where the position could be ascertained, the infant was in the prone position. The prone position was likely a major contributing factor to the suffocation and death of the infant.

Since the ban and following considerable evidence that sleeping in the prone position is a significant risk factor in sudden infant death syndrome (SIDS) incidents, a nationwide education campaign was launched in the United States recommending that infants be placed on their backs when put to sleep (Back to Sleep campaign). Since the launch of the Back to Sleep campaign there has been a dramatic drop in the number of SIDS incidents in the United States. The guidance provided by the campaign may make it less likely that infants will be placed on their stomachs to sleep, reducing the likelihood of suffocation. The Commission staff continues to believe that infant beanbag cushions, and similar infant cushions/pillows (including the Boston Billow nursing pillow) pose suffocation risks to infants if infants are placed in the prone position on them for sleeping. The same risk is not likely to be posed when infants are placed in the supine position. Accordingly, the Commission believes that the current regulation should be reexamined to evaluate the likely use patterns of these products, and any associated risk of injury.

#### D. Relevant Statutory Provisions

The petition was docketed under the FHSA, 15 U.S.C. 1261 *et seq.* Section 2(f)(1)(D) of the FHSA defines "hazardous substance" to include any toy or other article intended for use by children that the Commission determines, by regulation, presents an electrical, mechanical, or thermal hazard. 15 U.S.C. 1261(f)(1)(D). An article may present a mechanical hazard if "in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness." 15 U.S.C. 1261(s).

Under section 2(q)(1)(A) of the FHSA, a toy, or other article intended for use by children, which is or contains a hazardous substance accessible by a child is a "banned hazardous substance." 15 U.S.C. 1261(q)(1)(A). Currently, the Commission bans any article known as an infant cushion or infant pillow which contains a flexible fabric covering, is loosely filled with granular material (including but not limited to, polystyrene beads or pellets), is easily flattened, is capable of conforming to the body or face of an infant and is intended or promoted for

use by children under one year of age. 16 CFR 1500.18(a)(16)(i).

Section 3(f) through 3(i) of the FHSA, 15 U.S.C. 1262(f)-(i), governs a proceeding to promulgate a regulation determining that a toy or other children's article presents an electrical, mechanical, or thermal hazard. As provided in section 3(f), this proceeding is commenced by issuance of this ANPR. After considering any comments submitted in response to this ANPR, the Commission will decide whether to issue a proposed rule and a preliminary regulatory analysis in accordance with section 3(h) of the FHSA. If a proposed rule is issued, the Commission would then consider the comments received in response to the proposed rule in deciding whether to issue a final rule and a final regulatory analysis. 15 U.S.C. 1262(i).

#### E. Regulatory Alternatives

One or more of the following alternatives could be used to address the issues identified with infant cushions/pillows and pillow-like products.

1. *Amend regulation to allow exemption for certain infant cushions/pillows and pillow-like products.* The Commission could issue a rule amending the existing ban to exempt certain infant cushions/pillows and pillow-like products, such as the Boston Billows product, which currently fall within the scope of the ban, if the Commission finds that such products do not present an unreasonable risk of injury. If an exemption is granted, the Commission could still consider a labeling requirement if it found that such warnings were necessary to adequately protect children from hazards associated with infant cushions/pillows and pillow-like products.

2. *Amend regulation to delete, revise or add criteria to the ban.* The Commission could issue a rule amending the existing ban by deleting, revising or adding criteria, as the Commission found necessary to adequately address any risk of injury associated with infant cushions/pillows and pillow-like products used for sleeping. Thus, the Commission could either expand or narrow the ban to treat products of similar risk consistently.

3. *Leave existing regulation unchanged.* The Commission could leave the existing ban on infant cushions/pillows unchanged if the Commission finds that the existing banning criteria adequately address the risk of injury associated with infant cushions/pillows and pillow-like products.

4. *Repeal existing regulation.* The Commission could repeal the existing ban on infant cushions/pillows if the Commission finds that the currently banned infant cushions/pillows and pillow-like products no longer present an unreasonable risk of injury. If the existing regulation is repealed, the Commission has authority under section 15 of the FHSA, 15 U.S.C. 1274, to pursue corrective actions on a case-by-case basis. In addition, if the ban is repealed, the Commission could still consider a labeling requirement if it found that such warnings were necessary to adequately protect children from hazards associated with infant cushions/pillows and pillow-like products.

#### F. Solicitation of Information and Comments

This ANPR is the first step in a proceeding which could result in an amendment of the current ban on infant cushions/pillows. All interested persons are invited to submit to the Commission their comments on any aspect of the alternatives discussed above. In particular, the Commission solicits the following additional information on infant cushions/pillows or pillow-like products intended for use by infants less than one year of age, including, but not limited to, nursing pillows, infant beanbag seats or carriers, infant wedges, infant sleep aid pillows, or similar products:

1. The models and model numbers of infant cushions/pillows and pillow-like products and the annual sales figures for each model from the time such product was made available in the marketplace;
2. The names and addresses of manufacturers and distributors who make and sell infant cushions/pillows and pillow-like products;
3. Information on any children believed to have been injured or killed as a result of infant cushions/pillows and pillow-like products;
4. The circumstances under which these injuries and deaths occur, including the ages of the victims;
5. The current regulation lists five criteria that define a banned infant cushion/pillow. Should any of these criteria be revised? Should any of these criteria be deleted? Are there criteria not in the current ban that should be added?
6. Whether the risk of injuries and deaths could be reasonably reduced by (a) Limiting sale of infant cushions/pillows to certain healthcare products firms or medical professionals, (b) restricting a consumer's purchase of an infant cushion/pillow to consumers with a medical professional's written recommendation or prescription, and (c)

whether any such point-of-sale restriction would be practical or effective;

7. Other information on the potential costs and benefits of the regulatory options;

8. The likelihood and nature of any significant economic impact of a rule on small entities;

9. The basis for, and costs and benefits of, mandating a labeling or instructions requirement.

Also, in accordance with section 3(f) of the FHSA, the Commission requests:

(1) Written comments with respect to the risk of injury identified by the Commission, the regulatory alternatives being considered, and other possible alternatives for addressing the risk;

(2) Any existing standard or portion of a standard which could be issued as a proposed regulation;

(3) A statement of intention to modify or develop a voluntary standard to address the risk of injury discussed in this notice, along with a description of a plan to do so.

Comments and other submissions should be captioned "Infant Cushions/Pillows ANPR" and e-mailed to [cpssc-os@cpsc.gov](mailto:cpssc-os@cpsc.gov) or mailed or delivered, preferably in five copies, to the Office of the Secretary at Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, Maryland 20814. Comments and other submissions may also be filed by facsimile to (301) 504-0127. All comments and other submissions must be received by November 27, 2006.

Dated: September 21, 2006.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 06-8265 Filed 9-26-06; 8:45 am]

BILLING CODE 6355-01-P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[USCG-2006-25767; formerly CGD09-06-123]

#### Safety Zones; U.S. Coast Guard Water Training Areas, Great Lakes

AGENCY: Coast Guard, DHS.

ACTION: Notice of public meetings.

**SUMMARY:** This document provides the times and locations of the public meetings which will be held by the Coast Guard to discuss issues relating to the proposed permanent safety zones

located in the Great Lakes to conduct live gunnery training exercises. The meetings will be open to the public.

**DATES:** The Coast Guard will hold four public meetings as follows: Monday, October 16, 2006 in Duluth MN; Wednesday October 18, 2006 in Grand Haven/Spring Lake, MI; Thursday, October 19, 2006 in Port Huron/Marysville, MI; Monday, October 23, 2006 in Cleveland, OH. The public meetings at each location will be held from 5:30 p.m. to 8 p.m. (local), with an open house prior to the start of the public meeting beginning at 4 p.m. (local).

Comments and material related to the public meetings must reach the Docket Management Facility on or before October 6, 2006. If you are unable to attend, you may submit comments to the Docket Management Facility at the address under ADDRESSES by November 13, 2006.

**ADDRESSES:** The Coast Guard will hold the public meetings at the following addresses:

1. Duluth, MN: Duluth Convention Center, 350 Harbor Drive, Duluth, MN 55802, telephone (218) 722-5573.

2. Grand Haven/Spring Lake, MI: Grand Haven Waterfront Holiday Inn, 940 West Savidge, Spring Lake, MI 49456, telephone (616) 846-1000.

3. Port Huron/Marysville, MI: Crystal Gardens, 1200 Gratiot Boulevard, Marysville, MI, 48080, telephone, (810) 364-6650.

4. Cleveland OH: Anthony J. Celebrezze Federal Building, 31st floor auditorium, 1240 E 9th Street, Cleveland, OH 44199, telephone (216) 902-6020; photo identification required for entrance.

You may also submit your comments and related material by only one of the following means:

(1) By mail to the Docket Management Facility (USCG-2006-2567), U.S. Department of Transportation, room PL-401, 400 Seventh Street, SW., Washington, DC 20590-0001.

(2) By delivery to room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC between 9 a.m. and 5 p.m. Monday through Friday, except Federal Holidays. The telephone number is 202-366-9329.

(3) By fax to the Docket Management Facility at 202-493-2251.

(4) Electronically through the Web site for the Docket Management System at <http://dms.dot.gov>.

The Docket Management Facility maintains the public docket for the rulemaking. Comments and material received from the public will become

part of this docket and will be available for inspection or copying at room PL-401, located on the Plaza level of the Nassif Building at the same address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may electronically access the public docket by performing a "Simple Search" for docket number 25767 on the internet at <http://dms.dot.gov>.

Electronic forms of all comments received into any of our dockets can be searched by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor unit, etc.) and is open to the public without restriction. You may review the Department of Transportation's complete Privacy Act Statement in the Federal Register published on April 11, 2000 (65 FR 19477-78), or you may visit <http://dms.dot.gov/>.

**FOR FURTHER INFORMATION CONTACT:** For further information concerning this notice and the public meeting, contact Commander Gustav Wulfkuhle, Chief Enforcement Branch, Ninth Coast Guard District, Cleveland, Ohio at (216) 902-6091. If you have any questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-493-0402.

**SUPPLEMENTARY INFORMATION:** The Coast Guard encourages interested persons to submit written data, views, or comments. Persons submitting comments should please include their name and address and identify the docket number (USCG-2006-25767). You may submit your comments and material by mail, hand delivery, fax or electronic means to the Docket Management Facility at the address under ADDRESSES.

#### Regulatory History

On August 1, 2006, the Coast Guard published a notice of proposed rulemaking (NPRM) (71 FR 43402) to establish permanent safety zones throughout the Great Lakes, which would restrict vessels from portions of the Great Lakes during live fire gun exercises that will be conducted by Coast Guard cutters and small boats. The initial comment period for this NPRM ended on August 31, 2006. In response to public requests, the Coast Guard re-opened the comment period on this NPRM. (71 FR 53629, September 12, 2006) Re-opening the comment period from September 12, 2006 to November 13, 2006, provides the public more time to submit comments and recommendations. On September 19, 2006, the Coast Guard published a brief