



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

DATE: JUN 29 2006

**BALLOT VOTE SHEET**

**TO:** The Commission  
 Todd A. Stevenson, Secretary

**THROUGH:** Patricia M. Semple, Executive Director *PS*

**FROM:** Page C. Faulk, General Counsel *PCF*  
 Jeffrey R. Williams, Assistant General Counsel for Enforcement and Information  
 Hyun S. Kim, Attorney, OGC *HSK*

**SUBJECT:** Petition HP 05-1 Requesting Exemption from "infant pillow" Ban under 16 C.F.R. § 1500.18(a)(16).

Ballot Vote Due:                     JUL 10 2006                    

Attached is a briefing memo from the staff concerning a petition from Boston Billows, Inc., for an amendment to 16 C.F.R. § 1500.18(a)(16)(i)(A)-(E), banning any article known as an "infant cushion" or "infant pillow." The petitioner requests an exception to the Commission's regulations to permit the use of banned infant pillows when the pillow is designed, intended and promoted for a mother's use during breastfeeding and when such pillows are requested by a Pediatrician or a Board Certified Lactation Consultant. Staff recommends that the Commission grant the petition to the extent it requests the Commission to proceed with a rulemaking process to evaluate whether the Boston Billow nursing pillow and other infant pillows or pillow-like products, could result in the need for a broader exemption to the current ban on infant pillows and direct the staff to prepare an advance notice of proposed rulemaking (ANPR).

Please indicate your vote on the following options.

- I. Grant Petition HP 05-1 and direct staff to draft an ANPR.

\_\_\_\_\_  
 (Signature)

\_\_\_\_\_  
 (Date)

~~CPSC OFFICIAL EMPLOYEE~~  
 NO IMPROPER USES OR PRODUCTS IDENTIFIED  
 ACCEPTED BY PETITION RULEMAKING ADMIN. PROC.  
 WITH PORTIONS REMOVED:  
*6/29/06*

CPSC Hotline: 1-800-638-CPSC(2772) CPSC's Web Site: <http://www.cpsc.gov>

**NOTE:** This document has not been reviewed or accepted by the Commission.  
 Initial *ph* Date *6/29/06*

II. Deny Petition HP 05-1 and direct staff to prepare a letter of denial to the petitioner.

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\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

III. Defer decision on Petition HP 05-1.

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

IV. Take other action (please specify):

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\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

Attachment: Briefing memo on Petition HP 05-1.



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

JUN 29 2006

**MEMORANDUM**

**To :** The Commission  
Todd A. Stevenson, Secretary *puF*

**Through :** Page C. Faulk, General Counsel *PS*  
Patricia Semple, Executive Director

**From :** Jacqueline Elder, Assistant Executive Director *je*  
Office of Hazard Identification and Reduction  
Suad Wanna-Nakamura, PhD., Project Manager, Petition *W*  
Requesting Amendment to the Ban on Infant Pillows, HP 05-1  
Directorate for Health Sciences

**Subject :** Staff Briefing Package on Petition Requesting Amendment to the  
Ban on Infant Pillows, HP 05-1

**INTRODUCTION**

Petition HP 05-1, requesting an amendment to the ban on infant pillows, was submitted to the U.S. Consumer Product Safety Commission (CPSC) by Mr. Erik Skoug, president of Boston Billows, Inc., (petitioner) on July 17, 2005 and was docketed under the Federal Hazardous Substances Act (FHSA) on September 15, 2005. The Commission requested public comments on the petition. The public comment period closed on December 12, 2005. The petitioner specifically requests that the Commission amend the ban on infant pillows under 16 C.F.R. 1500.18(a) (16) (i) (A)-(E) to read: "An exception is made when the product is specifically designed, intended and promoted for mothers use when breastfeeding and requested by a pediatrician or board certified lactation consultant."

This memorandum discusses the petition, supporting information, and the comments received in response to the Commission's notice in the Federal Register.

**BACKGROUND**

**Past Commission Activities**

In 1992, CPSC became aware of 37 incidents, occurring between 1985 and 1992 associated with the use of infant bean bag cushions, 35 were fatal, one resulted in brain

~~CPSC WITH CHANGES~~  
 NO HAZARDOUS MATERIALS OR PRODUCTS IDENTIFIED *6/29/06*  
 EXCEPTED BY PETITIONER  
RULEMAKING ADMIN. PROCES  
 WITH PORTIONS REMOVED

**NOTE: This document has not been reviewed or accepted by the Commission.**  
 Initial *rd* Date *6/29/06*

damage, and one did not result in injury. Since 1992, CPSC is unaware of any deaths or injuries associated with this product. In all incidents where the infant's position could be determined, the infant was found sleeping in a prone position. In all but two of the incidents, the infant was less than four months of age. In 1992, pursuant to the Commission's authority under the Federal Hazardous Substances Act, the Commission banned infant cushions or infant pillows. Under 16 C.F.R. 1500.18 (a) (16) (i), the Commission currently bans any article designated 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 December 17, 2003, CPSC staff became aware that Boston Billows, Inc., was marketing nursing pillows that might fit the definition of an infant bean bag cushion. The nursing aid pillow is a C-shaped product designed to fit around the mother's waist as a nursing aid for breastfeeding mothers. The pillow contains a loose filling of plastic beads enclosed in a fabric. Commission staff examined the nursing pillow as it was marketed and determined that the nursing pillow met the definition of an infant cushion. On January 23, 2004, the Office of Compliance issued a letter to Mr. Skoug, president Boston Billows, Inc., reporting that Commission staff had examined his company's Boston Billow Nursing Pillow and related promotional literature, and had subsequently determined that the product met the definition of an infant cushion and was subject to the ban on infant pillows issued under 16 C.F.R. 1500.18(a) (16) (i), (A) through (E). The determination was based on the fact that the Boston Billow Nursing Pillow met all five characteristics of the "infant cushion" or "infant pillow" ban as described in the CFR. CPSC's Office of Compliance staff requested that Boston Billows, Inc., immediately cease production and distribution of their product.

On September 1, 2004, CPSC and Boston Billows, Inc., announced the recall of the Boston Billow Nursing Pillow and alerted the public to the potential suffocation hazard posed by such products if infants were placed on these pillows and left unattended.

On February 27, 2004, CPSC's Office of Compliance staff indicated to Boston Billows, Inc., that the staff would not move against the sale of the nursing pillow with a wipeable cover if sales were limited to hospitals and for use only in a supervised hospital setting. Because of the potential suffocation hazard to young infants from these infant cushions, the staff's enforcement discretion was based on the pillows not being taken from the hospital settings for home use.

## **Petition**

On July 17, 2005, CPSC received correspondence from Mr. Skoug, requesting that the Commission amend 16 C.F.R. 1500.18(a) (16) (i) Criteria # 5 to permit the use of banned nursing pillows such as the Boston Billow Nursing Pillow. Boston Billows, Inc., asked that an exemption be made when the product is specifically designed, intended and promoted for mothers to use when breastfeeding and when requested by a

pediatrician or a board certified lactation consultant. Mr. Skoug contended that the nursing pillow "in design and promotion is completely different from the infant cushion of 1991." He also asserted it is for use by a nursing mother and not by children under one year of age. In the petition, the petitioner asserts such an amendment is warranted under the discretion allowed by the CPSC's Office of Compliance, given the current endorsed use of the Boston Billow Nursing Pillow in hospitals and by lactation consultants. Boston Billows, Inc., asserts that due to the physical configuration of the Nursing Pillow, it is unlikely that an infant could fall asleep on it in a position that would compromise the infant's ability to breathe.

The request for an amendment to the ban on infant pillows was docketed as petition number HP 05-1 under the Federal Hazardous Substances Act, 15 U.S.C. 1261-1278 on October 12, 2005 (FR Doc. 05-20524). Mr. Skoug makes several claims to support this request for an amendment:

1. The Boston Billow Nursing Pillow does not present an unreasonable risk of death.
2. The Boston Billow Nursing Pillow is specifically designed and promoted to aid mothers when breastfeeding, and is not intended for infants to sleep on.

## **COMMENTS ON THE PETITION AND STAFF RESPONSES**

On October 13, 2005, the Commission published a Federal Register notice soliciting comments on Petition HP 05-1, 70 FR 59726. The comment period closed on December 12, 2005, during which time the Commission received three comments on the petition. Two additional comments in support of the petitioner were received after December 12, 2005. On April 20, 2006, an additional submission was received from Mr. Skoug reiterating his previous comments. Copies of all comments are available from the Office of the Secretary.

### **Comment:**

One submission from Mr. Erik Skoug, President of Boston Billows, Inc., detailed his rationale behind the requested amendment. The submission also included letters of support from board certified lactation consultants (BCLC). The letters in support of the petition, related the authors' expert opinions on the significant benefits of the Boston Billow Nursing Pillow for infants and their mothers, particularly those mothers who delivered by Caesarian-section, had post-delivery surgery, or were nursing premature infants. The nurses stated that premature babies have poor muscle tone and they are unable to hold their heads upright. The nursing pillow design helps support the mother's arm and raises the infant's head to breast level during nursing. The group (BCLC) 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. Mr. Skoug also submitted a letter of support from Dr. Beckwith, a medical doctor, who stated his opinion that the product is, "clearly not a device intended for use during prone sleeping" because its shape "would make such sleep virtually impossible."

**Response:**

CPSC staff agrees that there are beneficial uses for the Boston Billow Nursing Pillow and acknowledgement of this formed the basis for the exemption granted by the Office of Compliance for use of the product in a hospital setting.

**Comment:**

The petitioner agrees that the “continued ban of infant cushions filled with granular material” is warranted, but opines that the Boston Billow Nursing Pillow be exempt from the ban because its demonstrated usefulness outweighs any minimal suffocation risk.

**Response:**

Given the likely use pattern and the differences in risk of injury, the staff believes a reexamination of the nursing pillow may be warranted.

**Comment:**

The petitioner suggests that there is no medical basis on which to support the bean bag cushion ban, since subsequent research after the infant pillow ban was promulgated has led to questioning of the rebreathing theory as a possible cause of infant death.

**Response:**

While the rebreathing theory was offered as a possible mechanism contributing to suffocation of infants on certain types of sleeping surfaces, the petitioner incorrectly assumes that the Commission’s ban was based on this theory. The ban was, in fact, based on the association of 35 infant deaths with bean bag cushions and on the capacity of these types of cushions to conform to an infant’s face and pose a suffocation hazard\*. It should be noted that the Commission’s recall efforts and rulemaking to ban the infant bean bag pillow were underway in 1990 prior to the publication of the rebreathing studies of Drs. Thach and Kemp in June 1991.

**Comment:**

Two other comments in response to Petition HP 05-1 were submitted by Alan Korn, Safe Kids Worldwide, and Susan Brown, The Boppy Company, another maker of infant nursing and support pillows. Both support the Commission’s ban, and both argue for rejecting the petition.

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\* Final Rule on Infant Cushions, Briefing Package, United States Consumer Product Safety Commission, Marilyn L. Wind, 1992.

One commenter, Susan Brown, suggested that although the manufacturer indicates that their product is “specifically designed, intended and promoted for mothers for use when nursing,” outside the current supervised setting of a hospital, the use of the Boston Billows Nursing Pillow for non-breastfeeding purposes would be hard to control and poses a risk.

**Response:**

Staff agrees with the concerns raised in these comments that the use of the Boston Billow Nursing Pillow for non-breastfeeding purposes would be hard to control and must be reviewed.

**DISCUSSION**

Staff is aware that there has been a proliferation of infant pillows or pillow-like products in the marketplace. Some of these are: (1) similar in appearance to the original infant bean bag cushion and meet all the specific criteria stated in the ban; (2) dissimilar in appearance from the original infant bean bag cushion, but with a filling that meets the criteria stated in the ban; or (3) similar in appearance to the original infant bean bag cushion, but with a filling that does not meet the stated criteria.

Since the ban of infant cushions and following considerable evidence that sleeping in the prone position (on the stomach) was a significant risk factor in SIDS, a nation-wide education campaign was launched in the United States recommending that infants be placed on their backs when put to sleep. 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. This guidance may make it less likely that infants will be placed on their stomachs to sleep.

While staff continues to believe that the Boston Billow Nursing Pillow, infant bean bag cushions and similar infant cushions/pillows pose similar suffocation risks to infants as other types of pillows when infants are placed to sleep on them, staff believes that a reexamination of the Boston Billow Nursing Pillow and similar pillows/cushions may now be warranted.

**OPTIONS**

**A. Grant the petition.** If the Commission grants the petition, the staff would prepare a draft advance notice of proposed rulemaking (ANPR) for consideration. Publication of an ANPR in the Federal Register would initiate a rulemaking proceeding to identify the article and the risk of injury, summarize regulatory alternatives, and invite comments from the public.

**B. Deny the petition.** The Commission could deny the petition if it determines that available information indicates that the product is considered a banned product because it meets the definition of an infant bean bag cushion and no further action is needed.

This will be considered as final agency action.

**C. Defer a decision.** The Commission could defer a decision on the petition if it determines that there is insufficient information to make a decision, but that additional information could be obtained in the near future.

#### **STAFF RECOMMENDATION**

Staff recommends that the Commission grant the petition and direct the staff to prepare an ANPR to open a rulemaking to evaluate whether the Boston Billow Nursing Pillow, and other infant pillows or pillow-like products, could result in the need for a broader exemption to the current ban on infant pillows.