



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

BALLOT VOTE SHEET

Date: **AUG 15 2008**

TO : The Commission
 Todd A. Stevenson, Secretary

THROUGH: Patricia Semple, Executive Director ^{PS}
 Cheryl F. Falvey, General Counsel *Cheryl Falvey*

FROM : Hyun S. Kim, Attorney *HSK*

SUBJECT : Draft Notice of Proposed Rulemaking on Proposed Exemption for Boston Billow Nursing Pillow and Substantially Similar Nursing Pillows; Draft Notice Terminating Rulemaking Other than With Respect to Boston Billow Nursing Pillow and Substantially Similar Nursing Pillows

Ballot Vote Due: AUG 25, 2008

Attached is a staff memorandum updating the January 2008 briefing package on additional incident data on infant deaths associated with cushions/pillows for the period of July 2007 through May 2008. Also attached in accordance with prior votes of the Commission are a draft notice of proposed rulemaking (NPR) on a proposed exemption for the Boston Billow Nursing Pillow and substantially similar nursing pillows and a draft notice terminating the currently pending rulemaking other than with respect to the Boston Billow Nursing Pillow and substantially similar nursing pillows.

Please indicate your vote on the following options.

I. Boston Billows NPR

1. Approve the NPR for publication in the *Federal Register* as drafted.

 Signature

 Date

NOTE: This document has not been reviewed or accepted by the Commission
 Initials ph Date 8/18/08

8/18/08

2. Approve the NPR for publication in the *Federal Register* with the following changes:

Signature

Date

3. Do not approve the NPR for publication in the *Federal Register*.

Signature

Date

II. Notice of Termination

1. Approve the notice of termination of rulemaking other than with respect to Boston Billow Nursing Pillow and Substantially Similar Nursing Pillows for publication in the *Federal Register* as drafted.

Signature

Date

2. Approve the notice of termination of rulemaking other than with respect to Boston Billow Nursing Pillow and Substantially Similar Nursing Pillows for publication in the *Federal Register* with the following changes:

Signature

Date

3. Do not approve the notice of termination of rulemaking other than with respect to Boston Billow Nursing Pillow and Substantially Similar Nursing Pillows for publication in the *Federal Register*.

Signature

Date

III. Take other action (please specify):

Signature

Date

Attachments:

1. Staff Memorandum Updating January 2008 Briefing Package
2. Draft Notice of Proposed Rulemaking on Proposed Exemption for Boston Billow Nursing Pillow and Substantially Similar Nursing Pillows
3. Draft Notice Terminating Rulemaking Other than With Respect to Boston Billow Nursing Pillow and Substantially Similar Nursing Pillows



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: 15 AUG 2008

TO : Cheryl A. Falvey, General Counsel

THROUGH: Patricia Semple, Executive Director *PS*
Jay Howell, Acting Assistant Executive Director, Office of Hazard
Identification and Reduction *MAS*
Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Health
Sciences *MACD*

FROM : Suad Wanna-Nakamura, PhD., Physiologist *MACD for SW-N*
Directorate for Health Sciences

SUBJECT : Suffocation hazards to infants when placed to sleep on cushions and pillows:
update of death data

This memorandum provides updated death data reported to CPSC staff from June 2007 to May 2008.

Death Data

CPSC data files were searched for infant (under one year of age) deaths associated with pillows or cushions using the same methodology as described in the Directorate for Epidemiology memo of the staff's January 2008 briefing package¹ (Andres, 2008). The databases used for this purpose were: In-Depth Investigations (INDP)²; and Death Certificates (DTHS)³ (Andres, 2008, email communication). Staff previously reviewed the period from January 1992 through June 2007 which showed 484 infant deaths associated with pillows or cushions. From July 2007 through May 2008, CPSC staff received additional reports of 47 infant fatalities that occurred between January 2006 and May 2008. This brings the total infant death count associated with pillows or cushions from January 1992 through May 2008 to 531 (484 + 47)⁴. The majority of the deaths were on adult pillows and sofa cushions. One of the 47 deaths involved a polyester filled crescent-shaped nursing pillow. In that case, a 46 day old infant died from suffocation after being placed to sleep in a prone position inside a crib with his head propped on the nursing pillow. This death, which occurred in 2007, involved a nursing pillow which is not a product subject to the CPSC's infant cushion ban. The January 2008 briefing package noted a death in

¹ Epidemiology staff memo: Pillow related infant deaths, Andres 2008. Staff Response to Advance Notice of Proposed Rulemaking on Infant Pillows, Tab C. <http://www.cpsc.gov/library/foia/foia08/brief/briefing.html>

² 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.

³ 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.

⁴ Epidemiology staff memo: Pillow related infant deaths, Andres 2008. Staff Response to Advance Notice of Proposed Rulemaking on Infant Pillows, Tab C. <http://www.cpsc.gov/library/foia/foia08/brief/briefing.html>

2001 associated with a polyester filled nursing pillow when a four month old infant was placed in a prone position in a playpen with his head resting on the nursing pillow.

CPSC staff is also aware of three additional deaths where there was a nursing pillow in the infant's sleep environment⁵. The pillows involved with these deaths were polyester filled crescent-shaped nursing pillows not subject to the CPSC's infant cushion ban. The three deaths occurred in 2006, in Westchester County, New York. The cause of death in all cases was initially determined by the medical examiner to be Sudden Infant Death Syndrome (SIDS)/undetermined. In 2008, the New York Westchester County, Child Fatality Review Team examined the case files⁶.

Further investigation of these incidents, including review of documents and photographs from the New York Westchester County Child Fatality Review Team and investigator interviews, reveals that in two of the three deaths, while nursing pillows were in the sleep environment, the deaths were deemed to be caused by SIDS/undetermined and could not be causally connected to the nursing pillows. With regard to the third death, the infant was propped to sleep in a prone position on the crescent-shaped nursing pillow.

In summary, since 1992 to the present, CPSC staff is aware of a total of three cases where infants died from suffocation after being placed to sleep in a prone position with their heads propped on a crescent-shaped nursing pillow.

⁵ <http://blogs.consumerreports.org/safety/2008/02/crib-deaths.html?resultPageIndex=1&resultIndex=2&searchTerm=nursing%20pillow>

⁶ <http://www.westchesterda.net/pressreleases/80204cfrt6.htm>

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

**Exemption from Classification as Banned Hazardous Substance;
Proposed Exemption for Boston Billow Nursing Pillow and
Substantially Similar Nursing Pillows.**

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission is proposing to exempt the Boston Billow Nursing Pillow and substantially similar nursing pillows from the Commission's regulations banning infant cushions/pillows set forth in the Commission's regulations at 16 CFR § 1500.18(a)(16)(i).

DATE: Written comments in response to this notice must be received by **[insert date that is 30 days after publication of this notice]**.

ADDRESSES: Comments should be submitted to the Office of the Secretary by e-mail at *cpsc-os@cpsc.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 NPR."

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@cpsc.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"). In almost all of the cases where the infant's position could be determined, the infant was in a prone, face down, position. 55 FR 42202. The Commission initiated a rulemaking proceeding to determine whether a ban was necessary to address an unreasonable risk of injury and death associated with these types of infant cushions/pillows. 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 at 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, Inc. (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. The petitioner is the manufacturer of the Boston Billow Nursing Pillow, a granularly filled, C-shaped pillow intended for use by mothers when breastfeeding.

B. The ANPR

The Commission issued an advance notice of proposed rulemaking (ANPR) on September 27, 2006, to assess whether a rulemaking was necessary to address any unreasonable risk of injury or death which may be associated with infant cushions/pillows. 71 FR 56418. In addition to the Boston Billow Nursing Pillow, which met the criteria of the ban, there appeared to be a proliferation of other infant cushions/pillows or pillow-like products in the marketplace, including nursing pillows which met some, but not all, of the criteria set forth in the ban. The potential regulatory alternatives noted included whether to: 1) amend the

regulation to allow an exemption to the ban; 2) delete, revise or add criteria to the ban; 3) leave the existing regulation unchanged; or 4) repeal the existing regulation. Nine written comments were received in response to the ANPR in support of Boston Billows' request for exemption from the ban. After review of the comments, incident reports and other available information, the Commission determined 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, a notice terminating the rulemaking on infant cushions/pillows or pillow-like products intended for use by infants, other than with respect to the Boston Billow Nursing Pillow and substantially similar nursing pillows, appears elsewhere in this *Federal Register*.

C. The Proposed Exemption

The ban on infant cushions/pillows was promulgated pursuant to the Federal Hazardous Substances Act (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 which 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 its design or manufacture presents an unreasonable risk of personal injury or illness during normal use or when subjected to reasonably foreseeable damage or abuse. 15 U.S.C. 1261(s). To grant Boston Billows' request for an exemption, the Commission must find that the Boston Billow Nursing Pillow does not present an unreasonable risk of injury from the mechanical hazard that the banning rule was intended to prevent.

Commission staff reviewed the incident data on infant cushions and nursing pillows for the period of January 1992 through June 2007. Staff also reviewed additional data from July 2007 through May 2008. Since 1992, there have been no reported deaths associated with infant cushions meeting the definition of a banned infant cushion/pillow. However, staff identified 531 infant deaths associated with pillows and cushions that did not meet the definition of a banned infant cushion/pillow. (From January 1992 through June 2007, there were 484 deaths reported and from July 2007 through May 2008, there were an additional 47 deaths reported.) The majority of these incidents involved adult pillows and sofa cushions which possess many of the same characteristics as the banned bean bag cushions. These products have soft

covers and flexible filling material that can conform to an infant's face. A variety of pillow types and cushions with different types of filling including foam, feathers, and polyester were involved in the incidents. In this data set, two infant deaths have been associated with a polyester filled nursing pillow (which does not meet the definition of a banned infant cushion/pillow). One incident occurred in 2001 when a four month old infant was placed to sleep on his stomach in a playpen with his head resting on the nursing pillow. The second incident occurred in 2007, when a 46 day old infant was placed in a prone position inside a crib with his head propped on the nursing pillow.

CPSC staff was also made aware of three additional deaths in 2006 where a nursing pillow was in the infant's sleep environment. The pillows involved with these deaths were polyester filled crescent-shaped nursing pillows not subject to the CPSC's infant cushion ban. The cause of these deaths in all cases was initially determined by the medical examiner to be Sudden Infant Death Syndrome (SIDS)/undetermined. . In 2008, the New York Westchester County Child Fatality Review Team examined the case files for these deaths. Further investigation of these incidents, including review of documents and photographs from the New

York Westchester County Child Fatality Review Team and investigator interviews reveals that in two of the three deaths, while nursing pillows were in the sleep environment, the deaths were deemed to be caused by SIDS/undetermined and could not be causally connected to nursing pillows. With regard to the third death, the infant propped to sleep in a prone position on a crescent-shaped nursing pillow. In summary, from 1992 to the present, staff is aware of a total of three cases where infants died from suffocation after being placed to sleep in a prone position with their heads propped on polyester filled crescent-shaped nursing pillows.

Staff's review revealed that in the vast majority of the 531 deaths associated with pillows and cushions, the infants were found in the prone position, lying on top of the pillow/cushion or with the head or neck propped on the pillow/cushion. 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 banned infant bean bag cushion, these pillows and cushions can cause death by suffocation/asphyxiation when an infant is placed to sleep face down on them. According to staff, 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 are the primary risk factors. The comparative risk of suffocation based upon filling is unknown; however, the greatest common risk factor is that infants were found in the prone position, face down, in the majority of the 531 deaths.

Prone sleeping is a high risk factor for infant suffocation on cushions/pillows. 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 on their backs are especially at risk for suffocation on any type of soft pillow, regardless of the type of filling.

In 1992, the American Academy of Pediatrics, in an effort to reduce the risk of SIDS, recommended that babies always be placed on their backs when put to sleep. As a result of this campaign, Sudden Infant Death Syndrome (SIDS) deaths between 1992 and 2004 in the United States decreased from 5,000 per year to 2,246 per year (based on vital

statistics data of the United States). Although there has been a steady decrease in SIDS deaths, staff found there has not been a similar decrease in infant deaths associated with pillows and cushions. Even though the recommendation to place infants to sleep on their backs is being promoted, staff believes that the data indicates that there are still a significant number of people who continue to place infants to sleep in the prone position. For this reason, staff recommends increased information dissemination targeted at the population of caregivers whose infants are not placed to sleep in the supine position. Increased compliance with the recommendation for supine sleep, as well as continued vigilance in ensuring a safe sleeping environment, would have benefits in reducing the risk of infant suffocation deaths caused by adult pillows, sofa cushions, and other pillows as well as further reducing incidents involving SIDS.

In light of the ongoing risks posed by infant cushions/pillows when used in the sleep environment, the Commission found no justification for repealing the ban on infant cushions/pillows at this time. However, nursing pillows perform a related but different function than infant cushions/pillows. The purpose of nursing pillows is to

provide a place for the mother to rest her arms while breastfeeding. The nursing pillow may also serve to give moldable but firm support to enhance comfort during extended periods when changing position during breastfeeding is difficult. The main risk of suffocation arises if the nursing pillow enters into the infant sleeping environment because suffocation can occur if children fall asleep on them in the prone position. However, an infant placed to sleep on any pillow or cushion, including a nursing pillow, in the prone position, is at risk for suffocation, regardless of size, type, shape of pillow or filling. Staff's review showed that when used for its intended purpose--nursing--the risk of infant suffocation on nursing pillows, including the Boston Billow Nursing Pillow, is very low. Staff estimates that 900,000 new nursing pillows are sold annually and that nursing pillows were used by approximately 1.8 million mothers in 2004. Exempting the Boston Billow Nursing Pillow would increase consumer choice by allowing consumers an alternative to the nursing pillows already in the marketplace. Based on the staff's assessment, the Commission preliminarily concludes that an exemption from the ban on infant cushions/pillows should be granted for the Boston Billow Nursing Pillow and

substantially similar nursing pillows.^{1/}

D. Regulatory Flexibility Act Certification

Under the Regulatory Flexibility Act (RFA), when an agency issues a proposed rule, it generally must prepare an initial regulatory flexibility analysis describing the impact the proposed rule is expected to have on small entities. 5 U.S.C. 603. The RFA does not require a regulatory flexibility analysis if the head of the agency certifies that the rule will not have a significant effect on a substantial number of small entities.

The proposed exemption gives all companies more flexibility in the choice of material used in manufacturing nursing pillows. The exemption is deregulatory in nature and will not impose any additional costs on businesses of any size. Consequently, the Commission concludes that the proposed amendment exempting the Boston Billow Nursing Pillow and substantially similar nursing pillows would not

^{1/}On February 1, 2008, Acting Chairman Nancy Nord and Commissioner Thomas Moore voted 2-0 to direct the Office of the General Counsel to prepare a notice of proposed rulemaking proposing an exemption for the Boston Billow nursing pillow and substantially similar nursing pillows. Acting Chairman Nord also voted to request ASTM to develop a product warning label for the product class.

have a significant impact on a substantial number of small entities.

E. Environmental Considerations

Generally, CPSC rules are considered to "have little or no potential for affecting the human environment," and environmental assessments are not usually prepared for these rules (see 16 C.F.R. 1021.5(c)(1)). Nothing in this proposed rule alters that expectation. Therefore, the Commission does not expect the proposal to have any negative environmental impact.

F. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. The preemptive effect of this proposed regulation is stated in section 18 of the FHSA. 15 U.S.C. 1261n.

List of Subjects in 16 CFR Part 1500

Consumer protection, Hazardous materials, Hazardous substances, Imports, Infants and children, Labeling, Law enforcement, and Toys.

G. Conclusion

For the reasons stated above, the Commission proposes to amend title 16 of the Code of Federal Regulations as

follows:

PART 1500 - HAZARDOUS SUBSTANCES AND ARTICLES:

ADMINISTRATION AND ENFORCEMENT REGULATIONS

1. The authority for part 1500 continues to read as follows:

Authority: 15 U.S.C. 1261-1278.

2. Section 1500.86 is amended by adding a new paragraph (a) (8) to read as follows:

§ 1500.86 Exemptions from classification as banned toy or other banned article for use by children.

(a) * * *

(8) Boston Billow Nursing Pillow and substantially similar nursing pillows that may otherwise meet the criteria of the banned infant cushion/pillow at 16 C.F.R. § 1500.18 (a) (16) (i).

Dated: _____

Todd A. Stevenson, Secretary
Consumer Product Safety Commission

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Infant Cushions/Pillows; Termination of Rulemaking Other than With Respect to Boston Billow Nursing Pillow and Substantially Similar Nursing Pillows

AGENCY: Consumer Product Safety Commission.

ACTION: Termination of rulemaking proceeding other than with respect to Boston Billow Nursing Pillow and substantially similar nursing pillows.

SUMMARY: On September 27, 2006, the Commission issued an advance notice of proposed rulemaking (ANPR) to assess whether a rulemaking was necessary to address any unreasonable risk of injury or death which may be associated with the proliferation of infant cushions/pillows and pillow-like products intended for infants in the marketplace, including the Boston Billow Nursing Pillow. 71 FR 56418. After review of the comments, incident reports and other available information, the Commission has determined there is insufficient data or product information on infant cushions/pillows or pillow-like products, other

than the Boston Billow Nursing Pillow and substantially similar nursing pillows, to proceed with further rulemaking on those products at this time. Based on these findings, the Commission terminates the infant cushion/pillow rulemaking other than with respect to the Boston Billow Nursing Pillow and substantially similar nursing pillows.

DATE: The termination is effective upon publication of this notice in the *Federal Register*.

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@cpsc.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"). In almost all of the cases where the infant's position could be determined, the infant was in a prone, face down, position. 55 FR 42202. The Commission initiated a rulemaking proceeding to assess whether a ban was necessary to address an unreasonable risk of injury and

death associated with these types of infant cushions/pillows. 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 at 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, Inc. (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. The petitioner is the manufacturer of the Boston Billow Nursing Pillow, a granularly filled, C-shaped pillow intended for use by mothers when breastfeeding.

B. The ANPR

The Commission issued an ANPR on September 27, 2006, to assess whether a rulemaking was necessary to address any unreasonable risk of injury or death which may be associated

with infant cushions/pillows. 71 FR 56418. In addition to the Boston Billow Nursing Pillow, which met the criteria of the ban, there appeared to be a proliferation of other infant cushions/pillows or pillow-like products in the marketplace, including nursing pillows which met some, but not all, of the criteria set forth in the ban. The potential regulatory alternatives noted included whether to: 1) amend the regulation to allow an exemption to the ban; 2) delete, revise or add criteria to the ban; 3) leave the existing regulation unchanged; or 4) repeal the existing regulation. Nine written comments were received in response to the ANPR in support of Boston Billows' request for exemption from the ban.

C. Incident Data

Commission staff reviewed the incident data on infant cushions and nursing pillows for the period of January 1992 through June 2007. Staff also reviewed additional data from July 2007 through May 2008. Since 1992, there have been no reported deaths associated with infant cushions meeting the definition of a banned infant cushion/pillow. However, staff identified 531 infant deaths associated with pillows and cushions that did not meet the definition of a banned infant cushion/pillow. (From January 1992 through June 2007,

there were 484 deaths reported and from July 2007 through May 2008, there were an additional 47 deaths reported.) The majority of these incidents involved adult pillows and sofa cushions which possess many of the same characteristics as the banned bean bag cushions. These products have soft covers and flexible filling material that can conform to an infant's face. A variety of pillow types and cushions with different types of filling including foam, feathers, and polyester were involved in the incidents. In this data set, two infant deaths have been associated with a polyester filled nursing pillow (which does not meet the definition of a banned infant cushion/pillow). One incident occurred in 2001 when a four month old infant was placed to sleep on his stomach in a playpen with his head resting on the nursing pillow. The second incident occurred in 2007, when a 46 day old infant was placed in a prone position inside a crib with his head propped on the nursing pillow.

CPSC staff was also made aware of three additional deaths in 2006 where a nursing pillow was in the infant's sleep environment. The pillows involved with these deaths were polyester filled crescent-shaped nursing pillows not subject to the CPSC's infant cushion ban. The cause of these deaths in all cases was initially determined by the

medical examiner to be Sudden Infant Death Syndrome (SIDS)/undetermined. In 2008, the New York Westchester County Child Fatality Review Team examined the case files for these deaths. Further investigation of these incidents, including review of documents and photographs from the New York Westchester County Child Fatality Review Team and investigator interviews reveals that in two of the three deaths, while nursing pillows were in the sleep environment, the deaths were deemed to be caused by SIDS/undetermined and could not be causally connected to nursing pillows. With regard to the third death, the infant was propped to sleep in a prone position on a crescent-shaped nursing pillow. In summary, from 1992 to the present, staff is aware of a total of three cases where infants died from suffocation after being placed to sleep in a prone position with their heads propped on polyester filled crescent-shaped nursing pillows.

Staff's review revealed that in the vast majority of the 531 deaths associated with pillows and cushions, the infants were found in the prone position, lying on top of the pillow/cushion or with the head or neck propped on the pillow/cushion. 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 banned infant bean bag cushion, these pillows and cushions can cause death by suffocation/asphyxiation when an infant is placed to sleep face down on them. According to staff, 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 are the primary risk factors. The comparative risk of suffocation based upon filling is unknown; however, the greatest common risk factor is that infants were found in the prone position, face down, in the majority of the 531 deaths.

Prone sleeping is a high risk factor for infant suffocation on cushions/pillows. 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 on their backs are especially at risk for suffocation on any type of soft pillow, regardless of the type of filling.

In 1992, the American Academy of Pediatrics, in an

effort to reduce the risk of SIDS, recommended that babies always be placed on their backs when put to sleep. As a result of this campaign, Sudden Infant Death Syndrome (SIDS) deaths between 1992 and 2004 in the United States decreased from 5,000 per year to 2,246 per year (based on vital statistics data of the United States). Although there has been a steady decrease in SIDS deaths, staff found there has not been a similar decrease in infant deaths associated with pillows and cushions. Even though the recommendation to place infants to sleep on their backs is being promoted, staff believes that the data indicates that there are still a significant number of people who continue to place infants to sleep in the prone position. For this reason, staff recommends increased information dissemination targeted at the population of caregivers whose infants are not placed to sleep in the supine position. Increased compliance with the recommendation for supine sleep, as well as continued vigilance in ensuring a safe sleeping environment would have benefits in reducing the risk of infant suffocation deaths caused by adult pillows, sofa cushions, and other pillows as well as further reducing incidents involving SIDS.

D. Conclusion

In light of the ongoing risks posed by infant cushions/pillows when used in the sleep environment, the Commission finds no justification for repealing the ban on infant cushions/pillows at this time. Moreover, after review of the comments, incident reports and other available information, the Commission determines there is insufficient data or product information on infant cushions/pillows or pillow-like products intended for infants, other than with respect to the Boston Billow Nursing Pillow and substantially similar nursing pillows, to proceed with further rulemaking on those products at this time. Thus, the Commission is terminating the rulemaking on infant cushions/pillows or pillow-like products, other than with respect to the Boston Billow Nursing Pillow and substantially similar nursing pillows effective upon publication in the *Federal Register* for good cause shown in accordance with 5 U.S.C. 553(d)(3).^{1/} A proposed exemption

^{1/}On February 1, 2008, Acting Chairman Nancy Nord and Commissioner Thomas Moore voted 2-0 to direct the Office of the General Counsel to prepare a notice terminating the rulemaking other than with respect to the Boston Billow Nursing Pillow and substantially similar nursing pillows.

from the ban for the Boston Billow Nursing Pillow and substantially similar nursing pillows appears elsewhere in this *Federal Register*.^{2/}

Dated: _____

Todd A. Stevenson, Secretary
Consumer Product Safety Commission

^{2/}On February 1, 2008, Acting Chairman Nancy Nord and Commissioner Thomas Moore voted 2-0 to direct the Office of the General Counsel to prepare a notice of proposed rulemaking proposing an exemption for the Boston Billow Nursing Pillow and substantially similar nursing pillows. Acting Chairman Nord also voted to request ASTM to develop a product warning label for the product class.