United States
Consumer Product Safety Commission

This document has been electronically approved and signed.

Vote Sheet

TO: The Commission
Alberta E. Mills, Secretary

DATE: August 23, 2023

THROUGH: Austin C. Schlick, General Counsel
Jason K. Levine, Executive Director

FROM: Mary A. House, Acting Assistant General Counsel, Regulatory Affairs
Elisabeth Layton, Attorney, Regulatory Affairs

SUBJECT: Notice of Proposed Rulemaking: Safety Standard for Nursing Pillows

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THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: September 13, 2023

Pursuant to the Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), 15 U.S.C. § 2056a, which requires the Commission to promulgate consumer product safety standards for durable infant or toddler products, the Office of the General Counsel is forwarding for the Commission's consideration a staff briefing package recommending publication in the *Federal Register* of the attached draft notice of proposed rulemaking to establish a Safety Standard for Nursing Pillows. To implement the requirements of section 104, the draft proposed rule includes mandatory performance and labeling requirements that address suffocation, entrapment, and fall hazards associated with nursing pillows.

Please indicate your vote on the following options:

I. Approve publication of the attached notice in the *Federal Register*, as drafted.

_____ _____
(Signature) (Date)

U.S. Consumer Product Safety Commission
4330 East-West Highway
Bethesda, MD 20814

National Product Testing and Evaluation Center
5 Research Place
Rockville, MD 20850

II. Approve publication of the attached notice in the *Federal Register*, with the specified changes.

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_____ _____

(Signature) (Date)

III. Do not approve publication of the attached notice in the *Federal Register*.

_____ _____

(Signature) (Date)

IV. Take other action specified below.

_____

_____

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_____

_____ _____

(Signature) (Date)

Attachment: Notice of Proposed Rulemaking: Safety Standard for Nursing Pillows

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1242

[CPSC Docket No. 2023-XXXX]

Safety Standard for Nursing Pillows

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the U.S. Consumer Product Safety Commission (Commission or CPSC) to promulgate consumer product safety standards for durable infant or toddler products. The Commission is proposing a safety standard for nursing pillows. The Commission is also proposing to amend CPSC's consumer registration requirements to identify nursing pillows as durable infant or toddler products and proposing to amend CPSC's list of notice of requirements (NORs) to include such nursing pillows.

Nursing pillows provide support to caregivers by raising infants to the desired height for feeding, thereby reducing muscular strain and abdominal pressure on the caregiver and providing a buffering surface between the infant and the caregiver. When infants fall asleep or are left unattended on nursing pillows, however, they are at risk for death or serious injury by suffocation. This proposed rule would help ensure that consumers continue to have access to nursing pillows for feeding and while reducing s that have been identified for this product category.

DATES: Submit comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature requirements of the proposed rule should be directed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: CPSC Desk Officer, FAX: 202-395-6974, or e-mailed to oira_submission@omb.eop.gov.

Other comments, identified by Docket No. CPSC-2023-XXXX, may be submitted electronically or in writing, as follows:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: http://www.regulations.gov. Follow the instructions for submitting comments. CPSC typically does not accept comments submitted by email, except as described below. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Mail/Hand Delivery/Courier Written Submissions: Submit comments by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; telephone: (301) 504–7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: *cpsc-os@cpsc.gov*.

Instructions: All submissions received must include the agency name and docket number for this proposed rulemaking. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: *www.regulations.gov*. Do not submit electronically any confidential business information, trade

secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier written submissions.

Docket: For access to the docket to read background documents or comments received, go to: http://www.regulations.gov, insert the docket number, CPSC- 2023-XXXX, into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Timothy Smith, Project Manager, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; email: tsmith@cpsc.gov; telephone: (301) 987-2557.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

Section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, requires the Commission to (1) examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts, and (2) promulgate consumer product safety standards for durable infant and toddler products. 15 U.S.C. 2056a(b)(1). The Commission must continue to promulgate standards for all categories of durable infant or toddler products "until the Commission has promulgated standards for all such product categories." 15 U.S.C. 2056a(b)(2).

The Commission is issuing this notice of proposed rulemaking (NPR) to establish a consumer product safety rule for nursing pillows to further implement section 104 of the CPSIA. The briefing package prepared by Commission staff defines "nursing pillows" as "any

product intended, marketed, or designed to position and support an infant close to a caregiver's body while breastfeeding or bottle feeding. These products rest upon, wrap around, or are worn by a caregiver in a seated or reclined position." [1]

As required by section 104(b)(1)(A) of the CPSIA, CPSC consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and the public to develop this rule, including through participation in the juvenile products subcommittee meetings of ASTM. CPSC formally began the consultation process for this rulemaking in December 2021, via a letter from CPSC staff requesting that ASTM form a working group to develop a voluntary standard to reduce the risk of death and injury from hazards associated with infant pillow products, including nursing pillows.[2] CPSC staff provided ASTM incident data associated with both nursing pillows and infant support cushions. In response, ASTM formed the following subcommittees to develop two separate voluntary standards:

- the F15.16 Infant Feeding Supports subcommittee,[3] intended to develop a standard for nursing pillows, which the subcommittee refers to as infant feeding supports; and
- the F15.21 Infant Loungers subcommittee, with a remit including nursing pillows that are also intended for lounging.

CPSC staff has been actively participating in both ASTM subcommittees to develop voluntary standards that address hazards associated with these products.

Currently, no voluntary or mandatory safety standard for nursing pillows exists to address the hazards of infants sleeping on or in these products. Pursuant to section 104 of the

[1] Staff Briefing Package: Staff's Draft Proposed Rule for Nursing Pillows (Aug. 23, 2023) (Staff's NPR Briefing Package), available at: **[INSERT WEB LINK TO STAFF BRIEFING PACKAGE ON CPSC.GOV]**
[2] https://www.cpsc.gov/s3fs-public/Nursing-and-Support-Pillow-VS-request.pdf.
[3] The ASTM F15.16 Infant Feeding Supports subcommittee was initially called the Feeding and Infant Support Products subcommittee.

CPSIA, 15 U.S.C. 2056a, the Commission proposes to issue a mandatory standard for nursing pillows. Nursing pillows are sometimes used on elevated surfaces or inside an infant sleep product, which can lead to death or serious injury by suffocation, entrapment, or falls. CPSC staff identified 154 infant fatalities and 88 nonfatal incidents from January 1, 2010, to December 31, 2022, involving nursing pillows. Of the 154 fatalities, an infant was sleeping in or on the nursing pillow in 142 cases. In 1992, CPSC adopted a ban on certain types of hazardous "infant pillows" that contain loosely filled granular materials that conform to an infant's face or body, codified at 16 CFR § 1500.18(a)(16) (Infant Pillow Ban). Certain nursing pillows are exempt from the Infant Pillow Ban while others do not fall within its scope, such as pillows with a non-granular fill. Many products are currently marketed for both nursing and "lounging," despite the suffocation hazard posed of by propping up very young infants. In 2020, the most recent year for which CPSC has complete data, nursing pillows are associated with 38 fatalities and 14 injuries.

To address the risk of death and injury associated with nursing pillows, and as required in section 104 of the CPSIA, the Commission is issuing this proposed rule to establish mandatory performance and labeling requirements for nursing pillows. The proposed rule is intended to address the hazards associated with infants in nursing pillows. Accordingly, the proposed rule addresses:

(1) suffocation hazards associated with nursing pillows, by requiring nursing pillows to be sufficiently firm that the product is unlikely to conform to an infant's face and occlude its airways;

(2) entrapment hazards posed when the product restricts an infant's head movements, via performance standards requiring testing to assess this hazard;

(3) suffocation and fall risks due to infant restraints that could suggest to consumers that infants can safely be left unattended in or on the product; and

(4) the risks of suffocation, entrapment, or fall when an infant is left unattended in the product by requiring labeling and instructional literature to better communicate risks.

Section VI of this preamble, and Tabs B and C in Staff's NPR Briefing Package, provide a detailed explanation of proposed performance and labeling requirements.

Nursing pillows are a durable infant or toddler product under section 104(f) of the CPSIA. Section 104(f)(1) defines the term "durable infant or toddler product" as "a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years." 15 U.S.C. 2056a(f)(1). Section 104(f)(2) of the CPSIA provides a non-exhaustive list of product categories within the definition of "durable infant or toddler products." Although nursing pillows are not specifically listed in section 104(f)(2), they are "durable infant or toddler products" because (as explained in Part X below) they are durable products reasonably expected to be used by infants under the age of 5 years for support while they are being fed.

Section 104(d) of the CPSIA requires manufacturers of durable infant or toddler products to establish a product registration program and comply with CPSC's rule for product registration cards, 16 CFR part 1130. Any product defined in part 1130 as a "durable infant or toddler product" must comply with the product registration requirements, as well as testing and certification requirements for children's products, that are codified in 16 CFR parts 1107 and 1109. Because nursing pillows are durable infant products that will be subject to the proposed consumer product safety standard, the Commission proposes to amend part 1130 to include

nursing pillows in the list of durable infant or toddler products that must comply with these product registration requirements. *See* 16 CFR § 1130.2(a).

The testing and certification requirements of section 14(a) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2063(a), apply to standards promulgated under section 104 of the CPSIA. Section 14(a)(3) of the CPSA requires the Commission to publish an NOR for the accreditation of third party conformity assessment bodies (test laboratories) to assess conformity with a children's product safety rule to which a children's product is subject. The proposed rule would be a children's product safety rule that requires the issuance of a NOR.

II. The Product Category

A. Definition of Nursing Pillows

Nursing pillows are infant products intended to position and support an infant during breastfeeding—also referred to as nursing—or bottle feeding. These products generally rest upon or are "worn" by the caregiver while seated or partially reclined. Nursing pillows are most commonly C-, U-, or crescent- (or horseshoe-) shaped—to fit closely around the caregiver's torso. However, other designs exist, including a V-shaped or boomerang-shaped product, a round pod with a recessed center to support the infant, a stack of multiple petal-shaped pillows attached to a central tubular pillow, and E-shaped products for twins. Most nursing pillows are filled with synthetic batting or foam, but products filled with cotton, wool, or dried grains are available. *See* Tab E of Staff's NPR Briefing Package.

In addition to providing a support surface for infants, nursing pillows raise the infant to the desired height for feeding, thereby reducing muscular strain on the caregiver, and provide a buffering surface between the infant and the caregiver, reducing pressure on the caregiver's abdomen. This latter function is especially helpful where the caregiver has abdominal stitches

from a caesarean section. Some products include a strap or belt, sometimes with a buckle, to secure the product to the caregiver's body, and a few have restraints that attach the infant to the product. Many products come with removable fabric covers, and some products have small infant head support bolsters or fabric toys attached.[4]

Nursing pillows are not covered by an existing voluntary safety standard. However, CPSC staff has been working with ASTM's F15.16 Infant Feeding Supports subcommittee to develop requirements intended to address the primary hazards associated with nursing pillows. On March 20, 2023, ASTM's F15.16 subcommittee issued a preliminary draft of the ASTM Infant Feeding Supports voluntary standard (ASTM draft standard).[5] The ASTM draft standard defines an infant feeding support as a "product that is intended to position and support an infant (the occupant) close to a caregiver's body, and to reduce strain and pressure on the caregiver's body, while breastfeeding or bottle feeding." Although not part of the formal definition, the ASTM draft standard includes clarifying text that states: "These products are commonly U-shaped in appearance, and generally rest upon, wrap around, or are worn by a caregiver in a seated or reclined position. These products are commonly known as nursing pillows." Thus, the ASTM draft standard for infant feeding supports would include nursing pillows within the scope of covered products.

B. Market Description

As discussed in Staff's NPR Briefing Package at Tab E, CPSC estimates that annual sales of new nursing pillows likely total approximately $67 million. New nursing pillows range in price from $15 to $100, with most products in the $25 to $65 range. The more expensive

[4] *See* Staff NPR Briefing Package at 5, figures 1 and 2, for examples of nursing pillow designs.
[5] *See* Staff NPR Briefing Package at 12-17 and Engineering, Human Factors, and Health Sciences assessments, Tabs B, C, and D.

models tend to have removable covers. The Commission's estimate of $67 million per year in sales of new nursing pillows assumes an average price of approximately $50 and annual sales of 1.34 million units. Some parents, however, may already own a pillow that was purchased for an older child, make a pillow, or buy a used pillow to use for nursing. Used nursing pillows and replacement covers for nursing pillows are commonly available from secondary marketplaces such as eBay and Mercari, where prices are observed to range from less than $7 to more than $120. The widespread availability of replacement covers extends the useful life and durability of nursing pillows, allowing covers to be cleaned or replaced as needed.

Although more than a thousand businesses sell nursing pillows and nursing pillow covers online, just nine companies supply the models commonly sold in brick-and-mortar stores. Individual stores typically have fewer than four models of nursing pillows in stock, which limits consumers' ability to assess the safety-related characteristics of the products and to make selections on that basis.

C. Infant Cushion/Pillow Ban and Nursing Pillow Exemption

In 1992, pursuant to the Commission's authority under the Federal Hazardous Substances Act (FHSA), the Commission issued its Infant Pillow Ban. 57 FR 27912 (June 23, 1992). The Infant Pillow Ban bans "infant cushions," "infant pillows," and similar articles that are:

- loosely filled with granular material, including but not limited to, polystyrene beads or pellets;
- easily flattened;
- capable of conforming to the body or face of an infant; and
- intended or promoted for use by children under 1 year of age.

This proposed rule for nursing pillows does not change the FHSA ban. That ban was limited to infant cushions and infant pillows defined in the Infant Pillow Ban and the specific hazard presented by products with loosely filled granular material such as polystyrene beads or pellets.

In 2008, the Commission approved an exemption to the Infant Pillow Ban. 73 FR 77493 (Dec. 19, 2008). The exemption applies to Boston Billow Nursing Pillows and substantially similar nursing pillows that are designed to be used only as nursing aids for breastfeeding mothers. 16 CFR § 1500.86(a)(9). Examples of products that fall within this exemption include nursing pillows that are tubular in form, C- or crescent-shaped to fit around a caregiver's waist, round in circumference, and filled with granular material. The exemption applies only to the Infant Pillow Ban and is not applicable to this proposed rule. In approving the exemption, the Commission assessed the utility of nursing pillows and the risk of harm based on data from January 1992 to May 2008. The Commission found that the data available at that time did not support a ban on the sale of all nursing pillows under the FHSA. *Termination of Rulemaking Other Than With Respect to Boston Billow Nursing Pillow and Substantially Similar Nursing Pillows*, 73 FR 51386, 51387 (Sept. 3, 2008).

Unlike the Infant Pillow Ban, this proposed rule sets a performance standard pursuant to the CPSIA that allows for the sale of nursing pillows that meet the requirements in the standard. As described below, this proposed rule is based in part on new data concerning incidents that occurred between January 2010 through December 2022, many of which were fatal. The proposed rule does not alter either the Infant Pillow Ban at 16 CFR § 1500.18(a)(16) or the exemption codified at 16 CFR § 1500.86(a)(9), both of which would remain in place. Thus, products that are not banned under the Infant Pillow Ban but that meet this proposed rule's definition of a nursing pillow would need to comply with the proposed rule.

III. Incident Data and Hazard Patterns

CPSC staff searched the Consumer Product Safety Risk Management System (CPSRMS)[6] and National Electronic Injury Surveillance System (NEISS)[7] databases for fatalities, incidents, and concerns associated with nursing pillows and involving infants up to 12 months old, reported to have occurred between January 1, 2010, and December 31, 2022. Commission staff identified 154 fatal incidents and 88 nonfatal incidents and consumer concerns reported to CPSC during this time. Because reporting is ongoing, the number of reported fatalities and nonfatal incidents during this period may increase, especially for years 2021 and 2022. Tab A of Staff's NPR Briefing Package describes the incident and hazard patterns associated with nursing pillows.

A. Incident Severity

The Commission is aware of 242 incident reports associated with nursing pillows. Table 1 groups the reported cases by severity. Of the 242 reports, 154 (64 percent) involved a fatality.[8] Of the 88 nonfatal incidents, 64 (73 percent) resulted in an injury, and 24 (27 percent) reported no injury. Among the reported incidents without injury, some included concerns such

[6] CPSRMS is the epidemiological database that houses all anecdotal reports of incidents received by CPSC, "external cause"-based death certificates purchased by CPSC, all in-depth investigations of these anecdotal reports, as well as investigations of select NEISS injuries. CPSRMS documents include hotline reports, online reports, news reports, medical examiner's reports, death certificates, retailer/manufacturer reports, and documents sent by state and local authorities, among others.

[7] NEISS is a statistically valid surveillance system for collecting injury data. NEISS is based on a nationally representative probability sample of hospitals in the U.S. and its territories. Each participating NEISS hospital reports patient information for every emergency department visit associated with a consumer product or a poisoning to a child younger than five years of age. The total number of product-related hospital emergency department visits nationwide can be estimated from the sample of cases reported in the NEISS. *See* https://www.cpsc.gov/Research--Statistics/NEISS-Injury-Data.

[8] More than half of the fatalities of which CPSC staff is aware were reported to have occurred since 2019. Staff's NPR Briefing Package at Tab A. However, staff has noted that because the reported data are anecdotal, fluctuations in the numbers of reported incidents could simply reflect changes in reporting rather than an actual change in incident frequency. *Id.*

as product integrity or the smell of the nursing pillow that are unrelated to the hazards this proposed rule is intended to address. Table 1 provides the distribution of incidents by year.

Table 1: Reported Incidents and Injury Severity by Year, January 1, 2010 – December 31, 2022

Year	Fatalities	Injuries	No Injury	Total
2010	7	3	2	**12**
2011	5	0	1	**6**
2012	7	1	1	**9**
2013	5	0	6	**11**
2014	4	2	3	**9**
2015	10	3	0	**13**
2016	6	3	1	**10**
2017	10	5	0	**15**
2018	16	2	0	**18**
2019	17	5	0	**22**
2020	38	14	2	**54**
2021*	21	14	1	**36**
2022*	8	12	7	**27**
Total	**154**	**64**	**24**	**242**

Source: CPSRMS and NEISS
Reporting is ongoing; 2021-2022 are incomplete.

As reflected in Table 2, nearly all (144 of the 154, or 94 percent) of the reported fatalities associated with nursing pillows involved infants 6 months old and younger, and most (110 out of 154, or 71 percent) were deaths of infants 3 months old or younger. For more than two-thirds of the nonfatal incidents and nearly all the incidents without injury, however, the victim's age is not available.

Table 2: Reported Incidents and Injury Severity by Age, January 1, 2010 – December 31, 2022

Age	Fatalities	Injuries	No Injury	Total
1 month	44	7	0	**51**
2 months	36	4	0	**40**
3 months	30	5	0	**35**
4 months	15	4	1	**20**
5 months	10	4	0	**14**
6 months	9	1	0	**10**
7 months	6	1	0	**7**
8 months	2	1	0	**3**
9 months	1	1	0	**2**
Unknown	1	36	23	**60**
Total	**154**	**64**	**24**	**242**

Source: CPSRMS and NEISS
Reporting is ongoing. 2021-2022 are considered incomplete.

B. Fatalities and Associated Hazard Patterns

The official cause of death reported by the medical examiner in nearly all of the 154 reported fatalities was asphyxia, suffocation, overlay, sudden unexpected infant death (SUID), sudden infant death syndrome (SIDS; a sub-type of SUID), or a similar cause. Nearly all reported *fatalities* (142 of the 154) involved use of the nursing pillow for sleep, and these cases often involved additional unsafe sleep conditions including sleep-surface sharing—also known as co-sleeping—or the presence of other soft bedding such as pillows or blankets.

Nursing pillows are intended to be used for feeding when both infant and caregiver are awake, and the caregiver is able to ensure that the infant's airways are not covered by the pillow. However, because infants frequently fall asleep during or after feeding, nursing pillows are foreseeably misused for infant sleep, which creates a potential hazard for the infant. For example, if a sleeping infant rolls over so their face is pressed against the nursing pillow, the infant's airways may be blocked, causing suffocation. Similarly, if an infant falls into the opening where the caregiver is positioned during feeding, the infant can land face-down with the pillow surrounding their head, causing entrapment against the surface on which the pillow rests. Even if the infant remains with their back against the top of the nursing pillow, if the infant's position shifts so that their head falls against their chest or tilts backwards over the top of the pillow, the hyperextension or hyperflexion of the infant's neck can prevent breathing.

For the most part, there was no witness observing the fatal incidents, and 60 of the fatal cases (39 percent) had insufficient details to enable CPSC staff to determine the hazard pattern or scenario. However, CPSC staff classified the remaining 94 reported fatalities by hazard patterns, based on the best available information about the position in which the victim was found. Table 3 shows the distribution of the 154 reported fatalities by hazard scenario.

Table 3: Reported Fatalities by Hazard Scenario, January 1, 2010 – December 31, 2022

Hazard Scenario	Fatalities	Percent*
Face into product	32	21
Face into other object/bedding outside product	21	14
Face down in opening	14	9
Neck extension/flexion	13	8
Bedding over face	4	3
Face into product or bedding (unknown)	4	3
Entrapment/overlay while nursing	3	2
Overlay	3	2
Unknown	60	39
Total	**154**	**100**

Source: CPSRMS
Reporting is ongoing, especially for 2021-2022.
*Percentages may not sum to 100 due to rounding.

Sixty-two fatalities (40 percent) involved the nursing pillow product being used in another infant sleep product, such as a crib, portable playpen, or bassinet; 61 fatalities (40 percent) involved use of the product on an adult bed or mattress; and one fatality involved a mattress of unknown size. Eighteen reported fatalities (12 percent) involved the product being used on a couch, sofa, or loveseat; one fatality involved the product being used on the caregiver's lap in a recliner chair; and the use location for 11 fatalities is unknown. Table 4 displays fatal incidents by the location where the nursing pillow and infant were placed.

Table 4: Reported Fatalities by Pillow/Infant Placement, January 1, 2010 – December 31, 2022

Pillow/Infant Placement		Fatalities	Percent*
Infant sleep product		**62**	**40**
Bassinet		29	19
Crib		20	13
Portable playpen/crib		13	8
Adult sleep product		**61**	**40**
Adult bed		58	38
Adult mattress		3	2
Couch		**18**	**12**
Recliner chair		**1**	**1**
Unknown size mattress		**1**	**1**
Unknown		**11**	**7**
Total		**154**	**100**

Source: CPSRMS
Reporting is ongoing, especially for 2021-2022.
*Percentages may not sum to 100 due to rounding.

C. Nonfatal Incidents

Of the 88 nonfatal incidents associated with nursing pillows, 64 resulted in an injury to the infant and 24 did not lead to a reported injury. Of the 64 injury victims, 19 infants were known to have been treated and released from the emergency department. All 19 of these injuries involved the infant falling or rolling off, or out, of the nursing pillow. An additional 3 injuries, one involving a burn, one due to a fall, and one due to cardiopulmonary arrest after the infant was laying on the nursing pillow, resulted in hospital admission. The remaining 42 injuries where the level of care was not known included falls, near suffocation, near strangulation, choking, and skin irritation or allergy. Table 5 summarizes the hazard patterns for the nursing pillow-related nonfatal incidents.

Table 5: Reported Nonfatal Incidents by Hazard Pattern, January 1, 2010 – December 31, 2022

Hazard	Nonfatal Incidents	Percent*
Skin allergy/irritation	**29**	**33**
Fall/roll out	**23**	**26**
Elevated surface	19	22
Carrying in product	2	2
Same level	1	1
Unknown level	1	1
Filling coming out/choking hazard	**6**	**7**
Product integrity	**5**	**6**
Strong smell	**5**	**6**
Other	**20**	**23**
Total	**88**	**100**

Source: CPSRMS and NEISS
Reporting is ongoing for these databases, especially for 2021-2022.
*Percentages may not sum to 100 due to rounding.

Table 6 displays nonfatal injuries by the location in which the nursing pillow and infant were placed. In 66 percent (42 of 64) of the nonfatal injuries, the location was unknown, but the most common locations among the remaining incidents were couches and beds.

Table 6: Reported Nonfatal Injuries by Pillow/Infant Placement, January 1, 2010 – December 31, 2022

Pillow/Infant Placement	Injuries	Percent*
Couch	8	13
Adult bed^	5	8
Bed, unknown type	3	5
Infant being carried in product	2	3
Table	2	3
Bathroom counter	1	2
Rocking Chair**	1	2
Unknown	42	66
Total	**64**	**100**

Source: CPSRMS and NEISS
Reporting is ongoing for these databases, especially for 2021-2022.
*Percentages may not sum to 100 due to rounding.
^In one incident, the caregiver was breastfeeding while in an adult bed.
**Infant was placed on the caregiver's lap while in the rocking chair.

IV. The BSU Final Report[9]

CPSC awarded a contract to Boise State University (BSU) for infant biomechanics and suffocation research and consultancy services. One task under this contract was for research on pillows intended for infant care and use, and an analysis of the risk of injury or death to infants associated with the use of infant pillows marketed as aiding infants during activities such as feeding, nursing, sleeping, propping, and lounging; that is, nursing pillows and infant support cushions.

BSU delivered its final report on June 30, 2022 (the BSU Final Report).[10] The BSU Final Report provides recommendations and conclusions related to the performance and design of nursing pillows, including:

- *Firmness Testing.* The BSU Final Report recommends that all nursing pillows be required to undergo firmness testing, because products that lack firmness are more

[9] *See* Staff's NPR Briefing Package, Tab B.
[10] Mannen, E. M., Davis, W., Goldrod, S., Lujan, T., Siddicky, S. F., Whitaker, B., & Carroll, J. (2022). *Pillows Product Characterization and Testing*. Prepared for the U.S. Consumer Product Safety Commission under contract no. 61320620D0002, task order no. 61320621F1015. Available at: https://www.cpsc.gov/content/Pillows-Product-Characterization-and-Testing.

likely to conform around an infant's nose and mouth and to present a suffocation hazard. The report recommends testing using a 3-inch diameter, anthropometry-based hemispheric probe that is geometrically similar to, and sized to represent the breadth of, an infant's face. The report suggests that this probe should be applied to the product at three locations: the location of maximum thickness, the location of minimum thickness, and a thirdlocation that seems particularly soft or is otherwise most likely to result in failure. The force required to displace the probe 1 inch into the product at each location must exceed 10 Newtons (N). Passing this requirement would mean that the product has firmness comparable to crib mattresses, which are generally considered the safest place for an infant to sleep.

- *Airflow Testing.* The BSU Final Report recommends that products that do not pass firmness testing be required to pass an airflow test. Passing the airflow test would mean that the product has airflow characteristics comparable to current mesh crib liners, which the BSU researchers believe would mitigate the suffocation hazard. However, the report also recommends that airflow testing is not required for products that pass their proposed firmness testing, because a firm product is unlikely to form a seal around an infant's nose and mouth.
- *Sagittal-Plane Testing.* BSU developed prototype sagittal-plane testing devices to allow for more comprehensive assessments of infant positioning in and on nursing pillows and infant support cushions.[11] The BSU Final report emphasizes that further research is needed to determine appropriate worst-case positions for testing and to

[11] The sagittal plane is an anatomical plane that runs vertically through the human body, dividing it into left and right sections. It can be thought of as viewing the human body in profile.

set threshold values for acceptable body positions that would not negatively impact infant breathing.

- *Nursing Pillow Shape.* The BSU Final Report advises that nursing pillows that are firm and feature sharper corners, rather than cylindrical sides, are likely the safest option for infants, because there would be no reasonable way for consumers to use such a product for lounging, thereby limiting the hazards associated with sagittal-plane positioning in a nursing pillow.

CPSC considered the BSU Final Report and its recommendations when developing this proposed rule for nursing pillows. Tab B of Staff's NPR Briefing Package contains CPSC staff's assessment of how the proposed rule reflects the report's conclusions and recommendations.

V. ASTM's Draft Standard[12]

There are no published U.S. voluntary standards for nursing pillows. However, on March 20, 2023, ASTM issued ballot F15.16 (23-01), which included the ASTM draft standard. The ballot closed on April 20, 2023, and received 11 negative votes with comments and 6 other comments. Although not adopted, the ASTM draft standard reflects the types of performance requirements that are under consideration by industry, with input from CPSC staff.[13] It includes general requirements typically found in other ASTM juvenile product standards, such as requirements for lead, including lead in paints; prohibitions against small parts, hazardous sharp edges or points, and removable protective components; requirements to prevent injury from

[12] *See* Staff's NPR Briefing Package, Tab B.

[13] On August 21, 2023, ASTM issued ballot F15 (23-12), which included a revised draft of the ASTM Infant Feeding Supports voluntary standard. This new ballot is scheduled to close on September 21, 2023. Staff is currently reviewing the ballot

scissoring, shearing, and pinching; requirements for toy accessories that are attached to, removable from, or sold with the products; and permanency requirements for labels and warnings.

The ASTM draft standard also includes four performance requirements intended to address safety hazards specifically associated with nursing pillows:

- *Infant Restraints*: This requirement prohibits infant feeding supports from including an infant restraint system, which may entangle an infant and could invite misuse by suggesting to caregivers that it is acceptable to leave an infant unattended on the nursing pillow.
- *Fabric/Mesh Integrity*: This requirement is intended to address product integrity issues such as seam failures and material breakage.
- *Firmness*: This requirement places limits on the extent to which certain portions of the product can deflect when a 3-inch diameter hemispheric probe is applied to the product with a certain force. The proposed requirement and test method address the suffocation hazard when a nursing pillow conforms to an infant's face, and are based on the firmness recommendations in the BSU Final Report.[10] However, the BSU researchers' recommended requirements were applied not only to the top infant support surface, but also to the inner wall of the crescent-like opening of these products. Testing is performed at three locations on each of these two surfaces.
- *Occupant Containment*: This requirement applies a 9-inch diameter head probe to the opening of an infant feeding support; when moved laterally through this opening, the probe must not contact the side walls of the product. The requirement is intended to reduce the potential for an infant's head to become entrapped within this opening. This requirement also is intended to reduce the extent to which these products are used for infant propping or

lounging, by limiting the amount of lateral support available to young infants if they were placed within the opening.

The ASTM draft standard also includes marking, labeling, and instructional literature requirements. These include requirements for warnings that must appear on nursing pillows and other infant feeding supports covered by the standard. Figure 1 illustrates the ASTM draft standard's required warning statements that must appear on all nursing pillows:

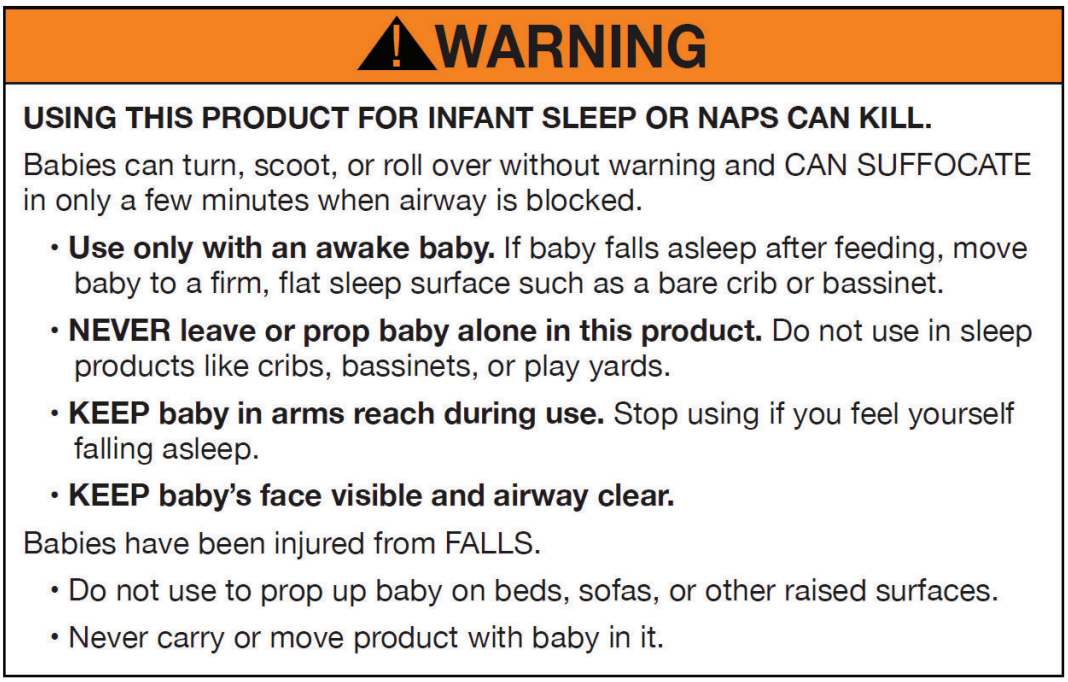


Figure 1: Warning Label in ASTM Draft Standard

The ASTM draft standard requires the warnings to be "permanent" and "conspicuous," which the draft standard defines as a "label that is visible, when the infant feeding support is in a manufacturer's recommended use position, to a person sitting near the infant feeding support at any position around the infant feeding support."

The draft voluntary standard also includes requirements for package warnings against using nursing pillows for sleep or in sleep products, and to state the manufacturer's recommended weight, height, age, developmental level, or combination thereof, of the infant. In addition, the

package cannot include warnings, statements, or graphics that indicate or imply that the infant may be left in the product without an adult caregiver in attendance.

Lastly, ASTM's draft voluntary standard includes requirements for instructional literature to accompany products covered by the standard. In addition to the warnings on the product, there must be instructions to consumers to: (1) read all instructions before using the product; (2) keep the instructions for future use; and (3) not use the product if it is damaged or broken. The instructions also must indicate the manufacturer's recommended maximum weight, height, age, developmental level, or combination thereof, of the infant. If the product is not intended for use by a child for a specific reason (*e.g.*, a disability that would prevent safe use of the product), the instructions must state this limitation.

VI. Description of the Proposed Mandatory Standard for Nursing Pillows[14]

To address established risks of death and injury associated with infant suffocations, entrapments, and falls, and as required in section 104 of the CPSIA, the Commission is issuing this proposed rule to establish mandatory performance and labeling requirements for nursing pillows. The proposed rule addresses:

(1) suffocation hazards associated with nursing pillows, by requiring nursing pillows to be sufficiently firm so that the product is unlikely to conform to an infant's face and occlude its airways;

(2) entrapment hazards posed when the product restricts an infant's head movements, via performance standards requiring testing to assess this hazard;

(3) suffocation and fall risks due to infant restraints that could suggest that infants can safely be left unattended in the product; and

[14] *See* Staff's NPR Briefing Package, Tab B.

(4) the risks of suffocation, entrapment, or fall when an infant is left unattended in the product by requiring labeling and instructional literature to better communicate risks.

The text of the proposed rule is based on an evaluation of the nursing pillow market, the existing Infant Pillow Ban and its associated exemption, the ASTM draft standard for infant feeding supports that is under development, and the recommendations of the BSU Final Report. The proposed rule would apply to all nursing pillows, as defined below. The proposed rule is summarized below and explained in more detail in Tabs B and C of Staff's NPR Briefing Package.

A. Scope

Section 1242.2 of the proposed rule defines "nursing pillow" as:

> Any product intended, marketed, or designed to position and support an infant close to a caregiver's body while breastfeeding or bottle feeding. These products rest upon, wrap around, or are worn by a caregiver in a seated or reclined position.

The definition of "nursing pillow" excludes maternity pillows, also known as pregnancy pillows, which staff defines as "a large body pillow intended, marketed, and designed to provide support to a pregnant adult's body during sleep or while lying down," and sling carriers, as defined in 16 CFR part 1228, which are already required to meet CPSC's sling carrier safety standard.

This definition is intended to encompass all nursing pillows on the market and within the available incident data, while excluding products that are not intended primarily for nursing (maternity pillows) or that might be used for nursing but whose hazards are already addressed by another standard (sling carriers). This definition is similar to the definition developed by the ASTM infant feeding supports subcommittee for the ASTM draft standard. The proposed rule, however, does not include additional language used in the ASTM draft standard's definition of

"infant feeding support," which states that these products are commonly U-Shaped in appearance. That language is not needed because all products that meet the definition in the proposed rule are subject to the same hazards and should be considered within the scope of the proposed rule regardless of the details of their shape.

B. General Requirements

The proposed rule includes many of the general requirements included in the ASTM draft standard for infant feeding supports to address the potential hazards associated with lead in paints; small parts; sharp edges or points; toy accessories that are attached to, removable from, or sold with the nursing pillow; and the removal of protective components. However, the requirement in the ASTM draft standard to prevent the removal of protective components has been augmented in the proposed rule to include other possibly detachable components that are present, such as zipper pulls and buttons. If detached, these components can expose the infant to hazards such as sharp points, sharp edges, and choking hazards.

The proposed rule also includes the warning permanency requirements in the ASTM draft standard, with an additional permanency requirement for "free-hanging" labels that attach to the product at only one end and are particularly susceptible to attempts at removal or alteration by consumers. Section 1242.3(e)(4) of the proposed rule includes the following warning permanency requirement:

> Warning labels that are attached to the fabric of nursing pillows with seams shall remain in contact with the fabric around the entire perimeter of the label, when the product is in all manufacturer-recommended use positions, when tested in accordance with [reference to existing test method for assessing permanency of warning labels attached with seams].

C. Proposed Performance Requirements

1. Infant Restraints

To address a potential entanglement hazard, the proposed rule prohibits nursing pillows from including an infant restraint system. The draft ASTM voluntary standard for infant feeding supports includes a similar requirement. Proper use of a nursing pillow involves actively attending to the infant during use, and the presence of restraints could suggest to consumers that infants properly can be left unattended on the product.

2. Seam Strength

Under the proposed rule nursing pillow seams would be subject to a tension test similar to that applied to toys intended for children up to 18 months old under ASTM F963, *Standard Consumer Safety Specification for Toy Safety* (the toy standard),[15] but tested at a higher tension force of 15 pounds rather than 10 pounds, because nursing pillows may be used for multiple children or passed on to other caregivers, meaning these products would be subject to stress over a usable life that can span more than a single infant's use. CPSC is aware of one injury associated with seam failures, where an infant reportedly choked on filling that came out of the product, and has received additional reports of nonfatal incidents involving product integrity issues such as seam failures *See* Staff's NPR Briefing Package at Tab A. The seam strength requirement and test method in the proposed rule would address such incidents.

3. Caregiver Attachments

To address the potential for infant falls if the buckled belts, straps, or other features intended to secure the product to the caregiver fails, the proposed rule includes a requirement and test method for the strength of caregiver attachments. Specifically, the proposed rule would

[15] Incorporated by reference in 16 CFR part 1250, *Safety Standard Mandating ASTM F963 for Toys.*

require that each element of the caregiver attachment system (*e.g.*, strap or buckle) that is included on nursing pillows be required to withstand a static load equal to the recommended weight limit of the product, or 20 pounds, whichever is greater.

4. Firmness

The proposed rule includes a firmness requirement that applies to each nursing pillow's infant support surface, as well as the inner wall of the nursing pillow opening (*e.g.*, within the crescent-like opening). As explained in Tab B of Staff's NPR Package, the proposed firmness requirement and test method is based on the recommendations of the BSU Final Report, with modifications including the addition of a requirement to test the inner wall of the opening. The test applies a 3-inch diameter hemispheric probe, which is similar in size and shape to an infant's face, to three test locations on each surface. To meet the firmness requirement, the force required to displace the probe 1 inch into each test location must exceed 10 N (about 2.25 pounds), which results in product firmness that is comparable to crib mattresses. The diagrams in Figure 2, below, illustrate the firmness test being applied to the two surfaces of a nursing pillow. This requirement is intended to reduce the likelihood that the infant support surface or

the interior opening of the nursing pillow can conform to an infant's face and suffocate the child.

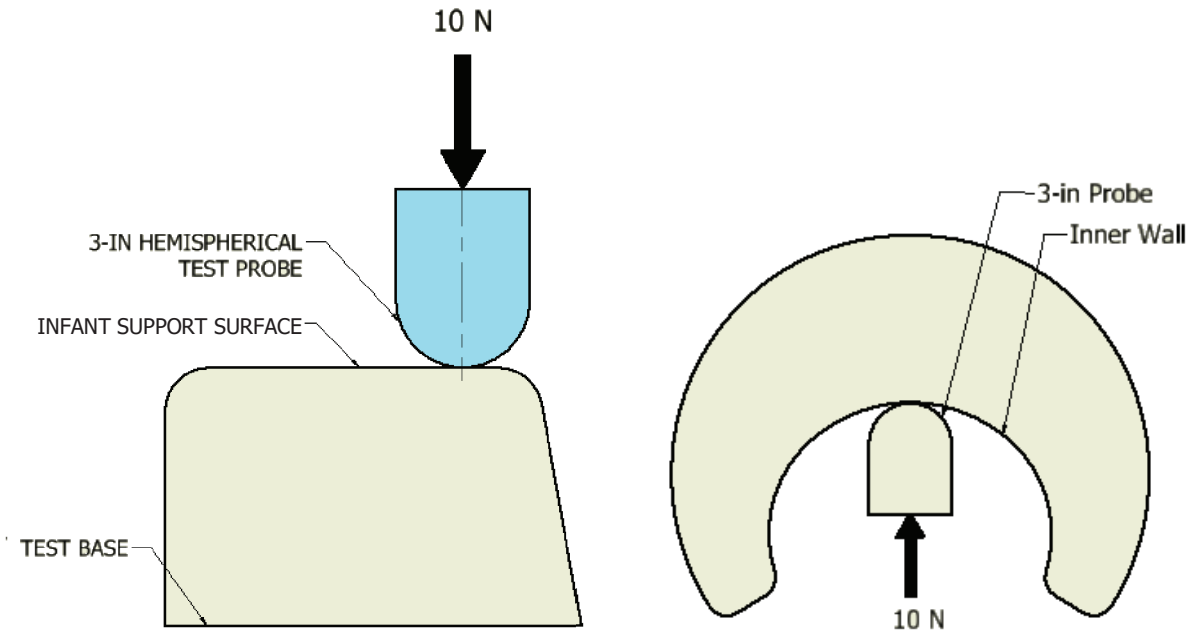


Figure 2: Illustration of Firmness Test Applied to Two Surfaces of Nursing Pillow

ASTM's draft voluntary standard includes a firmness requirement similar to the firmness requirement in the proposed rule, including for the inner wall of the nursing pillow opening.

5. Infant Containment

The proposed rule requires nursing pillow openings to be of a size that is more appropriate for an adult user, rather than an infant, and limits the amount of lateral support for young infants who might be placed within the nursing pillow opening. This requirement also reduces the potential for an infant's head to become entrapped in the nursing pillow's opening or for the product to restrict a young infant's head movements, should the infant find themselves in the opening.

As shown in Figure 3, a 9-inch probe is used to ensure that the product opening is wider than the probe and that the probe can be moved outward from inside the nursing pillow without contacting its surface.

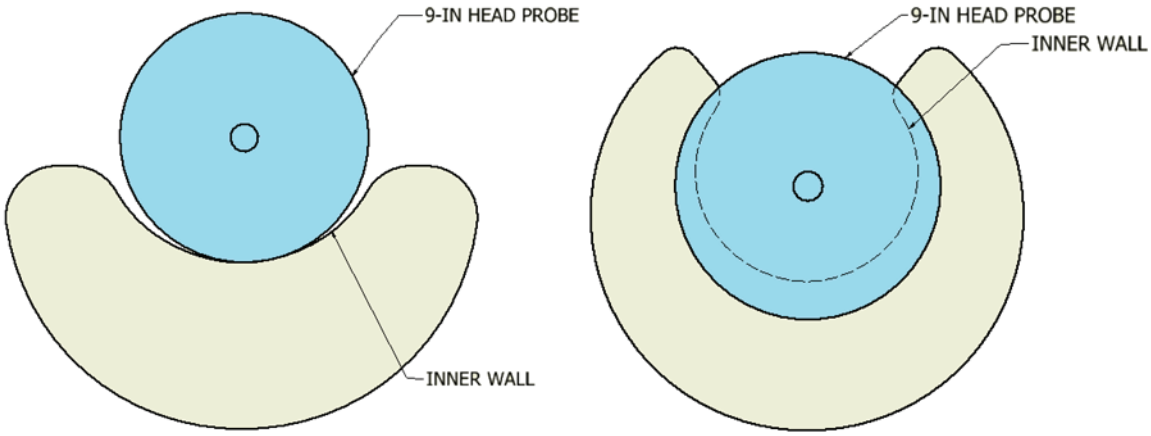


Figure 3: Illustration of nursing pillows that pass (left) and fail (right) CPSC's proposed infant containment provision.

Tab B in Staff's NPR Briefing Package contains a detailed description of this proposed testing method. The requirement in the proposed rule is similar to the requirement that appears in the ASTM draft standard for infant feeding supports. The proposed rule, however, includes an additional requirement that the nursing pillow cannot extend beyond the opposite end of the probe, and also requires testing to be performed both with and without any caregiver attachments secured, as shown in Figure 4, below.

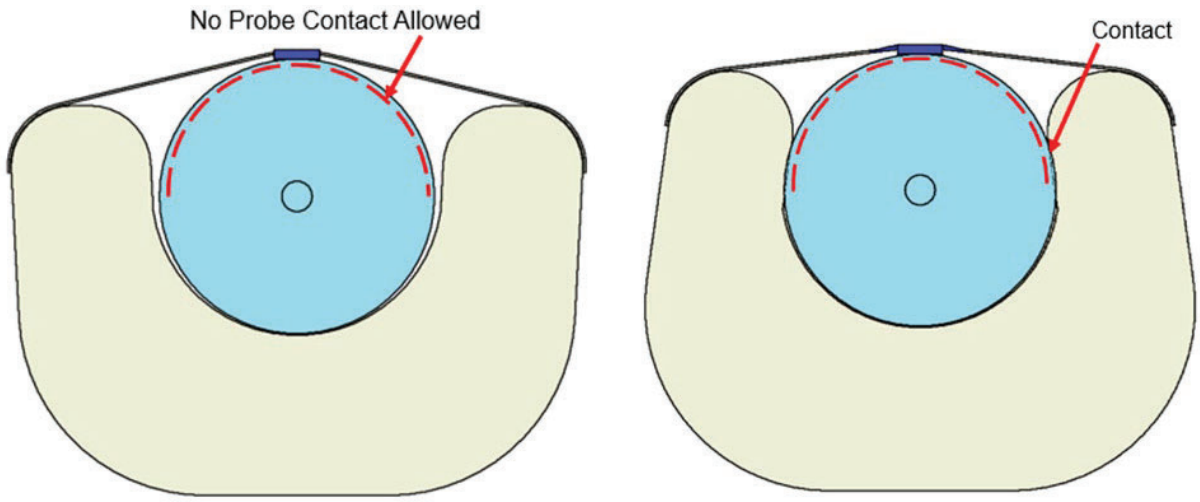


Figure 4: Example of Infant Containment Tests with Caregiver Attachments

D. Performance Requirements Considered But Not Proposed

1. Airflow Requirement

The BSU Final Report recommends that nursing pillows that do not pass firmness testing be required to pass an airflow test that would demonstrate the product has airflow characteristics comparable to mesh crib liners, which the authors concluded would mitigate the suffocation hazard. However, the report also stated that airflow testing is not needed for a product that passes the proposed firmness testing, because a firm product is unlikely to form a seal around an infant's nose and mouth. BSU Final Report at 49-63. Because the proposed rule would require that all nursing pillows meet firmness testing that is at least as stringent as that recommended in the BSU Final Report, an airflow requirement for nursing pillows is unnecessary.

2. Angular Requirement

The BSU Final Report assessed that nursing pillows that are firm and feature sharper corners, rather than cylindrical sides, might be safer for infants because there would be no

reasonable way for consumers to use such a product as an infant support cushion. The proposed rule does not include an angular requirement, however, because of uncertainties surrounding what would be appropriate pass-fail criteria and the potential for such a requirement to increase the risk of positional asphyxia by neck hyperflexion or hyperextension if the nursing pillow is used as a support cushion for lounging. *See* Staff NPR Briefing Package at 21-22 and Tab C at 66-67.

The Commission invites public comments on this issue. Specifically, the Commission is interested in information on the potential effectiveness of an angular requirement, including what pass-fail criteria would effectively discourage use of a nursing pillow for infant lounging; the potential risks associated with such a requirement; and whether an alternative requirement could better discourage consumers from using nursing pillows for infant lounging without concurrently increasing risks if the product is used in that manner.

E. Warning and Instructional Requirements

Compared to the performance requirements described above, warnings are likely to be less effective in eliminating or adequately reducing exposure to nursing pillow hazards. Nevertheless, prominent and well-designed warnings can be a secondary safety mechanism that provides consumers important information about the hazards associated with these products and appropriate behaviors to avoid the hazards. Thus, the proposed rule includes requirements for on-product warnings that address the primary hazards associated with nursing pillows, with particular emphasis on the potentially deadly consequences of using these products for naps or sleep.

The proposed rule includes warning content and format requirements that are similar to those in the ASTM draft standard, with minor changes for clarity and internal consistency.

Figure 5 shows the warning statements and format that would be required on all nursing pillows:

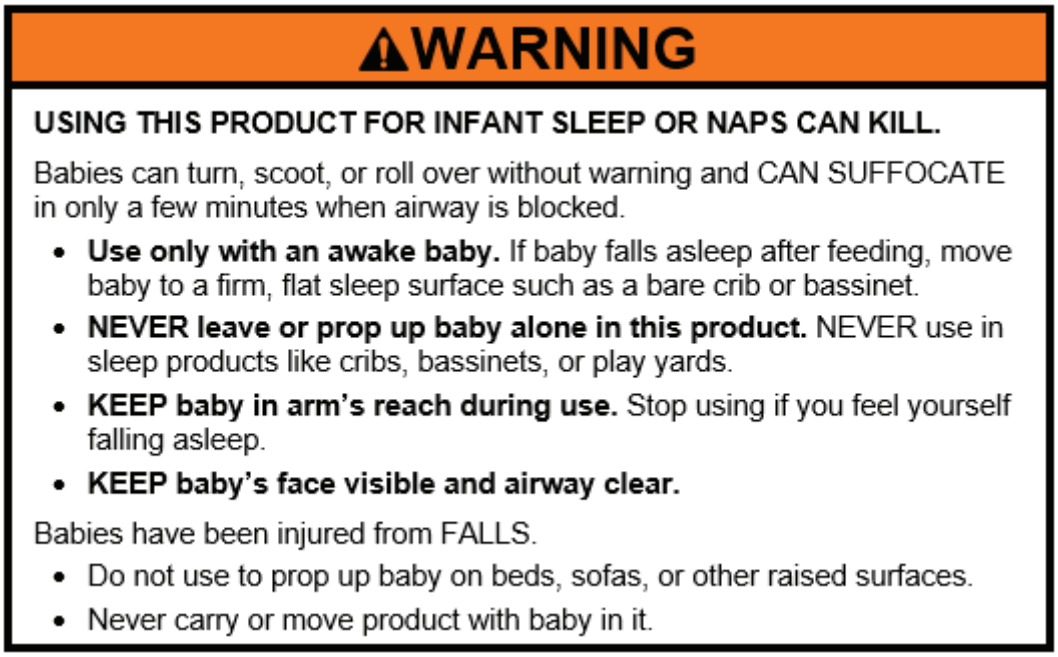


Figure 5: Warning Statement Required On All Nursing Pillows

The ASTM draft standard requires the warning to be "conspicuous," which the ASTM draft standard defines as a "label that is visible, when the infant feeding support is in a manufacturer's recommended use position, to a person sitting near the infant feeding support at any position around the infant feeding support." The proposed rule does not rely on this definition, because it would allow the warning to be placed on a side of the product that is not visible to the caregiver who is using the product (*e.g.*, the side opposite the crescent-like opening). Instead, the proposed rule defines "conspicuous" as "visible, when the nursing pillow is in each manufacturer's recommended use position, to a person while placing an infant into or onto the nursing pillow."

More specifically, the proposed rule incorporates by reference the following provisions of the ANSI warning format requirements published in ANSI Z535.4, *Product Safety Signs and Labels* (ANSI Z535.4): sections 6.1–6.4, which include requirements related to safety alert

symbol use, signal word selection, and warning panel format, arrangement, and shape; sections 7.2–7.6.3, which include color requirements for each panel; and section 8.1, which addresses letter style. *See* Staff's NPR Briefing Package, 72-73.

The ASTM draft standard also requires the warnings to be "permanent" and includes warning permanence requirements among the General Requirements for infant feeding supports. As discussed in Part VI.B. above, the proposed rule includes an additional permanence requirement to further reduce the potential for the warnings to be torn, ripped, or cut off.

In addition to on-product warnings, the ASTM draft standard includes basic warning requirements for the packaging that accompanies nursing pillows, largely based on the ASTM Ad Hoc Language task group's recommended requirements for package warnings. The requirements in the ASTM draft standard include warning statements about not using the product for sleep or in sleep products such as cribs, bassinets, or play yards; information about the manufacturer's recommended weight, height, age, or developmental stage; and a prohibition against other warnings, statements, or graphics that indicate or imply that an infant can be left in the product without an adult caregiver present. The package warnings also are required to have formatting similar to the on-product warnings. The proposed rule includes these requirements. The ASTM draft standard for infant feeding supports includes requirements for instructional literature to accompany nursing pillows, including requirements for the instructions to include all on-product warnings and to instruct consumers to read all instructions before using the product, to keep the instructions for future use, and not to use the product if it is damaged or broken. Like the package requirements, the instructions must provide information about the manufacturer's recommended weight, height, age, or developmental stage, at a minimum.

These requirements are based on meetings of the ASTM Infant Feeding Supports Warnings task group and on the recommended requirements for instructional literature by the ASTM Ad Hoc Language task group. The proposed rule includes these instructional literature requirements.

VII. Proposed Amendment to 16 CFR part 1112 to Include NOR for Nursing Pillows

Products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Certification of children's products subject to a children's product safety rule must be based on testing conducted by a CPSC-accepted third party conformity assessment body. 15 U.S.C. 2063(a)(2). The Commission must publish an NOR for the accreditation of third party conformity assessment bodies to assess conformity with a children's product safety rule to which a children's product is subject. 15 U.S.C. 2063(a)(3). The proposed standard for nursing pillows would be a children's product safety rule that requires the issuance of an NOR.

The Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies,* 78 FR 15836, which is codified at 16 CFR part 1112. Part 1112 became effective on June 10, 2013, and establishes requirements for accreditation of third-party conformity assessment bodies (or laboratories) to test for conformance with a children's product safety rule in accordance with section 14(a)(2) of the CPSA. Part 1112 also lists the NORs that the CPSC has published. Accordingly, the Commission proposes to amend part 1112 to include the Safety Standard for Nursing Pillows in the list of other children's product safety rules for which the CPSC has issued NORs.

Laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard are required to meet the third party conformity

assessment body accreditation requirements in part 1112. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, the laboratory can apply to the CPSC to have the *Safety Standard for Nursing Pillows* included in its scope of accreditation as reflected on the CPSC Web site at: www.cpsc.gov/labsearch.

VIII. Product Registration Rule Amendment

In addition to requiring the Commission to issue safety standards for durable infant or toddler products, section 104 of the CPSIA also directed the Commission to issue a rule requiring that manufacturers of durable infant or toddler products establish a program for consumer registration of those products. 15 U.S.C. 2056a(d). Section 104(f) of the CPSIA defines the term "durable infant or toddler product" as "a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years," and lists 12 distinct product categories. 15 U.S.C. 2056a(f). The product categories listed in section 104(f)(2) of the CPSIA represent a non-exhaustive list of durable infant or toddler product categories. Nursing pillows are not included in the statutory list of durable infant or toddler products.

In 2009, the Commission issued a rule implementing the consumer registration requirement. 74 FR 68668 (Dec. 29, 2009) (establishing 16 CFR part 1130). As the CPSIA directs, the consumer registration rule requires each manufacturer of a durable infant or toddler product to provide a postage-paid consumer registration form with each product; keep records of consumers who register their products with the manufacturer; and permanently place the manufacturer's name and certain other identifying information on the product.

When issuing the consumer registration rule, the Commission identified six additional products as durable infant or toddler products: children's folding chairs; changing tables; infant

bouncers; infant bathtubs; bed rails; and infant slings. *Id.* at 68669. The Commission explained that the specified statutory categories were not exclusive, and that the Commission is charged with identifying the product categories that are covered. "Because the statute has a broad definition of a durable infant or toddler product but also includes 12 specific product categories," the Commission noted, "additional items can and should be included in the definition, but should also be specifically listed in the rule." *Id.* at 68670.

The Commission proposes in this NPR to amend part 1130 to include "Nursing pillows," as defined, as durable infant or toddler products. The Commission tentatively finds that nursing pillows are a category of "durable infant or toddler product" for purposes of CPSIA section 104 because they: (1) are intended for use, and may be reasonably expected to be used, by children under the age of 5 years; (2) are products similar to the other feeding support products listed in section 104(f)(2), such as high chairs, booster chairs, and hook-on chairs; and (3) are commonly available for resale or "handed down" for use by other children over a period of years.

IX. Incorporation by Reference

Section 1242.6(d)(4) of the proposed rule incorporates by reference American National Standards Institute (ANSI) Z535.4–2011, *American National Standard for Product Safety Signs and Labels*, sections 6.1–6.4, 7.2–7.6.3, and 8.1, with modifications to further reduce the risk of injury associated with nursing pillows. In accordance with regulations of the Office of the Federal Register (OFR), 1 CFR part 51, section VI.E of this preamble summarizes the provisions of ANSI Z535.4–2011 that the Commission proposes to incorporate by reference. The ANSI standard is reasonably available to interested parties in several ways. By permission of ANSI, the standard can be viewed as a read-only document during the comment period on

this NPR, at: https://www.surveymonkey.com/r/DQVJYMK. To download or print the standard, interested persons may purchase a copy of ANSI Z535.4–2011 from ANSI via its website, https://www.ansi.org, or by mail from ANSI, 25 West 43rd Street, 4th Floor, New York, NY 10036, USA, telephone: (212)-642-4900. Alternatively, interested parties may inspect a copy of the standard at CPSC's Office of the Secretary by contacting Alberta E. Mills, Commission Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: 301-504-7479; e-mail: cpsc-os@cpsc.gov.

X. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). The Commission proposes an effective date of 180 days after publication of the final rule in the *Federal Register*, such that the requirements of the rule would apply to all nursing pillows manufactured after that date. This amount of time is typical for rules issued under section 104 of the CPSIA. Six months is also the period that JPMA typically allows for products in their certification program to shift to a new standard once that new standard is published. Therefore, juvenile product manufacturers are accustomed to adjusting to new standards within this time. A 180-day effective date should also be sufficient for manufacturers to comply with this rule because the proposed requirements do not demand significant preparation by testing laboratories. For example, no new complex testing instruments or devices would be required to test nursing pillows for compliance to the proposed rule. The Commission invites comments, particularly from small businesses, that provide specific data addressing whether the proposed 180-day effective date period is appropriate.

XI. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA); 5 U.S.C. 601-612, requires that agencies review a proposed rule's potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that agencies make an initial regulatory flexibility analysis (IRFA) available to the public for comment when the NPR is published. The IRFA must describe the impact of the proposed rule on small entities and identify significant alternatives that accomplish the statutory objectives and minimize any significant economic impact of the proposed rule on small entities. CPSC Staff prepared an IRFA for this rulemaking that appears at Tab E of the Staff's NPR Briefing Package. We summarize the IRFA below.

A. Reasons and Legal Basis for the NPR

Section I of this preamble describes the reasons and legal basis for this NPR. As discussed in sections VI-VIII of this preamble, and detailed in Tab B of Staff's NPR Briefing Package, the proposed rule sets out mandatory requirements for nursing pillows to address the suffocation, entrapment, fall, and other hazards associated with these products, adds nursing pillows to the list of products for which a registration card is required, and adds nursing pillows to the list of durable infant products for which an NOR is required. "

B. Small Entities to Which the Proposed Rule Would Apply

As explained in Tab E to Staff's NPR Briefing Package, Commission staff has identified 22 small U.S. manufacturers, 6 small U.S. importers, and more than 500 U.S. non-employer businesses that would be impacted by the proposed NPR in the United States. The majority of nursing pillow suppliers to the U.S. market are small U.S. manufacturers, importers, or non-employee businesses.

C. Impact of the Proposed Rule on Small Manufacturers and Importers

This proposed rule would likely have a significant impact on a substantial number of these small entities, based on the estimated costs of modifying nursing pillows to achieve compliance, and the ongoing cost of testing to demonstrate compliance. The Commission considers one percent of annual revenue to be a "significant" economic impact on a company, consistent with regulatory flexibility analyses used by other federal government agencies.

1. Costs Associated with Modifying Products

Most in-scope products on the market will require redesign to meet the requirements in the proposed rule, and redesign costs would be potentially significant for a substantial number of small firms for the first year that a rule is effective. With an estimated 1,000 models to be redesigned, the total cost of redesign to the industry in the first year could be as high as $13.5 million. The cost of redesign is likely to be significant for a substantial number of small U.S. firms, particularly small home crafters.

2. Third Party Testing Costs

If issued, a final rule would require all manufacturers and importers of nursing pillows to meet additional third-party testing requirements under section 14 of the CPSA. As specified in 16 CFR part 1109, though, entities that are not manufacturers of children's products, such as importers and wholesalers, may rely on the certificate of compliance provided by others. Further, manufacturers would pass on at least some of the cost of testing for compliance to importers and wholesalers.

Third party testing costs for nursing pillows under the proposed rule are estimated at $500 to $1,000 per model. The annual cost of samples for testing is estimated at around $150, bringing the overall annual cost to an estimated $650 to $1,150 per model. However, some

small volume suppliers would likely be able to raise retail prices to cover at least some of their testing costs. For example, a hand crafter selling 200 nursing pillows a year could cover the entire testing cost by raising the price by $3.25, while a smaller supplier could cover at least some of their costs with a modest price increase.

3. Summary of Impacts

The best-selling nursing pillows are from companies that have sufficient sales volume to spread the cost of compliance over thousands of units and are unlikely to exit the market. It is likely that the products currently in stores, and the best-selling online-only products, would still be available, with modest redesigns. However, there may be some loss in sales of specific products if the redesigned products are less appealing to consumers.

The redesign could increase wholesale or retail prices by a few dollars, but likely not a significant amount, given that the materials and production methods are likely to remain roughly similar. Warning labels, registration forms, and instruction manuals could add up to $1 to the cost of the product. If companies decide to pass the ongoing cost of testing onto consumers, the additional retail price increase of perhaps $1, added to the additional $1 cost of the warning labels and instruction manuals, would total $2, or 4 percent of the price of a $50 item.

D. Other Federal Rules that May Duplicate, Overlap, or Conflict with the Proposed Rule

CPSC has not identified any other federal rules that duplicate, overlap, or conflict with the proposed rule.

E. Alternatives Considered to Reduce the Impact on Small Entities

The Commission considered the following alternatives to the proposed rule to reduce the impact on small businesses. The Commission requests comments on these alternatives or other alternatives that could reduce the potential burden on small entities.

1. Not Establishing a Safety Standard

The Commission considered not establishing a safety standard for nursing pillows. While this alternative would result in no regulatory impact on small businesses, deaths and injuries from the use of nursing pillows would likely continue to occur at similar rates as those observed during the 2010-2022 time period. As discussed earlier, CPSC observed 88 nonfatal incidents and 154 fatalities during this time period. In 2020 alone – the most recent year for which there is complete data – there were 38 fatalities and 14 injuries from nursing pillows.

2. Delay To Await Publication of a Voluntary Standard

The Commission considered delaying the draft proposed rule to allow possible publication of a voluntary standard. Although this alternative would delay any impact on small businesses, it would also allow the hazard to continue indefinitely, as there is no clear date at which ASTM or any other voluntary standards organization will adopt a relevant standard; nor any assurance that a voluntary standard, if published, would be complied with or adequately address the identified hazards.

3. "Angular" Performance Requirement

The Commission considered including in the proposed safety standard an "angular" performance requirement based upon the BSU Final Report's suggestion that nursing pillows that are firm and feature sharper corners are likely safer for babies because there is no reasonable way to use these products for lounging. However, as the BSU Final Report notes, its

recommendation on that point is preliminary and the Commission is seeking comment from the public on this point.

4. Earlier Effective Date

The Commission is proposing an effective date 180 days after publication of the final rule in the *Federal Register*. 180 days has generally been sufficient time for suppliers to come into compliance with durable infant or toddler product rules. Additionally, six months from the change in a voluntary standard is the period that JPMA uses for its certification program, so compliant manufacturers are used to this time frame to comply with a modified standard. Testing laboratories should have no difficulty preparing to test to the proposed new mandatory standards within a 180-day period.

The Commission considered adopting an earlier effective date to achieve the safety benefits of the rule more quickly, but a shorter period would increase the burden on small businesses to quickly redesign and test their products. In addition, a significantly earlier effective date could result in temporary shortages of nursing pillows due to a lack of availability of testing laboratory resources.

F. Impact on Testing Labs

Section 14 of the CPSC requires that all products that are subject to a children's product safety rule must be tested by a third party conformity assessment body that has been accredited by CPSC. One of the roles of these third party conformity assessment bodies is to test products for compliance with applicable children's product safety rules. Testing laboratories that want to conduct testing must meet the NOR for third-party conformity testing. *See* 16 CFR part 1112.

The Commission does not expect a significant adverse impact on any testing laboratories as a result of this rule. Laboratories will not need to acquire complex or costly testing

instruments or devices to test nursing pillows for compliance, and laboratories will decide for themselves whether to offer testing services for nursing pillow compliance.

XII. Environmental Considerations

Certain categories of CPSC actions normally have "little or no potential for affecting the human environment" and therefore do not require an environmental assessment or an environmental impact statement. Safety standards providing requirements for consumer products come under this categorical exclusion. 16 CFR § 1021.5(c)(1). The proposed rule for nursing pillows falls within the categorical exclusion.

XIII. Paperwork Reduction Act

This proposed rule for nursing pillows contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501–3521). In this document, pursuant to 44 U.S.C. 3507(a)(1)(D), we set forth:

- a title for the collection of information;
- a summary of the collection of information;
- a brief description of the need for the information and the proposed use of the information;
- a description of the likely respondents and proposed frequency of response to the collection of information;
- an estimate of the burden that shall result from the collection of information; and
- notice that comments may be submitted to the OMB.

Title: Safety Standard for Nursing Pillows.

Description: The proposed rule would require each nursing pillow within the scope of the rule to meet the rule's new performance and labeling requirements. It would require suppliers to conduct third party testing to demonstrate compliance and provide the specified warning label and instructions. These requirements fall within the definition of a "collection of information," as defined in 44 U.S.C. 3502(3).

Description of Respondents: Persons who manufacture or import nursing pillows.

Estimated Burden: We estimate the burden of this collection of information as follows:

Table 7: Estimated Annual Reporting Burden

Burden Type	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours
Labeling and instructions	844	1	844	2	1,688

While some products currently have labels, all products would have to meet the specific labeling requirements and instructions specified in the proposed rule, which provides the text and graphics for the required labels and instructions. Specialized expertise in graphics design would not be required to develop the warnings and instructions. Most reporting and recordkeeping requirements in this proposed rule would be new for all suppliers.

CPSC estimates there are 844 entities that would respond to this collection annually.[16] We estimate that the time required to create and modify labeling and instructions is about 2 hours per response. Therefore, the estimated burden associated with this collection is 844 responses × 1 response per year × 2 hours per response = 1,688 hours annually.

We estimate the hourly compensation for the time required to respond to the collection is $37.41 (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation,"

[16] Although Commission staff estimate the total number of nursing pillow suppliers to the United States to be more than 1,000, staff anticipates that only a portion of those suppliers will respond to the collection each year based on when they introduce new product models or redesign previous models.

March 2023, Table 4, total compensation for all sales and office workers in goods-producing private industries: https://www.bls.gov/news.release/archives/ecec_06162023.pdf). Therefore, the estimated annual labor cost of the collection is $63,148 ($37.41 per hour x 1,688 hours = $63,148.08).

Based on this analysis, the proposed standard for nursing pillows would impose an additional burden to industry of 1,688 hours at a cost of $63,148.

Comments. CPSC has submitted the information collection requirements of this proposed rule to OMB for review in accordance with PRA requirements. 44 U.S.C. 3507(d). CPSC requests that interested parties submit comments regarding information collection to the Office of Information and Regulatory Affairs, OMB (see the **ADDRESSES** section at the beginning of this NPR). Pursuant to 44 U.S.C. 3506(c)(2)(A), the Commission invites comments on:

- whether the collection of information is necessary for the proper performance of the CPSC's functions, including whether the information will have practical utility;
- the accuracy of the CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- ways to enhance the quality, utility, and clarity of the information to be collected;
- ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology; and

- the estimated burden hours associated with label modification, including any alternative estimates.

XIV. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that when a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a standard or regulation that prescribes requirements for the performance, composition, contents, design, finish, construction, packaging, or labeling of such product dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as "consumer product safety rules." Therefore, if finalized, the preemption provision of section 26(a) of the CPSA would apply to this rule for nursing pillows.

XV. Request for Comments

The Commission seeks public comment on all aspects of the proposed rule. In particular, however, the Commission seeks comment on the potential effectiveness of an angular requirement not included in the proposed rule; including what pass-fail criteria would effectively discourage the use of nursing pillows for lounging, the potential risks associated with such a requirement, and whether an alternative requirement could assist in discouraging consumers from using nursing pillows for infant lounging without increasing risks to those infants whose caregivers still choose to use the product this way. The Commission also specifically requests comments on the proposed effective date and the costs of compliance with, and testing to, the proposed Safety Standard for Nursing Pillows.

Comments should be submitted in accordance with the instructions in the **ADDRESSES** section at the beginning of this notice.

List of Subjects

16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third party conformity assessment body.

16 CFR Part 1130

Administrative practice and procedure, Business and industry, Consumer protection, Reporting and recordkeeping requirements.

16 CFR Part 1242

Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, Nursing, Pillows, and Toys.

For the reasons discussed in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulations as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

1. The authority citation for part 1112 continues to read as follows:

Authority: Pub. L. 110-314, section 3, 122 Stat. 3016, 3017 (2008); 15 U.S.C. 2063.

2. Amend § 1112.15 by adding paragraph (b)(56) to read as follows:

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule and/or test method?

* * * * *

(b) * * *

(56) 16 CFR part 1242, Safety Standard for Nursing Pillows.

* * * * *

3. The authority citation for part 1130 continues to read as follows:

Authority: 15 U.S.C. 2056a(d), 2065(b).

4. Amend § 1130.2 by adding paragraph (a)(19) to read as follows:

PART 1130—REQUIREMENTS FOR CONSUMER REGISTRATION OF DURABLE INFANT OR TODDLER PRODUCTS

§ 1130.2 Definitions.

* * * * *

(a) * * *

(19) Nursing pillows.

* * * * *

5. Add part 1242 to read as follows:

PART 1242—SAFETY STANDARD FOR NURSING PILLOWS

Sec.

§ 1242.1 Scope, purpose, application, and exemptions.

(a) *Scope and Purpose*. This part 1242, a consumer product safety standard, prescribes requirements intended to reduce the risk of death and injury from hazards associated with nursing pillows, as defined in § 1242.2.

(b) *Application*. Except as provided in paragraph (c) of this section, all nursing pillows that are manufactured after [180 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*], are subject to the requirements of this part 1242.

(c) *Exemptions*. The following products are exempt from this part 1242: (1) Maternity pillows, as defined in § 1242.2, and (2) Sling carriers, as defined in 16 CFR part 1228.

§ 1242.2 Definitions.

Maternity pillow, also known as a pregnancy pillow, means a large body pillow intended, marketed, and designed to provide support to a pregnant adult's body during sleep or while lying down.

Caregiver attachment means a portion of the product intended to secure the nursing pillow to the caregiver and not intended to secure the infant to the nursing pillow. A caregiver attachment may comprise components including, but not limited to, straps, buckles, or latches.

Caregiver opening means the surface of the nursing pillow, excluding the caregiver attachment, intended to fit against the caregiver's torso during use. This surface is typically, but not necessarily, crescent-like in shape.

Conspicuous means visible, when the nursing pillow is in each manufacturer's recommended use position, to a person while placing an infant into or onto the nursing pillow.

Infant restraint system means a portion of a product intended to secure or hold an infant in place on the product. These typically take the form of straps or harnesses that are secured by the caregiver.

Nursing pillow means any product intended, marketed, or designed to position and support an infant close to a caregiver's body while breastfeeding or bottle feeding. These products rest upon, wrap around, or are worn by a caregiver in a seated or reclined position.

Infant support surface means the manufacturer's intended support surface for the infant during nursing or feeding.

Safety alert symbol means a symbol consisting of an exclamation mark surrounded by an equilateral triangle, or an equilateral triangle with a contrasting superimposed exclamation mark. The safety alert symbol precedes the signal word "WARNING," or other signal word, in the signal word panel of a warning.

§ 1242.3 General requirements.

(a) *Lead in Paints*. All paint and surface coatings on the product shall comply with the requirements of 16 CFR part 1303.

(b) *Small Parts*. There shall be no small parts, as defined in 16 CFR part 1501, before testing or liberated as a result of testing.

(c) *Hazardous Sharp Edges or Points*. There shall be no hazardous sharp points or edges, as defined in 16 CFR § 1500.48 and 16 CFR § 1500.49, before or after testing.

(d) *Removal of Components*. When tested in accordance with § 1242.5(b), any removal of components that are accessible to an infant while in the product or from any position around the product shall not present a small part, sharp point, or sharp edge as required in § 1242.3(b) and § 1242.3(c).

(e) *Permanency of Labels and Warnings.* (1) Warning labels (whether paper or non-paper) shall be permanent when tested in accordance with § 1242.5(c)(1) through § 1242.5(c)(3).

(2) Warning statements applied directly onto the surface of the product by hot stamping, heat transfer, printing, wood burning, etc. shall be permanent when tested in accordance with § 1242.5(c)(4).

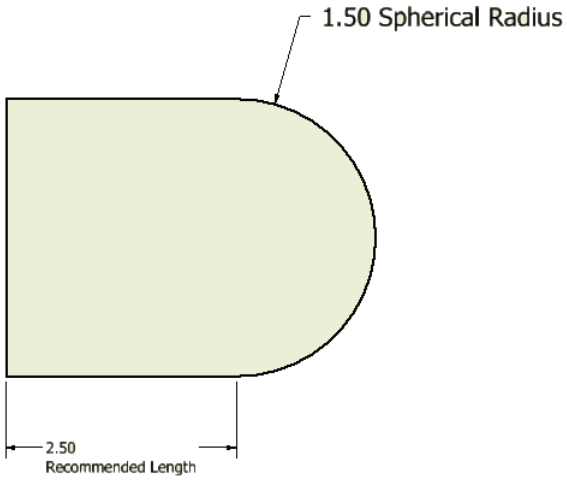
(3) Non-paper labels shall not liberate small parts when tested in accordance with § 1242.5(c)(5).

(4) Warning labels that are attached to the fabric of infant feeding supports with seams shall remain in contact with the fabric around the entire perimeter of the label, when the product is in all manufacturer-recommended use positions, when tested in accordance with § 1242.5(c)(3).

§ 1242.4 Performance requirements.

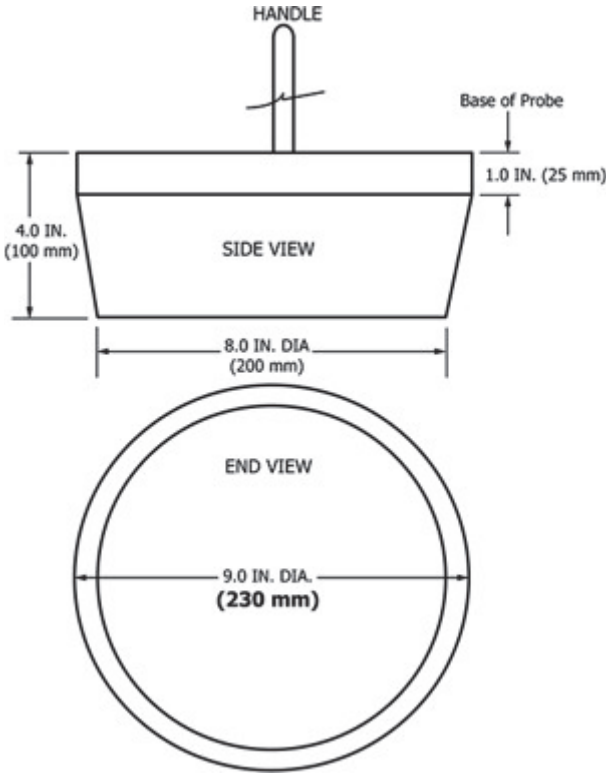
(a) *Firmness*. When tested in accordance with § 1242.5(d), § 1242.5(e) and § 1242.5(f), the force required for a 1.00-in. (2.54 cm) displacement of the 3-inch (76.2 mm) diameter hemispheric probe (Figure 1 to this paragraph (a) - 3-in. head probe) at any measurement location shall be greater than 10.0 N (2.24 lb).

Figure 1 to paragraph (a) - 3-in Head probe



(b) *Infant Containment*. When tested in accordance with § 1242.5(g), the surfaces within the caregiver opening of the product shall not contact the 9-inch (230 mm) diameter head probe (Figure 2 to this paragraph (b) - 9-in. head probe) such that the probe is constrained within the caregiver opening and, when placed according to § 1242.5(g)(6), the probe must extend past the caregiver opening.

Figure 2 to paragraph (b) - 9-in. head probe



(c) *Infant Restraints*. Nursing pillows shall not include any infant restraint system.

(d) *Seam Strength*. When tested in accordance with § 1242.5(h), fabric/mesh seams and points of attachment shall not fail such that a small part, sharp point, or sharp edge is presented, as required in § 1242.3(b) and § 1242.3(c).

(e) *Caregiver Attachment Strength*. When tested in accordance with § 1242.5(i), material seams, points of attachment, and attachment components shall not fail, and shall create no

hazardous conditions, such as small parts or sharp edges, as required in § 1242.3(b) and § 1242.3(c).

§ 1242.5 Test methods.

(a) *Test Conditions*. (1) Condition the product for 48 hours at 23 °C +/- 2 °C (73.4 °F +/- 3.6 °F) and a relative humidity of 50 % +/- 5 %.

(2) Secure the firmness fixture to a test base such that the 3-in. head probe (Figure 1 to § 1242.4(a)) does not deflect more than 0.01 in. (0.025 cm) under a 10 N (2.2 lb) load applied in each orientation required in the test methods.

(b) *Removal of Components Test Method*. (1) For torque and tension tests, any suitable device may be used to grasp the component, provided that it does not interfere with the attachment elements that are stressed during the tests.

(2) *Torque Test*. Gradually apply a 4 lb-in. (0.4 N-m) torque over 5 seconds (s.) in a clockwise rotation to 180 degrees or until 4 lb-in. has been reached. Maintain for 10 s. Release and allow component to return to relaxed state. Repeat the torque test in a counterclockwise rotation.

(3) *Tension Test*. For components that can reasonably be grasped between thumb and forefinger, or teeth, apply a 15 lb (67 N) force over 5 s., in a direction to remove the component. Maintain for 10 s. A clamp such as shown in Figure 3 to this paragraph (b)(3) may be used if the gap between the back of the component and the base material is 0.04 in. (0.1 cm) or more.

Figure 3 to paragraph (b)(3) - Tension Test Adapter Clamp

(c) *Permanency of Labels and Warnings*. (1) A paper label (excluding labels attached by a seam) shall be considered permanent if, during an attempt to remove it without the aid of tools or solvents, it cannot be removed, it tears into pieces upon removal, or such action damages the surface to which it is attached.

(2) A non-paper label (excluding labels attached by a seam) shall be considered permanent if, during an attempt to remove it without the aid of tools or solvents, it cannot be removed or such action damages the surface to which it is attached.

(3) A warning label attached by a seam shall be considered permanent if it does not detach when subjected to a 15-lbf (67-N) pull force applied in the direction most likely to cause failure using a 3⁄4-in. (1.9 cm) diameter clamp surface. Gradually apply the force within a period of 5 s. and maintain for an additional 10 s.

(4) Adhesion Test for Warnings Applied Directly onto the Surface of the Product:

(i) Apply the tape test defined in Test Method B of Test Method D3359, eliminating parallel cuts.

(ii) Perform this test once in each different location where warnings are applied.

(iii) The warning statements will be considered permanent if the printing in the area tested is still legible and attached after being subjected to this test.

(iv) A non-paper label, during an attempt to remove it without the aid of tools or solvents, shall not fit entirely within the small parts cylinder defined in 16 CFR part 1501 if it can be removed.

(d) *Infant Support Surface Firmness Test Method*. Perform the following steps to determine the infant support surface firmness of the product as received from the manufacturer.

(1) Conduct tests at three locations on the surface to be tested, with 3 in. (7.62 cm) or more separation: maximum thickness perpendicular to the test surface and two other locations most likely to fail.

(2) Lay the product, with the infant support surface facing up, on a test base that is horizontal, flat, firm, and smooth.

(3) Prevent movement of the product in a manner that does not affect the force or deflection measurement of the product surface under test. Provide no additional support beneath the product.

(4) Orient the axis of the 3-in. head probe (Figure 1 to § 1242.4(a)) perpendicular to the test surface and aligned with a force gauge and parallel to a distance measurement device or gauge.

(5) Using a lead screw or similar device to control movement along a single direction, advance the probe onto the product and set the deflection to 0.0 in. when a force of 0.1 N (0.02 lb) force is reached.

(6) Continue to advance the head probe into the product at a rate not to exceed 0.1 inch per second and pause when the force exceeds 10.0 N (2.24 lb), or the deflection is equal to 1.00 in. (2.54 cm).

(7) Wait 30 s. If the deflection is less than 1.00 in. and the force is 10.0 N or less, repeat steps § 1242.5(d)(6) and § 1242.5(d)(7)).

(8) Record the final force and deflection amounts.

(9) Repeat the infant support surface firmness tests on any other infant support surface and in all manufacturer-intended configurations that could affect the infant support surface, such as the folding or layering of parts of the product.

(e) *Inner Wall Firmness Test Method*. For nursing pillows with a caregiver opening, perform the steps in § 1242.5(d)(1) through § 1242.5(d)(8) on the inner wall of the caregiver opening, and perform the following, to determine the inner wall firmness as received from the manufacturer. Repeat the inner wall firmness tests in all manufacturer-intended configurations that could affect the inner wall firmness.

(f) *Product Conditioning Firmness Test Method*. Following the firmness testing in § 1242.5(d) and § 1242.5(e), perform the following steps to determine the product firmness after conditioning.

(1) Launder and dry the product according to the manufacturer's instructions.

(2) Repeat § 1242.5(d) *Infant Support Surface Firmness Test Method*.

(3) Repeat § 1242.5(e) *Inner Wall Firmness Test Method*.

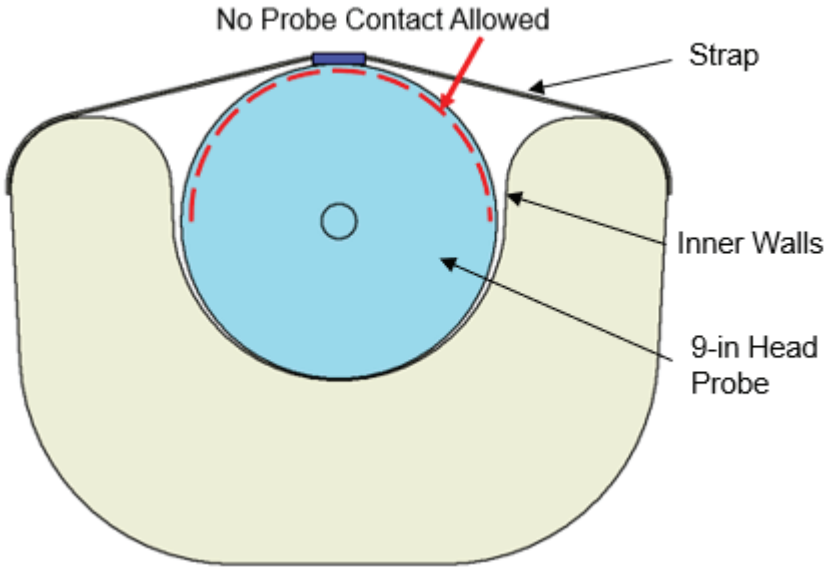
(g) *Infant Containment Test Method*. (1) Lay the product, with the infant support surface facing up, on a test base that is horizontal, flat, firm, and smooth.

(2) For nursing pillows with a caregiver attachment, adjust and latch the caregiver attachment to the minimum length allowed by the product.

(3) Place the 9-in. head probe (Figure 2 to § 1242.4(b)) inside the caregiver opening such that the flat bottom of the probe rests on the test surface and the probe's perimeter contacts the innermost surface of the caregiver opening.

(4) If any inner surfaces of the caregiver opening contact the outwardly facing portions of the probe, or the inner surfaces interfere with placing the probe down, the caregiver opening is considered to constrain the probe. *See* Figure 4 to this paragraph (g)(4). Do not include in the assessment any contact with a caregiver attachment.

Figure 4 to paragraph (g)(4) - Infant Containment, Example
In § 1242.5(g), the inner walls of the nursing pillow, excluding the strap, shall not constrain the 9-in. head probe in the caregiver opening, such that no contact with the outwardly facing portion (red arc) of the probe is allowed.



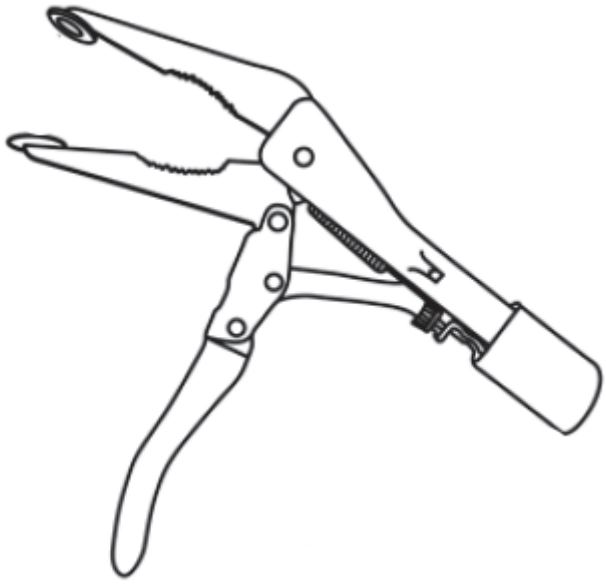
(5) Unlatch and move any caregiver attachment away from the caregiver opening. Conduct steps § 1242.5(g)(3) and § 1242.5(g)(4) in the procedure.

(6) With the probe at the position contacting the innermost surface within the caregiver opening, determine if any portion of the probe extends beyond a line projected across the outside limits of the caregiver opening.

(7) Slide the probe horizontally out of the caregiver opening to the outside of the nursing pillow. Determine if the probe is constrained by any inner surfaces of the caregiver opening contacting the outwardly facing portions of the probe. Do not include in the assessment any contact with a caregiver attachment.

(h) *Seam Strength Test Method*. (1) *Equipment*. Clamps with 0.75 in. (1.9 cm) diameter clamping surfaces capable of holding fabric and with a means to attach a force gauge. Figure 5 to this paragraph (h)(1), or equivalent. The force gauge must have an accuracy of +/- 0.5 lb (1.1 N).

Figure 5 to paragraph (h)(1) - Seam Clamp



(2) Clamp the fabric of the nursing pillow on each side of the seam under test with the 0.75 in. clamping surfaces placed not less than 0.5 in. (1.2 cm) from the seam.

(3) Apply a tension of 15 lb (67 N) evenly over 5 s. and maintain for an additional 10 s.

(4) Repeat the test on every distinct seam and every 6 in. (15 cm) along each seam.

(i) *Caregiver Attachment Test Method.* (1) *Equipment*. Any suitable clamping devices with means to attach a force gauge with accuracy of 0.5 lb (1.2 N) may be used. The clamping surfaces shall grasp across the entire width of the strap or attachment element.

(2) Support the nursing pillow to resist the pull forces and release the buckle or clasp of the caregiver attachment.

(3) Clamp one side of the attachment or strap of the nursing pillow not less than 0.5 in. (1.2 cm) from the attachment to the nursing pillow.

(4) Apply a tension of 20 lb (89 N) evenly over 5 s. and maintain for an additional 10 s.

(5) Repeat the test on the other side of the attachment or strap.

(6) Join the buckle or clasp of the attachment or straps.

(7) Clamp both sides of the attachment or straps across the buckle or clasp, one on each side and not less than 0.5 in. (1.2 cm) from the buckle or clasp.

(8) Apply a tension of 20 lb (89 N) evenly over 5 s. and maintain for an additional 10 s.

§ 1242.6 Marking and labeling.

(a) Each product and its retail package shall be marked or labeled clearly and legibly to indicate the following:

(1) The name, place of business (city, state, and mailing address, including zip code), and telephone number of the manufacturer, distributor, or seller.

(2) A code mark or other means that identifies the date (month and year as a minimum) of manufacture.

(3) The marking or labeling in § 1242.6(a)(1) and § 1242.6(a)(2) are not required on the retail package if they are on the product and are visible in their entirety through the retail

package. When no retail packaging is used to enclose the product, the information provided on the product shall be used for determining compliance with § 1242.6(a)(1) and § 1242.6(a)(2). Cartons and other materials used exclusively for shipping the product are not considered retail packaging.

(b) The marking and labeling on the product shall be permanent.

(c) Any upholstery labeling required by law shall not be used to meet the requirements of this section.

(d) Warning Design for Product: (1) The warnings shall be easy to read and understand and be in the English language at a minimum.

(2) Any marking or labeling provided in addition to those required by this section shall not contradict or confuse the meaning of the required information or be otherwise misleading to the consumer.

(3) The warnings shall be conspicuous and permanent.

(4) The warnings shall conform to ANSI Z535.4–2011, *American National Standard for Product Safety Signs and Labels*, sections 6.1 through 6.4, 7.2 through 7.6.3, and 8.1 (incorporated by reference, see § 1242.8), with the following changes.

(i) In sections 6.2.2, 7.3, 7.5, and 8.1.2, replace “should” with “shall.”

(ii) In section 7.6.3, replace “should (when feasible)” with “shall.”

(iii) Strike the word “safety” when used immediately before a color (for example, replace “safety white” with “white”).

Note 1 to paragraph (d)(4) - For reference, ANSI Z535.1, *American National Standard for Safety Colors*, provides a system for specifying safety colors.

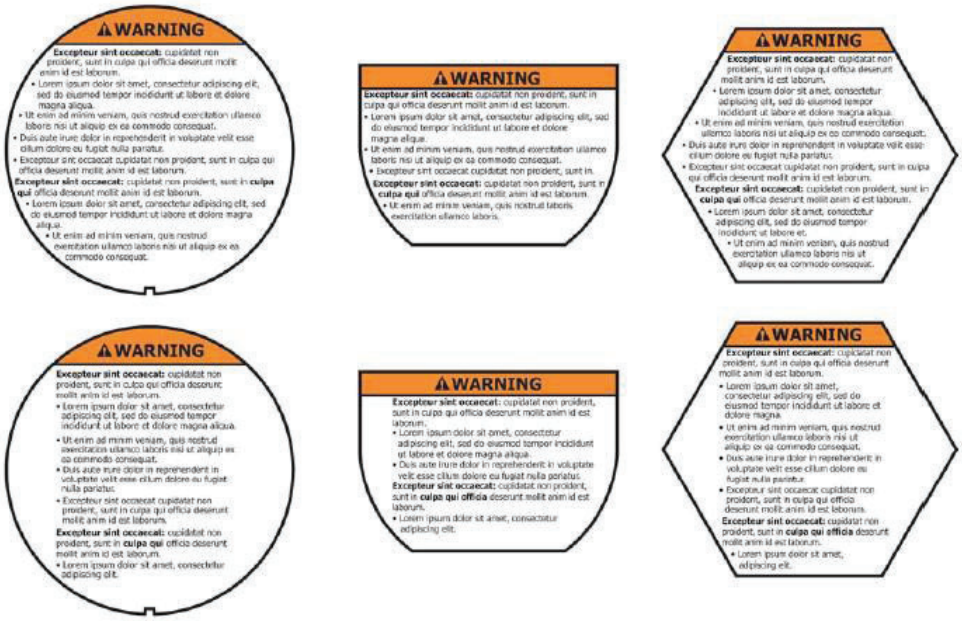
(5) The safety alert symbol and the signal word “WARNING” shall be at least 0.2 in. (5 mm) high. The remainder of the text shall be in characters whose upper case shall be at least 0.1 in. (2.5 mm), except where otherwise specified.

Note 2 to paragraph (d)(5) - For improved warning readability, avoid typefaces with large height-to-width ratios, which are commonly identified as “condensed,” “compressed,” “narrow,” or similar.

(6) *Message Panel Text Layout*. (i) The text shall be left-aligned, ragged-right for all but one-line text messages, which can be left-aligned or centered.

Note 3 to paragraph (d)(6)(i) - Left-aligned means that the text is aligned along the left margin, and in the case of multiple columns of text, along the left side of each individual column. *See* Figure 6 to this paragraph (d)(6)(i) for examples of left-aligned text.

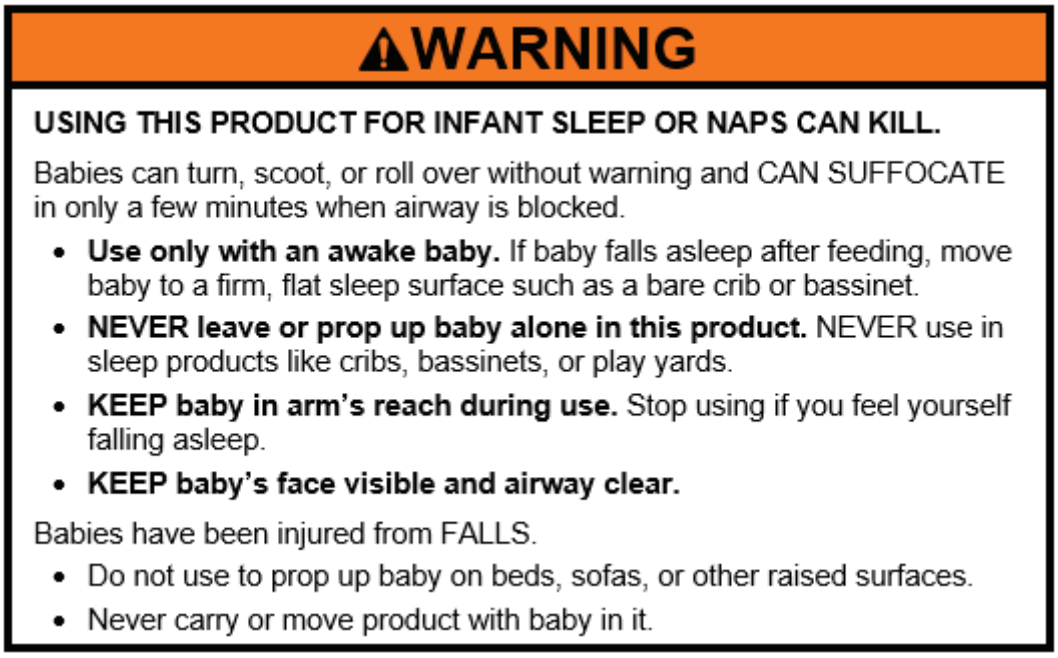
Figure 6 to paragraph (d)(6)(i) - Examples of Left-Aligned Text.
The text shown for these warnings is filler text, known as lorem ipsum, commonly used to demonstrate graphic elements.



(ii) The text in each column should be arranged in list or outline format, with precautionary (hazard avoidance) statements preceded by bullet points. Multiple precautionary statements shall be separated by bullet points if paragraph formatting is used.

(7) An example warning in the format described in this section is shown in Figure 7 to this paragraph (d)(7).

Figure 7 to paragraph (d)(7) - Example of Warning.



(e) *Warning Statements*. Each product shall have warning statements. The text must address the warnings as shown in Figure 7 to paragraph (d)(7), Example of Warning.

Note 4 to paragraph (e) - "Address" means that verbiage other than what is shown can be used as long as the meaning is the same or information that is product-specific is presented.

(f) *Package Warnings*. (1) The warnings and statements are not required on the retail package if they are on the product and are visible in their entirety through the retail package. Cartons and other materials used exclusively for shipping the product are not considered retail packaging.

(2) *Warning Statements*. Each product's package shall have warning statements to address the following, at a minimum, as specified in § 1242.6(d)(1), § 1242.6(d)(2), § 1242.6(d)(4), § 1242.6(d)(5), and § 1242.6(d)(6):

(i) Do not use for sleep.

(ii) Do not use in sleep products like cribs, bassinets, or play yards.

(3) Each product's retail package shall address the manufacturer's recommended weight, height, age, or developmental stage or combination thereof of the infant.

(4) Warnings, statements, or graphic pictorials on the product and package shall not indicate or imply that the infant may be left in the product without an adult caregiver in attendance.

§ 1242.7 Instructional literature

(a) Instructions shall be provided with the product and shall be easy to read and understand and shall be in the English language at a minimum. These instructions shall include information on assembly, maintenance, cleaning, and use, where applicable.

(b) The instructions shall include all warnings specified in § 1242.6(e).

(c) The instructions shall address the following additional warnings:

(1) Read all instructions before using this product.

(2) Keep instructions for future use.

(3) Do not use this this product if it is damaged or broken.

(4) Instructions shall indicate the manufacturer's recommended maximum weight, height, age, developmental level, or combination thereof, of the infant for whom the nursing pillow is intended. If this product is not intended for use by a child for a specific reason, the instructions shall so state this limitation.

(d) The cautions and warnings in the instructions shall meet the requirements specified in § 1242.6(d)(4), § 1242.6(d)(5), and § 1242.6(d)(6), except that sections 6.4 and 7.2 through 7.6.3 of ANSI Z535.4 – 2011, *American National Standard for Product Safety Signs and Labels*, need not be applied. However, the signal word and safety alert symbol shall contrast with the background of the signal word panel, and the cautions and warnings shall contrast with the background of the instructional literature.

Note 5 to paragraph (d) - For example, the signal word, safety alert symbol, and the warnings may be black letters on a white background, white letters on a black background, navy blue letters on an off-white background, or some other high-contrast combination.

(e) Any instructions provided in addition to those required by this section shall not contradict or confuse the meaning of the required information or be otherwise misleading to the consumer.

Note 6 to paragraph (e) - For additional guidance on the design of warnings for instructional literature, please refer to ANSI Z535.6, *American National Standard: Product Safety Information in Product Manuals*, Instructions, and Other Collateral Materials.

§ 1242.6 Incorporation by Reference

ANSI Z535.4-2011, *American National Standard for Product Safety Signs and Labels*, approved October 20, 2017, is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the U.S. Consumer Product Safety Commission and at the National Archives and Records Administration (NARA). Contact the U.S. Consumer Product Safety Commission at: the Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, telephone (301) 504-7479, email:

cpsc-os@cpsc.gov. For information on the availability of this material at NARA, email fr.inspection@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibr-locations.html. A free, read-only copy of the standard is available for viewing on the ANSI website at https://ibr.ansi.org/Standards/nema.aspx. You may also obtain a copy from American National Standards Institute (ANSI), 25 West 43rd Street, 4th Floor, New York, NY 10036, USA, telephone: (212)-642-4900, www.ansi.org.

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Alberta E. Mills, Secretary
Consumer Product Safety Commission

United States
Consumer Product Safety Commission

Staff Briefing Package

Staff's Draft Proposed Rule for Nursing Pillows

August 23, 2023

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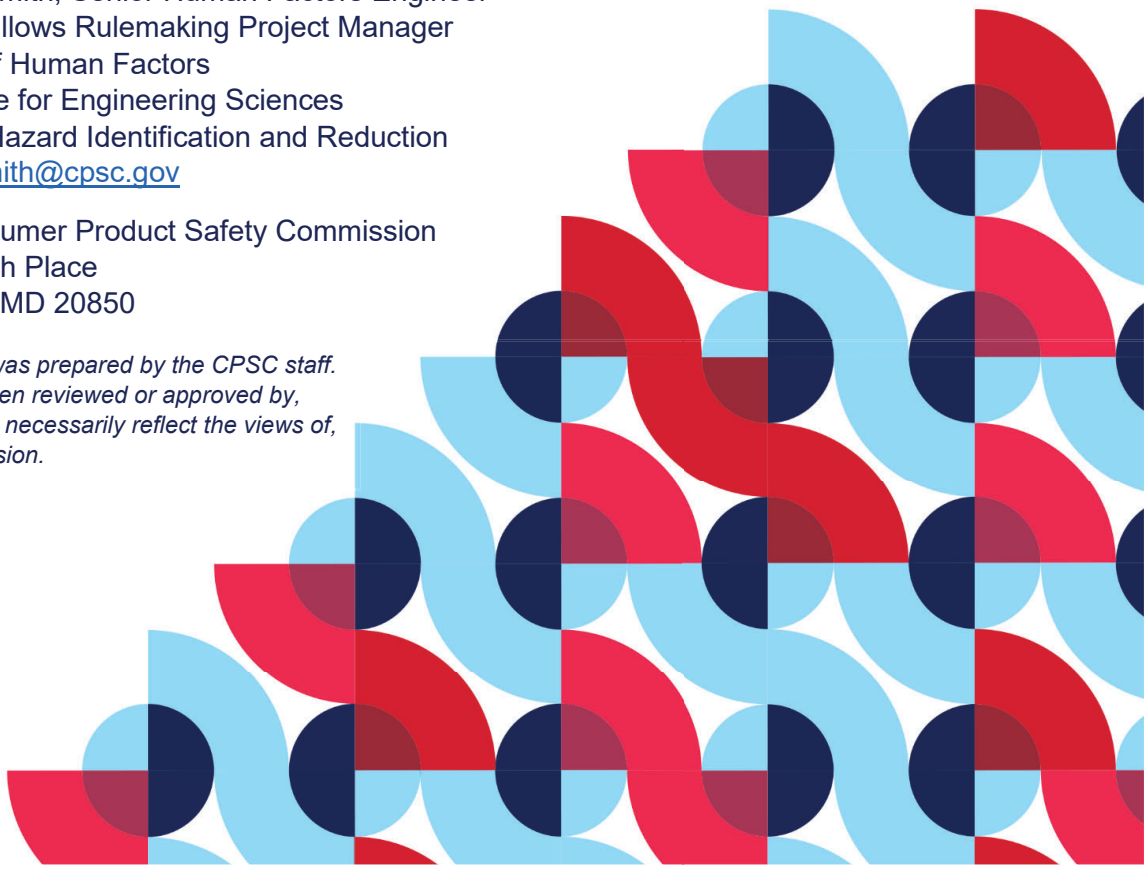
This report was prepared by the CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.



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Briefing Memorandum

United States
Consumer Product Safety Commission

Memorandum

TO: The Commission
Alberta E. Mills, Secretary
Austin C. Schlick, General Counsel
Jason K. Levine, Executive Director
DeWane Ray, Deputy Executive Director of Operations

DATE: August 23, 2023

FROM: Duane E. Boniface, Assistant Executive Director,
Office of Hazard Identification and Reduction

Timothy P. Smith, Nursing Pillows Rulemaking Project Manager,
Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Staff's Draft Proposed Rule for Nursing Pillows

I. Introduction

This briefing package presents staff's draft proposed rule for nursing pillows under the Danny Keysar Child Product Safety Notification Act, *i.e.*, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA). Nursing pillows are infant products intended to position and support an infant during breastfeeding or bottle feeding. Staff has identified 154 fatal incidents and 88 nonfatal incidents and consumer concerns reported to the U.S. Consumer Product Safety Commission (CPSC) from January 1, 2010, through December 31, 2022, associated with nursing pillows and involving infants up to 12 months of age.

Section 104 of the CPSIA requires the CPSC to:

1) examine and assess voluntary safety standards for durable infant or toddler products; and

2) promulgate mandatory consumer product safety standards that are substantially the same as the voluntary standards or more stringent than the voluntary standards, if the Commission determines that more stringent standards would further reduce the risk of injury associated with these products.

15 U.S.C. § 2056a(b). The Commission must continue promulgating safety standards for infant and toddler products until it "has promulgated standards for all such product categories." 15 U.S.C. § 2056a(b)(2).

Section 104(f) of the CPSIA defines "durable infant or toddler products" as "durable products intended for use, or that may be reasonably expected to be used, by children under the age of 5

years." 15 U.S.C. § 2056a(f). Section 104(f)(2) sets forth a non-exhaustive list of durable infant or toddler products that fall within the definition. 15 U.S.C. § 2056a(f)(2). Although nursing pillows are not specifically listed, they are "durable infant or toddler products" because they are durable products used by infants for support while they are being fed.

Section 104 of the CPSIA requires the Commission to examine and assess the effectiveness of any relevant voluntary standards, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts. 15 U.S.C. § 2056a(b)(1)(A). This consultation process has been ongoing with CPSC staff's participation in the juvenile product subcommittee meetings of ASTM International, whose subcommittee members represent producers, users, consumers, government, and academia. Staff began the consultation process for this rulemaking in December 2021, with a letter to ASTM requesting that ASTM form a working group under its F15 committee to develop a voluntary standard to reduce the risk of death and injury from hazards associated with infant support pillows such as nursing pillows.[1] Accompanying the letter were incident data associated with nursing pillows and infant loungers. ASTM formed two subcommittees to develop two separate voluntary standards:

1) the F15.16 Infant Feeding Supports subcommittee,[2] intended to develop a standard for nursing pillows, which the subcommittee refers to as infant feeding supports; and

2) the F15.21 Infant Loungers subcommittee, intended to develop a standard for infant loungers, including nursing pillows that are also intended for lounging.[3]

Since then, staff has been actively participating in both ASTM subcommittees to develop voluntary standards that address hazards associated with these products. As of the date of this briefing package, neither subcommittee has published a voluntary standard.

This briefing package presents staff's recommendations for a draft proposed rule for nursing pillows, including staff's assessment of the performance requirements and other requirements under consideration by the ASTM F15.16 Infant Feeding Supports subcommittee; discusses the impact of the draft proposed rule on small businesses; and provides staff's recommendations to the Commission. This package also recommends updating 16 C.F.R. part 1130 to include nursing pillows as "durable infant or toddler products" requiring consumer registration under section 104(b) of the CPSIA, 15 U.S.C. § 2056a(d), and updating 16 C.F.R. part 1112 to include a Notice of Requirements (NOR) for the accreditation of third-party conformity assessment bodies, or testing laboratories, to test for conformity with the proposed nursing pillow rule.

[1] https://www.cpsc.gov/s3fs-public/Nursing-and-Support-Pillow-VS-request.pdf
[2] The ASTM F15.16 Infant Feeding Supports subcommittee was initially called the Feeding and Infant Support Products subcommittee.
[3] Staff's assessment of the requirements under consideration by the ASTM F15.21 Infant Loungers subcommittee for its voluntary standard, and staff's recommendations for a draft proposed rule for infant support cushions, which includes nursing pillows that are intended, marketed, or designed to support an infant or any portion of an infant up to 12 months old for lounging, rest, or sleep, is addressed under a separate rulemaking activity, and separate staff briefing package, for infant support cushions.

II. Background

A. Products and the Market

Nursing pillows are infant products intended to position and support an infant during breastfeeding—also referred to as nursing—or bottle feeding. Examples of these products are shown in Figure 1 and Figure 2. These products generally rest upon or are "worn" by the caregiver while seated or partially reclined, as shown in Figure 3. Nursing pillows are most commonly C-, U-, or crescent-shaped—sometimes referred to as horseshoe-shaped—to fit closely around the caregiver's torso; however, other designs exist, including a V- or boomerang-shaped product, a round pod with a recessed center to support the infant, a stack of multiple petal-shaped pillows attached to a central tubular pillow, and E-shaped products for twins. Most products are filled with synthetic batting or foam, but products filled with cotton, wool, or dried grains are available.

FIGURE 1. Examples of various nursing pillow designs marketed solely for nursing or feeding.

FIGURE 2. Examples of nursing pillows with secondary propping or lounging functions.

In addition to providing a support surface for infants, nursing pillows provide support to the caregiver by raising the infant to the desired height for nursing, thereby reducing muscular strain on the caregiver, and by providing a buffering surface between the infant and the caregiver, reducing pressure on the caregiver's abdomen. This latter function is especially helpful in cases where the caregiver has abdominal stitches from a caesarean section.[4] Some products include a strap or belt, sometimes with a buckle, to secure the product to the caregiver's body, and a few have restraints that attach the infant to the product. Many products come with removable fabric covers, and some products have small infant head support bolsters or fabric toys attached.

FIGURE 3. Example of nursing pillow in use.

[4] See, for example, https://www.askdrsears.com/topics/feeding-eating/breastfeeding/rightstart-techniques/breastfeeding-after-cesarean-section/.

Some nursing pillows are marketed solely as a support for nursing or feeding; examples of these products are shown in Figure 1. However, many also are marketed for secondary uses, such as for propping, tummy time, or seated/sitting support of the infant. For example, some products are marketed for use for tummy time, with the infant propped up so their chest is on the product, to assist developing infants in strengthening their neck and back muscles. Many nursing pillows also function as sitting or lounging aids for infants who have not yet developed the core strength to maintain a sitting position on their own. In these cases, the infant generally is propped up within the crescent-shaped opening, where the caregiver's body would be located when the product is used for nursing, and the ends of the product curve around the infant to provide side, or lateral, support. Figure 2 shows examples of nursing pillows that offer secondary propping or lounging functions. Some products that originally were marketed for secondary uses like propping no longer are marketed for such use and focus instead on the nursing or feeding function.

As staff of CPSC's Directorate for Economic Analysis (EC) discusses in Tab E, new nursing pillows range in price from under $15 to more than $100, with most products in the $25 to $65 range. These products are available from brick-and-mortar retail and baby specialty stores, as well as online general retail stores, baby product websites, and online marketplaces for hand-crafted items. The more expensive models tend to have removable covers and tend to be sold at brick-and-mortar stores. Used nursing pillows are sometimes available from secondary marketplaces such as eBay and replacement covers are also available on such marketplaces.[5]

The Breastfeeding Infant Development Support Alliance recently estimated sales of new nursing pillows in the U.S. at 1.34 million units per year, using sales data from JPMA, the trade association for juvenile products.[6] The number of nursing pillows in use is likely higher than the estimated sales, because some parents may already own a pillow that was purchased for an older child, make a pillow, or buy a used pillow.

B. CPSC Infant Cushion/Pillow Ban and Nursing Pillow Exemption

In 1992, pursuant to the Commission's authority under the Federal Hazardous Substances Act (FHSA), the Commission banned certain infant cushions and infant pillows. Specifically, 16 C.F.R. § 1500.18(a)(16) bans any article known as an "infant cushion" or "infant pillow," and any other similar article, that has all of the following features:

- has a flexible fabric covering;
- is loosely filled with granular material, including but not limited to, polystyrene beads or pellets;
- is easily flattened;

[5] See also Tab C, prepared by staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF), who performed a simple search in eBay using the phrase "nursing pillow," with the results filtered to include only items in "used" condition and to show only "sold listings." The search resulted in 145 listings—primarily nursing pillows and nursing pillow covers—dated between March 15, 2023, and June 12, 2023. These sales suggest that consumers perceive nursing pillows as having a future useful life beyond the initial infant user. Moreover, sales of used nursing pillows on commercial second-hand sites likely underestimates the prevalence of consumers reusing nursing pillows, because some consumers are likely retaining and reusing nursing pillows for future children of their own rather than selling the products on secondary marketplaces.

[6] https://bfidsa.org/2-5-million-times-daily-quantifying-the-importance-of-nursing-pillows/

- is capable of conforming to the body or face of an infant; and
- is intended or promoted for use by children under 1 year of age.

FIGURE 4. Boston Billow Nursing Pillow.

However, 16 C.F.R. § 1500.86(a)(9) exempts the Boston Billow Nursing Pillow, an image of which appears in Figure 4, and substantially similar nursing pillows that are designed to be used only as a nursing aide for breastfeeding mothers. Examples of products that fall under this exemption are described in 16 C.F.R. § 1500.86(a)(9) and include nursing pillows that are tubular in form, C- or crescent-shaped to fit around a nursing mother's waist, round in circumference, and filled with granular material. Products subject to the nursing pillow exemption in 16 C.F.R. § 1500.86(a)(9) are included within the scope of the current rulemaking for nursing pillows and would need to comply with the draft proposed rule. The draft proposed rule does not disturb the FHSA ban at 16 C.F.R. § 1500.18(a)(16) or the 16 C.F.R. § 1500.86(a)(9) exemption to that ban, which would remain in place.

III. Incident Data

As staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA), discusses in Tab A, staff's search of the Consumer Product Safety Risk Management System (CPSRMS) and National Electronic Injury Surveillance System (NEISS) databases identified 154 fatal incidents and 88 nonfatal incidents and consumer concerns reported to CPSC from January 1, 2010, through December 31, 2022—a period of 13 years—associated with nursing pillows and involving infants up to 12 months of age. The data obtained from NEISS do not meet the minimum criteria to enable staff to compute a national estimate of the number of emergency department-treated injuries to infants involving nursing pillows; thus, these cases are included with the other reported incident data. Because reporting is ongoing, the number of reported fatalities and nonfatal incidents and concerns during the specified timeframe might increase in the future, especially for years 2021 and 2022. More detailed analyses of the incident data can be found in the EPHA staff memorandum in Tab A, as well as the memoranda in Tabs C and D, prepared by staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF), and CPSC's Directorate for Health Sciences (HS), respectively.

A. Fatalities and Associated Hazard Patterns

CPSC has identified 154 fatalities associated with nursing pillows from January 1, 2010, through December 31, 2022. More than half (84) of these 154 fatalities were reported to have occurred since 2019; however, these data are anecdotal, so fluctuations in the numbers of reported fatalities could reflect changes in reporting rather than changes in incident frequency.

All reported fatalities for which the victim's age was identified involved an infant 9 months old or younger.[7] Nearly all reported fatalities (144 of the 154, or 94 percent) involved an infant 6

[7] Only one reported infant fatality did not report the victim's age.

months old or younger, and almost three-quarters (110 of the 154, or 71 percent) involved an infant 3 months old or younger.

The official cause of death in nearly all reported fatalities was asphyxia; suffocation; overlay; sudden unexpected infant death (SUID); sudden infant death syndrome (SIDS), a sub-type of SUID; or similar. Even with a full autopsy, it can be difficult, and often impossible, to distinguish between SIDS/SUID deaths and suffocations/asphyxiations with a soft object.[8] Furthermore, in those cases where a medical examiner reported the cause of death as SUID or unknown, asphyxia generally could not be ruled out. Thus, for the purposes of this analysis, staff is not distinguishing among the causes of these deaths.

Nearly all reported fatalities (142 of the 154 fatalities, or 92 percent) involved use of the nursing pillow for sleep, and these cases often involved additional unsafe sleep conditions, including sleep-surface sharing—also known as co-sleeping—or the presence of other soft bedding such as pillows or blankets. Additional cases also might have involved sleep, but the incidents lacked sufficient details to enable staff to draw a conclusion. Seven incidents occurred while the product was being used for nursing or other feeding; in four of these seven cases, the nursing pillow also was used for sleep, as the infant was initially feeding and then fell asleep on the product.

The reported fatalities were largely unwitnessed, and 60 cases (39 percent) had insufficient details to enable CPSC staff to determine the hazard pattern or scenario. However, staff classified the remaining 94 reported fatalities into the following hazard patterns, based primarily on the position in which the victim was found:

- ***Face into product*** *(32 fatalities)*: The infant was found with their face into the nursing pillow, typically after turning or rolling over.

- ***Face into other object/bedding outside product*** *(21 fatalities)*: The infant was found with their face against another object or bedding outside the nursing pillow, typically after rolling off or out of the product.

- ***Face down in opening*** *(14 fatalities)*: The infant was found face-down in the opening of the nursing pillow, with the pillow surrounding the head and the face into the mattress or other bedding beneath the product.

- ***Neck hyperextension/hyperflexion*** *(13 fatalities)*: The infant was found in contact with the nursing pillow, with their neck hyperflexed and the head pressed against their chest, or the neck hyperextended and the head tilted backward over the top of the product.

- ***Bedding over face*** *(4 fatalities)*: The infant was found with bedding over or covering their head or face.

- ***Face into product or bedding (unknown)*** *(4 fatalities)*: The infant was found with their face into either the nursing pillow or other bedding, but the specific product is unknown.

[8] See the memorandum prepared by HS staff, in Tab D, for more on this issue.

- ***Entrapment/overlay while nursing*** *(3 fatalities)*: The infant was entrapped or overlayed by the caregiver when the caregiver fell asleep while breastfeeding.

- ***Overlay*** *(3 fatalities)*: The infant was found with a caregiver, with whom they were co-sleeping, overlaying the infant.

Staff also found that 124 of the 154 reported fatalities (81 percent) involved the nursing pillow being used in or on a sleep product. Specifically, 62 fatalities (40 percent) involved the product being used in another infant sleep product, such as a crib, portable playpen, or bassinet; 61 fatalities (40 percent) involved use of the product on an adult bed or mattress; and one fatality involved a mattress of unknown size. Eighteen reported fatalities (12 percent) involved the product being used on a couch, sofa, or loveseat; one fatality involved the product being used on the caregiver's lap in a recliner chair; and the use location for 11 fatalities is unknown.

B. Nonfatal Incidents and Associated Hazard Patterns

Although reported fatalities associated with nursing pillows are of utmost concern, CPSC staff also searched for nonfatal incidents and reported consumer concerns associated with these products to identify other possible risks of injury. Staff has identified 88 nonfatal incidents and consumer concerns associated with nursing pillows reported to CPSC from January 1, 2010, through December 31, 2022. Of these 88 reports, 64 resulted in injury to the infant and 24 reported no injury to the infant. Incidents resulting in injury commonly involved skin irritation from the product or infants falling or rolling out of the product. Nonfatal incidents that did not result in injury included consumer concerns about a strong odor from the product and other reported concerns with the nursing pillow such as product integrity issues.

About two-thirds of the nonfatal incidents and consumer concerns (59 of the 88) involved a victim of unknown age, and all but one of the reports without injury involved a victim whose age was unknown. Like the reported fatalities, all nonfatal incidents and concerns for which the victim's age was identified involved an infant 9 months old or younger, with the majority (16 of 29) 3 months old or younger.

CPSC staff classified the 88 nonfatal incidents and consumer concerns as follows:

- ***Skin allergy/irritation*** *(29 cases)*: The infant developed a skin irritation or an allergic reaction to the product.

- ***Fall/roll out*** *(23 cases)*: The infant either fell or rolled out of the nursing pillow. These cases are divided further, as follows:

    - ***Elevated surface*** *(19 cases)*: The infant fell or rolled out of the product from an elevated surface, such as a couch or bed.

    - ***Carrying in product*** *(2 cases)*: The infant fell or rolled out of the product while a caregiver was carrying the infant in the product.

    - ***Same level*** *(1 case)*: The infant fell or rolled out of the product onto the same level surface as the product.

  - ***Unknown level*** *(1 case)*: The infant fell or rolled out of the product from an unknown level.

- ***Filling coming out/choking hazard*** *(6 cases)*: The filling material came out of the nursing pillow, causing choking or presenting a choking hazard.

- ***Product integrity*** *(5 cases)*: The consumer reported issues with product integrity, posing a potential hazard. These issues included holes in the product, the seam of the product opening, and a crack in a clip on the product.

- ***Strong smell*** *(5 cases)*: The consumer reported a strong odor coming from the product.

- ***Other*** *(20 cases)*: Other uncommon nursing pillow-related incidents, including burn, entanglement, scratch, neck sprain, near-strangulation, and near-suffocation.

As with the reported fatalities, staff also determined the placement of the nursing pillow and infant among the 64 nonfatal incidents that resulted in injury. In most cases (42, or 66 percent of the 64 incidents), the placement was unknown, but common locations among the remaining incidents included a couch (8 injuries), an adult bed (5), and a bed of unknown type (3).

IV. CPSC Contractor Report

In September 2020, CPSC staff awarded a contract to 21 State University (BSU) for infant biomechanics and suffocation research and consultancy services.[9] One task under this contract, initiated in September 2021, was for research on pillows intended for infant care and use, and included an analysis of the risk of injury or death to infants associated with the use of infant pillows marketed as aiding infants during activities such as feeding, nursing, sleeping, propping, and lounging; that is, nursing pillows and infant support cushions.[10]

BSU delivered a final report on the results of its research on June 30, 2022.[11] The report includes recommendations and conclusions related to the performance and design of nursing pillows and infant support cushions, including the following:

- *Firmness Testing.* BSU recommended that all nursing pillows and infant support cushions be required to undergo firmness testing, because products that lack firmness are more likely to conform around an infant's nose and mouth and to present a suffocation hazard. BSU recommended testing using a 3-inch diameter anthropometry-based hemispheric probe that is geometrically similar to, and of a size that is representative of the breadth of, an infant's face. This probe is applied to the product at three locations: the location of maximum thickness, the location of minimum thickness, and a subjective location of interest (*i.e.*, a separate location that seems particularly soft or is otherwise most likely to result in failure). The force required to displace the probe 1 inch into the product at each location must exceed 10 Newtons (N). Passing this

[9] Contract No. 61320620D0002.The key personnel for performance under this contract are Dr. Erin M. Mannen, Ph.D. (Principal Investigator), and Dr. John Carroll, MD (Co-Investigator).
[10] Task Order No. 61320621F1015.
[11] Mannen, E. M., Davis, W., Goldrod, S., Lujan, T., Siddicky, S. F., Whitaker, B., & Carroll, J. (2022). *Pillows Product Characterization and Testing*. Prepared for the U.S. Consumer Product Safety Commission under contract no. 61320620D0002, task order no. 61320621F1015. Available: https://www.cpsc.gov/content/Pillows-Product-Characterization-and-Testing.

requirement would mean that the product has firmness comparable to crib mattresses,[12] and crib mattresses are generally considered the safest place for an infant to sleep.

- *Airflow Testing.* BSU recommended that products that do not pass firmness testing be required to pass an airflow test, using a contractor-developed test device and test method. Passing the airflow test would mean that the product has airflow characteristics comparable to current mesh crib liners, which BSU concluded would mitigate the suffocation hazard. However, also BSU concluded that airflow testing was not required for products that pass their proposed firmness testing, because a firm product is unlikely to form a seal around an infant's nose and mouth.

- *Sagittal-Plane Testing.* BSU developed new, prototype sagittal-plane testing devices to allow for more comprehensive assessments of infant positioning in and on nursing pillows and infant support cushions than similar testing devices.[13] BSU stated that further research was needed to determine appropriate worst-case positions for testing and to set threshold values for acceptable body positions that would not negatively impact infant breathing.

- *Nursing Pillow Shape.* BSU concluded that nursing pillows that are firm and feature sharper corners, rather than cylindrical sides, are likely the safest option for infants, because there would be no reasonable way for consumers to use such a product as a lounger, thereby limiting the hazards associated with sagittal-plane positioning in a nursing pillow.

CPSC staff shared this report with the ASTM Infant Feeding Supports subcommittee to assist in the development of its draft voluntary standard, and staff considered this report and its recommendations when developing the draft proposed rule for nursing pillows.

V. Draft ASTM Voluntary Standard

There are no published U.S. voluntary standards for nursing pillows. However, ASTM has established an F15.16 subcommittee on Infant Feeding Supports,[3] and on March 20, 2023, ASTM issued ballot F15.16 (23-01), which included a preliminary draft of the ASTM Infant Feeding Supports voluntary standard. The draft standard defined an infant feeding support as a "product that is intended to position and support an infant (the occupant) close to a caregiver's body, and to reduce strain and pressure on the caregiver's body, while breastfeeding or bottle feeding." Although not part of the formal definition, this definition includes clarifying text that states the following: "These products are commonly U-shaped in appearance, and generally rest upon, wrap around, or are worn by a caregiver in a seated or reclined position. These products are commonly known as nursing pillows." Thus, nursing pillows are included within the scope of products covered by the proposed voluntary standard and are treated as essentially synonymous with infant feeding supports.

[12] BSU found that sample crib mattresses tested using the hemispheric probe required more than 10 N to displace the probe 1 inch. A force of 10 N also approximates the weight of an infant's head.
[13] The sagittal plane is an anatomical plane that runs vertically through the human body, dividing it into left and right sections. Thus, it can be thought of as viewing the human body in profile. The test devices represent infants and are hinged to allow one to assess how the various body segments (*e.g.*, head, trunk) might be positioned relative to one another, in profile, when an infant is placed on the product.

CPSC staff has been working with the F15.16 Infant Feeding Supports subcommittee to develop requirements intended to address the primary hazards associated with nursing pillows. The draft voluntary standard included in ballot F15.16 (23-01), discussed below, illustrates the types of requirements that are being considered by the subcommittee, with CPSC staff's input. The ballot closed on April 20, 2023, and received 11 negative votes with comments and 6 other comments. On May 2, 2023, the subcommittee co-chair briefly summarized the negative comments, which were extensive and covered numerous topics, and the co-chair stated that these and the other comments would be forwarded to and addressed by the relevant task groups. Work in the subcommittee is ongoing.[14]

A. Draft General Requirements and Performance Requirements

The draft voluntary standard includes general requirements typically found in other ASTM juvenile product standards, such as requirements for lead, including lead in paints; prohibitions against small parts, hazardous sharp edges or points, and removable protective components; requirements to prevent injury from scissoring, shearing, and pinching; requirements for toy accessories that are attached to, removable from, or sold with the products; and permanency requirements for labels and warnings. The draft voluntary standard also includes a requirement for infant feeding supports that can be converted into another product, or that has use features for which another voluntary standard exists, to comply with the applicable requirements of all applicable standards. This requirement was added primarily because another ASTM subcommittee, F15.21 Infant Loungers, is in the process of developing a voluntary standard for infant loungers, and CPSC staff understands that the intention of both subcommittees is to require infant feeding supports that also function as loungers to meet the requirements of the eventual infant lounger standard as well.

The draft voluntary standard also includes four performance requirements to address nursing pillow hazards:

- *Infant Restraints*: This requirement prohibits all infant feeding supports from including an infant restraint system, which may entangle an infant and could invite misuse by suggesting to consumers that it is acceptable to leave an infant unattended in the nursing pillow.

- *Fabric/Mesh Integrity*: This requirement is intended to address product integrity issues such as seam failures and material breakage.

- *Firmness*: This requirement places limits on the extent to which certain portions of the product can deflect when a 3-inch diameter hemispheric probe is applied to the product with a certain force. The proposed requirement and test method are based on the firmness recommendations in the BSU pillows research report to CPSC.[12] However, the requirements were expanded to be applied not only to the top infant support surface, but also to the inner wall of the crescent-like opening of these products. Testing is performed at three locations on each of these two surfaces. The purpose of this requirement is to

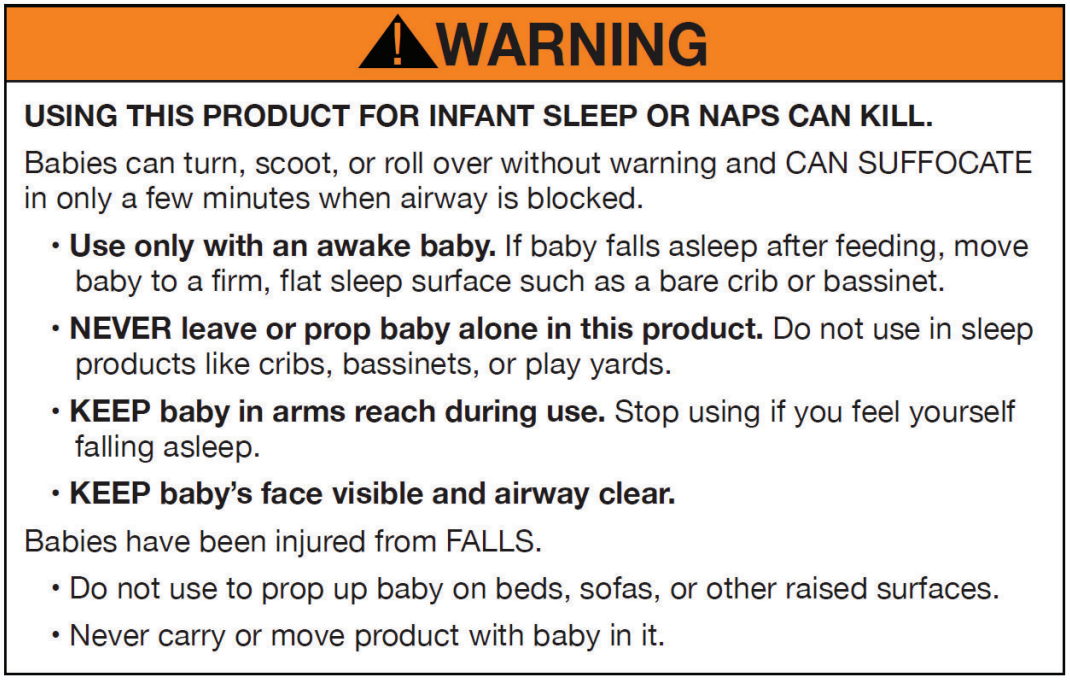
[14] On August 21, 2023, ASTM issued ballot F15 (23-12), which included a revised draft of the ASTM Infant Feeding Supports voluntary standard. This new ballot is scheduled to close on September 21, 2023. Staff is currently reviewing the ballot.

reduce the likelihood that the infant support surface or the interior opening of the infant feeding support can conform to an infant's face and pose a suffocation hazard.

- *Occupant Containment*: This requirement applies a 9-inch diameter head probe to the opening of an infant feeding support; when moved laterally through this opening, the probe must not contact the side walls of the product. The requirement is intended to reduce the potential for an infant's head to become entrapped within this opening. This requirement also is intended to reduce the extent to which these products are used for infant propping or lounging, by limiting the amount of lateral support available to young infants if they were placed within the opening.

B. Draft Marking, Labeling, and Instructional Literature Requirements

The draft voluntary standard also includes marking, labeling, and instructional literature requirements. The marking and labeling requirements include requirements for warnings that must appear on nursing pillows and other infant feeding supports covered by the standard. The following shows the draft standard's required warning statements that must appear on all nursing pillows, formatted to be consistent with the design requirements also specified in the draft standard (shown approximately to scale):



The draft standard requires the warnings to be "permanent" and "conspicuous," which the draft standard defines as a "label that is visible, when the infant feeding support is in a manufacturer's recommended use position, to a person sitting near the infant feeding support at any position around the infant feeding support."

The draft voluntary standard also includes requirements for package warnings to warn against sleep and using the nursing pillow in sleep products, and to address the manufacturer's recommended weight, height, age, developmental level, or combination thereof, of the infant. In

addition, the package cannot include warnings, statements, or graphics that indicate or imply that the infant may be left in the product without an adult caregiver in attendance.

Lastly, the draft voluntary standard includes requirements for instructional literature to accompany products covered by the standard. These requirements state that the instructional literature must include the warnings on the product, as well as the following additional warnings:

- Read all instructions before using this product.
- Keep instructions for future use.
- Do not use this product if it is damaged or broken.

The instructions also must indicate the manufacturer's recommended maximum weight, height, age, developmental level, or combination thereof, of the infant. If the product is not intended for use by a child for a specific reason (*e.g.*, a disability that would prevent safe use of the product), the instructions must state this limitation.

VI. Staff's Draft Proposed Rule

The subsections that follow discuss staff's recommended scope and requirements for the draft proposed rule for nursing pillows. See Tabs B, C, and D for more detailed discussions of these issues by staff of CPSC's Directorate for Laboratory Sciences, Division of Mechanical Engineering (LSM), ESHF staff, and HS staff, respectively. Tab F includes the draft regulatory language for the draft proposed rule.

A. Scope

CPSC staff considered the appropriate scope for the draft proposed rule based on the nursing pillow market, the existing FHSA infant cushion/pillow ban and associated exemption, the draft ASTM voluntary standard for infant feeding supports that is under development, and the ongoing CPSC rulemaking activity for infant support cushions. Staff's draft proposed rule would apply to all nursing pillows, as defined below.[15] Nursing pillows that also are intended, marketed, or designed for infant lounging or propping would be required to meet the additional requirements specified in the draft proposed rule for infant support cushions, whose scope includes infant loungers.

Staff recommends the following definition for "nursing pillow" in the draft proposed rule:

> Any product intended, marketed, or designed to position and support an infant close to a caregiver's body while breastfeeding or bottle feeding. These products rest upon, wrap around, or are worn by a caregiver in a seated or reclined position.

[15] Staff had considered defining the products subject to the draft proposed rule as nursing pillows intended *solely* for nursing or feeding, similar to the exemption language for the infant cushion/pillow ban. However, staff concluded that doing so would mean that nursing pillows that also function as loungers would not have to meet the requirements of the draft proposed rule for nursing pillows and would not be subject to similar requirements unless those requirements also were included within the draft proposed rule for infant support cushions.

Staff recommends that "nursing pillow" exclude:

- maternity pillows, also known as pregnancy pillows, which staff defines as "a large body pillow intended, marketed, and designed to provide support to a pregnant adult's body during sleep or while lying down," and

- sling carriers, as defined in 16 C.F.R. part 1228, which are already required to meet CPSC's sling carrier safety standard.

Staff concludes that the definition above is broad enough to encompass all nursing pillows on the market and within the available incident data, while excluding products that are not intended primarily for nursing (maternity pillows) or that might be used for nursing but whose hazards are already addressed by another standard (sling carriers). This definition is very similar to the definition developed by the ASTM infant feeding supports subcommittee, in coordination with CPSC staff, for their draft voluntary standard.[16]

B. General Requirements

Staff recommends that the draft proposed rule include many of the general requirements included in the draft ASTM voluntary standard for infant feeding supports to address the potential hazards associated with lead in paints, small parts, sharp edges or points, and the removal of protective components. However, staff recommends that the requirement to prevent the removal of protective components be expanded to include other possibly detachable components that are present such as zipper pulls and buttons. If detached, these parts can expose the infant to hazards such as sharp points, sharp edges, and choking hazards.

Staff also recommends that the draft proposed rule include the warning permanency requirements in the draft voluntary standard, but with an additional warning-permanency requirement that would address "free-hanging" labels; that is, labels that attach to the product at only one end of the label. Free-hanging warning labels are more likely to be torn or ripped off, or otherwise altered by the consumer, which would eliminate the potential safety benefit of the warning for future users of the product. Thus, staff recommends that the draft proposed rule include the following additional warning permanency requirement:

> Warning labels that are attached to the fabric of nursing pillows with seams shall remain in contact with the fabric around the entire perimeter of the label, when the product is in all manufacturer-recommended use positions, when tested in accordance with [reference to existing test method for assessing permanency of warning labels attached with seams].

C. Performance Requirements

i. Infant Restraints

Staff recommends that the draft proposed rule include a requirement that prohibits all in-scope products from including an infant restraint system. The draft ASTM voluntary standard for infant

[16] The draft voluntary standard's definition of "infant feeding support" states that these products also are intended to reduce strain and pressure on the caregiver's body, and states that these products are commonly U-shaped in appearance. However, staff concludes that this language is not needed, as products that meet the rest of the definition should be considered within scope, regardless of these details.

feeding supports includes a similar requirement, which was recommended by the ASTM Infant Feeding Supports subcommittee to address the potential risk associated with infants becoming entangled in such a restraint. In addition, CPSC staff and the consensus of the subcommittee was that infant restraints were unnecessary because proper use involves actively attending to the infant during use, and the presence of restraints could suggest to consumers that infants could be left unattended in the product.

ii. Seam Strength

Staff recommends that the draft proposed rule include a requirement and associated test methods to address seam failures with nursing pillows. Specifically, staff recommends that nursing pillow seams be subject to a tension test similar to that applied to toys intended for children up to 18 months old in ASTM F963, *Standard Consumer Safety Specification for Toy Safety*,[17] but tested at a higher tension force of 15 pounds rather than 10 pounds, because nursing pillows may be used for multiple children or passed on to other caregivers, meaning these products would be subject to stress over a usable life that can span more than a single infant's use. Staff is aware of one injury associated with seam failures, where an infant reportedly choked on filling that came out of the product, and staff has received additional reports of nonfatal incidents involving product integrity issues, such as seam failures and filling coming out of the product and posing a potential choking hazard. Staff concludes that the recommended seam strength requirement and test method would address these incidents and recommends that they be included in the draft proposed rule.

iii. Caregiver Attachment Strength

As staff noted previously, some nursing pillows, particularly nursing pillows intended solely for nursing, include a buckled belt, strap or other feature intended to secure the product to the caregiver. Although staff is not aware of any incidents associated with these "caregiver attachments," staff is aware of one report of crack in a clip on the product that could be relevant to this issue. In addition, during nursing pillow use, the caregiver may engage in repositioning or similar activities that might result in caregiver attachments bearing the full weight of the infant, who is supported by the nursing pillow. Thus, staff recommends that the draft proposed rule include a requirement and test method for the strength of these attachments, if included on the nursing pillow, to address the potential for infant falls if the attachment fails. Specifically, staff recommends that each element of the caregiver attachment system (*e.g.*, strap, buckle) that is included on nursing pillows be required to withstand a static load equal to the recommended weight limit of the product, or 20 pounds, whichever is greater.

iv. Firmness

Staff recommends that the draft proposed rule include a firmness requirement that applies to each nursing pillow's infant support surface, as well as the inner wall of the nursing pillow opening (*e.g.*, within the crescent-like opening). Staff's recommended firmness requirement and test method is based on the recommendations of BSU, in their pillows research report to

[17] Incorporated by reference in 16 C.F.R. part 1250, *Safety Standard Mandating ASTM F963 for Toys*

CPSC,[12] with modifications that add certain procedural steps to improve the test method,[18] and the addition of a requirement to test the inner wall of the opening. The test applies a 3-inch diameter hemispheric probe, which is similar in size and shape to an infant's face, to three test locations on each surface.[19] To meet the firmness requirement, the force required to displace

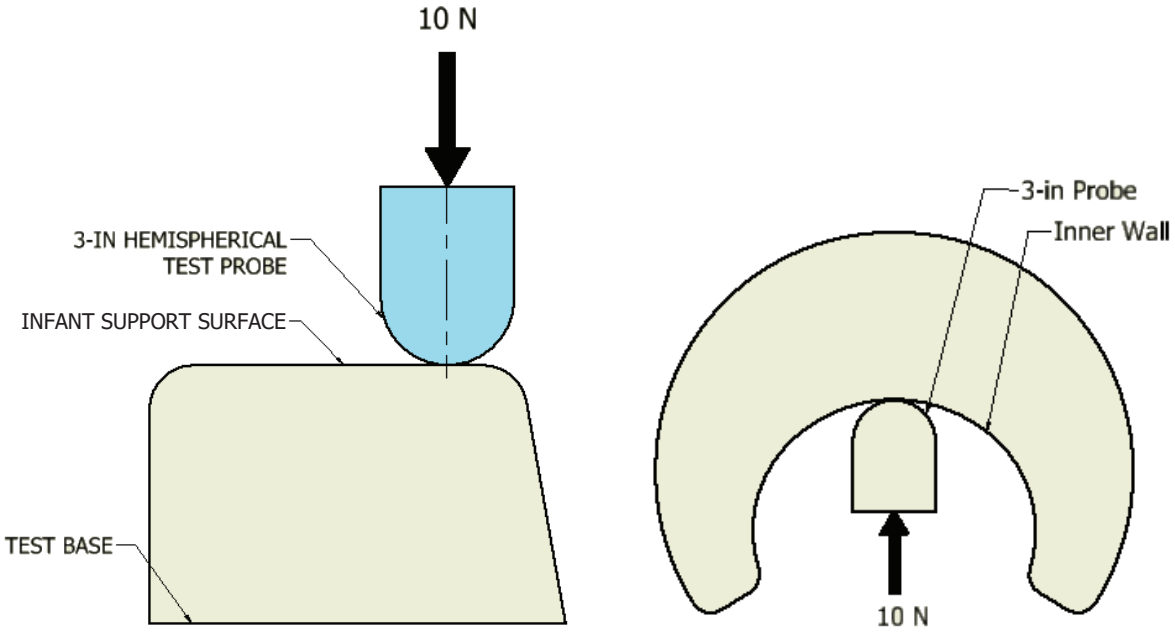


FIGURE 5. Illustration of firmness test being applied to infant support surface (left, side view) and inner wall of opening (right, top view).

the probe 1 inch into each test location must exceed 10 N (about 2.25 pounds), which results in product firmness that is comparable to crib mattresses. The diagrams in Figure 5 illustrate the firmness test being applied to the two surfaces of a nursing pillow. This requirement is intended to reduce the likelihood that the infant support surface or the interior opening of the nursing pillow can conform to an infant's face and pose a suffocation hazard and addresses the numerous fatalities where the infant was found with their face into the product.

Staff recommended that the ASTM Infant Feeding Supports subcommittee adopt a firmness requirement to address the suffocation hazard posed by nursing pillows, and the draft voluntary standard for infant feeding supports includes a firmness requirement similar to what staff is recommending for the draft proposed rule, including the application of the firmness requirement to the inner wall of the nursing pillow opening.

[18] For example, although the BSU test method allows the applied force to stabilize for about 1 minute before measuring the final force at the 1-inch deflection, staff determined that a 30-second stabilization period is sufficient. In other procedural steps, staff recommends that the firmness test method include a rate of approach for the probe of 1 inch per 10 seconds, and a waiting period of 5 minutes between successive tests if adjacent test locations are within 3 inches. Additional details regarding staff's recommended firmness requirement and test method can be found in the LSM staff memorandum, Tab B.

[19] The BSU test method identifies the three test locations as the locations of maximum thickness, minimum thickness, and another "most onerous" location. However, staff recommends replacing the "minimum thickness" location with an additional "onerous" location, because areas with minimal thickness are generally less likely to conform than thicker areas to the infant's face, and therefore, less likely to pose the same suffocation hazard.

v. Infant Containment

Staff recommends that the draft proposed rule include a provision to limit infant containment in the crescent-like openings in nursing pillows, using a 9-inch probe. The probe is initially placed against the rearmost portion of the opening and then the following two assessments are made:

1. The probe must extend beyond the opening of the product; that is, no portion of the nursing pillow, other than a caregiver attachment, if present, may extend beyond the opposite end of the probe.

2. When moved laterally outward, the probe cannot contact any surface of the nursing pillow, except for a caregiver attachment, if present.

If a caregiver attachment is present, the two assessments are made with the caregiver attachment unsecured and then secured at its minimum adjustable length. Figure 6 illustrates nursing pillows without a caregiver attachment that pass and fail staff's recommended infant containment provision, and Figure 7 illustrates nursing pillows with a secured caregiver attachment that pass and fail the requirement. In cases where the secured caregiver attachment prevents movement of the probe, a failure would be contact between the probe and the portion of the nursing pillow that is not a caregiver attachment but constrains movement of the probe through the opening (*e.g.*, by pulling in the sides of the nursing pillow).

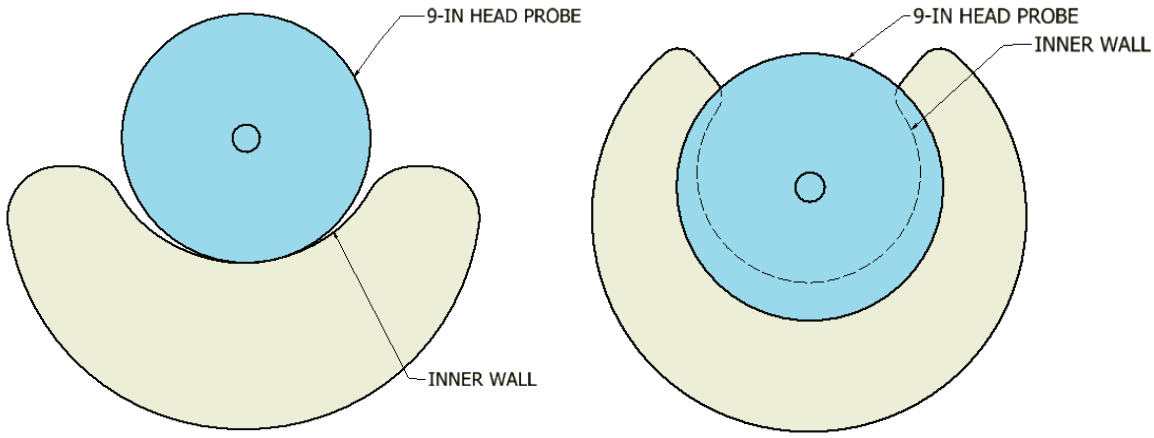


FIGURE 6. Illustration of nursing pillows that pass (left) and fail (right) staff's proposed infant containment provision.

CPSC staff recommended that the ASTM Infant Feeding Supports subcommittee include a provision to limit infant containment in its draft voluntary standard, and the requirement staff is recommending for the draft proposed rule is similar to the occupant containment requirement that appears in the draft ASTM voluntary standard for infant feeding supports. However, staff's recommended requirement includes the additional requirement that the nursing pillow cannot extend beyond the opposite end of the probe and requires testing to be performed both with and without any caregiver attachments secured.

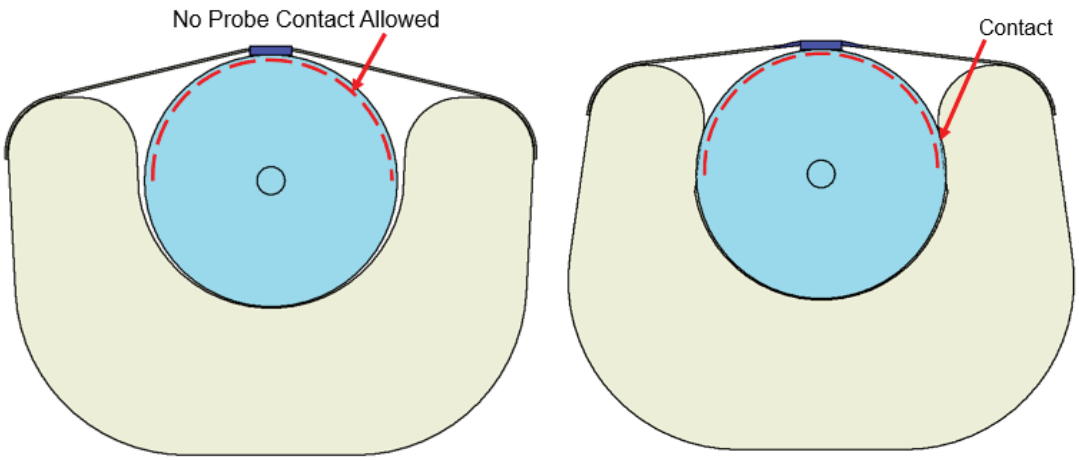


FIGURE 7. Illustration of nursing pillows with secured caregiver attachment that pass (left) and fail (right) staff's proposed infant containment provision.

Staff's proposed provision to limit infant containment is intended to reduce the degree to which a nursing pillow can envelop or support a young infant for lounging by requiring nursing pillow openings to be of a size that is more appropriate for an adult user, rather than an infant, and by reducing the amount of lateral support for young infants who might be placed within the nursing pillow opening. The requirement eliminates certain designs of nursing pillows that have been marketed for lounging and are known to be used for infant lounging and sleeping, which is the primary hazard associated with nursing pillows, and staff concludes that this requirement, combined with the firmness requirement, will reduce the likelihood that consumers will use nursing pillows for infant lounging.

The requirement also reduces the potential for an infant's head to become entrapped in nursing pillow openings or for the product to restrict a young infant's head movements, should the infant find themselves in such an opening. The available incident data include multiple nursing pillow-related fatalities where the infant was found face-down within the product's opening, with the nursing pillow surrounding the infant's head. In such a situation, where an infant's head movement is restricted by the product, the infant may be unable to change position and relieve an airway blockage, resulting in oxygen deprivation, suffocation, and ultimately death.

D. Performance Requirements Considered but Not Recommended

i. Airflow Requirement

In its pillow research report to CPSC, BSU recommended that nursing pillows that do not pass firmness testing be required to pass an airflow test that would demonstrate the product has airflow characteristics comparable to mesh crib liners, which BSU concluded would mitigate the suffocation hazard. However, BSU also stated that airflow testing is not needed for a product that passes the proposed firmness testing, because a firm product is unlikely to form a seal around an infant's nose and mouth. Because staff is recommending that all nursing pillows be required to meet firmness testing that is at least as stringent as that recommended by BSU, and the ASTM Infant Feeding Supports subcommittee is recommending a similar firmness requirement for all infant feeding supports in its draft voluntary standard, staff concludes that an airflow requirement for nursing pillows is unnecessary.

ii. Angular Requirement

In its pillow research report to CPSC, BSU also noted that some products that are marketed solely for nursing include features like sharper corners, which do not easily facilitate lounging, and concluded that nursing pillows that are firm and feature sharper corners, rather than cylindrical sides, might be the safest option for infants because there would be no reasonable way for consumers to use such a product as a lounger. Although BSU did not provide a specific recommendation for an "angular" requirement or test method, staff did consider the possibility of such a requirement. Nevertheless, staff is not recommending an angular requirement at this time because of uncertainties surrounding what would be appropriate pass-fail criteria and the potential for such a requirement to increase the risk of positional asphyxia by neck hyperflexion or hyperextension if the requirement were ineffective in discouraging lounging.

As ESHF staff discusses in Tab C, the BSU report states that sagittal-plane testing of nursing pillows that also function as loungers resulted in concerning and extreme neck flexion angles when the test devices were placed in a slumped position on the product. Yet, staff is concerned that a nursing pillow that is firm and has sharper edges to be more "angular" would likely yield similarly extreme, and possibly more extreme, neck flexion angles under the same conditions. In addition, such a product would likely result in a more acute neck extension for an infant placed in the product for lounging, with their head on the intended infant support surface, and this could pose a greater risk of suffocation by neck hyperextension relative to a product that is not designed to meet such a requirement.

Thus, although staff agrees that nursing pillows with sharper edges might, in principle, discourage some consumers from using the product for infant lounging, staff concludes that it is premature to include an angular performance requirement in the draft proposed rule, particularly given the potential for increasing the positional asphyxia risk if infants are placed in these products for lounging, contrary to the products' intended use. In addition, staff's draft proposed rule includes an infant containment provision that staff concludes is likely to discourage lounging.[20]

Staff recommends seeking public comments on this issue; specifically, staff is interested in information on the potential effectiveness of an angular requirement, including what pass-fail criteria would effectively discourage lounging; the potential risks associated with such a requirement; and whether an alternative requirement could further discourage consumers from using nursing pillows for infant lounging without concurrently increasing risks to those infants whose caregivers still choose to use the product in this way, relative to nursing pillows that do not meet the requirement.

E. Warning and Instructional Requirements

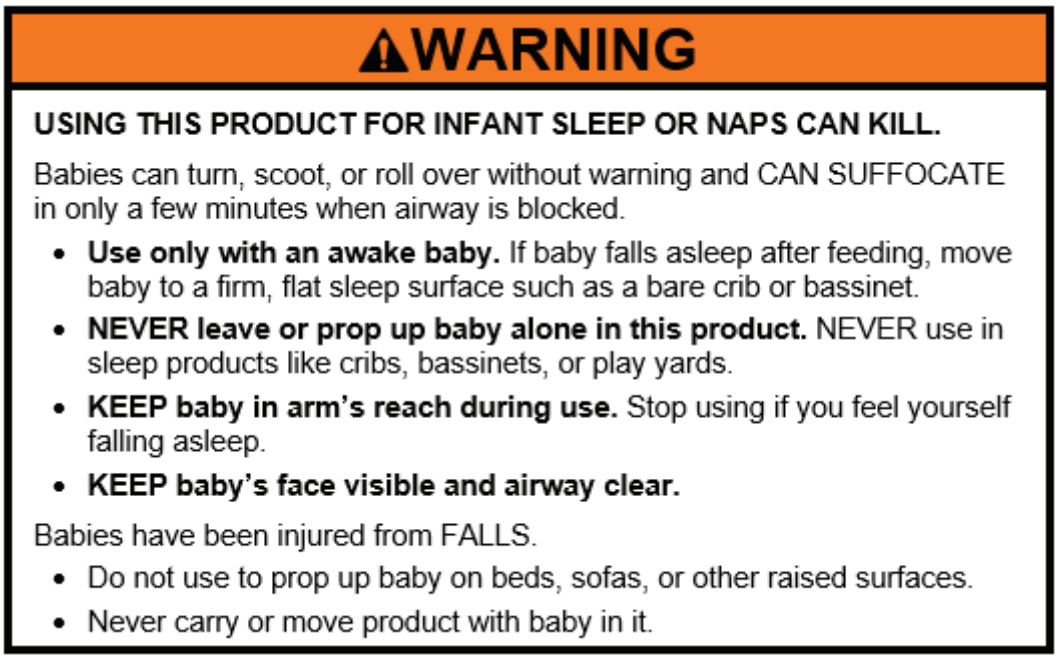
i. Marking and Labeling

Compared to the performance requirements described above, warnings are unlikely to be very effective in eliminating or reducing exposure to nursing pillow hazards. Nevertheless, prominent well-designed warnings can serve as a secondary safety mechanism by providing consumers

[20] Staff also notes that nursing pillows intended, marketed, or designed to support an infant or any portion of an infant up to 12 months old for lounging, rest, or sleep would be subject to the additional requirements of the Infant Support Cushions rule.

important information about the hazards associated with these products and appropriate behaviors to avoid these hazards. Thus, staff recommends that the draft proposed rule include requirements for on-product warnings that address the primary hazards associated with nursing pillows, with particular emphasis on the potentially deadly consequences of using these products for naps or sleep.

CPSC staff worked with the ASTM Infant Feeding Supports subcommittee to develop on-product warning requirements for the draft voluntary standard and recommends that the draft proposed rule include warning content and format requirements that are similar to those requirements, with minor changes for clarity and internal consistency, as discussed by ESHF staff in Tab C. The following shows the staff's recommended warning statements for the draft proposed rule that must appear on all nursing pillows, formatted to be consistent with the design, or format, requirements that also are specified in the draft proposed rule (shown approximately to scale):



The draft voluntary standard includes a warning placement requirement that requires the warning to be "conspicuous," which the draft standard defines as a "label that is visible, when the infant feeding support is in a manufacturer's recommended use position, to a person sitting near the infant feeding support at any position around the infant feeding support." Staff does not agree with the draft proposed rule relying on this definition, which staff concludes is too broad and would allow the warning to be placed on a side of the product that is not visible to the caregiver who is using the product (*e.g.*, the side opposite the crescent-like opening). Instead, staff recommends the following definition of "conspicuous" for the draft proposed rule:

> visible, when the nursing pillow is in each manufacturer's recommended use position, to a person while placing an infant into or onto the nursing pillow.

The draft voluntary standard also requires the warnings to be "permanent" and includes warning permanence requirements among the General Requirements for infant feeding supports. Earlier in this memorandum, staff discussed its recommended warning permanence requirements,

including an additional permanence requirement to further reduce the potential for the warnings to be torn, ripped, or cut off.

In addition to on-product warnings, the draft voluntary standard includes basic warning requirements for the packaging that accompanies nursing pillows, largely based on the ASTM Ad Hoc Language task group's recommended requirements for package warnings, which staff was involved in developing. The requirements in the draft voluntary standard include warning statements about not using the product for sleep or in sleep products like cribs, bassinets, or play yards; information about the manufacturer's recommended weight, height, age, or developmental stage, at a minimum; and a prohibition against other warnings, statements, or graphics that indicate or imply that an infant can be left in the product without an adult caregiver present. The package warnings also are required to have formatting similar to the on-product warnings. Staff recommends adopting these requirements for the draft proposed rule.

ii. Instructional Literature

Staff recommends that the draft proposed rule include requirements for instructional literature that must accompany nursing pillows. The draft ASTM voluntary standard for infant feeding supports includes requirements for instructional literature to accompany nursing pillows, including requirements for the instructions to include all on-product warnings and to instruct consumers to read all instructions before using the product, keeping the instructions for future use, and not using the product if it is damaged or broken. Like the package requirements, the instructions also must provide information about the manufacturer's recommended weight, height, age, or developmental stage, at a minimum. These requirements are based on meetings of the ASTM Infant Feeding Supports Warnings task group and on the recommended requirements for instructional literature by the ASTM Ad Hoc Language task group. CPSC staff participated in both task groups and assisted in the development of these requirements. Thus, staff recommends adopting these instructional literature requirements in the draft proposed rule for nursing pillows.

VII. Potential Small Business Impact

As required by the Regulatory Flexibility Act, 5 U.S.C. § 603, EC staff discusses in Tab E that there are more than 1,000 suppliers—that is, manufacturers, importers, and foreign direct shippers—of nursing pillows to the U.S. market. Most nursing pillow suppliers to the U.S. market are small U.S. manufacturers, importers, or U.S. non-employer businesses, which include small hand crafters that ship from the United States.

Most in-scope products on the market will require redesign to meet the requirements in the draft proposed rule, and EC staff concludes that redesign costs will be potentially significant for a substantial number of small firms for the first year that the rule is effective. One time redesign costs, including costs of designing warning labels and instruction manuals, are estimated at $13,500 per model, based on current Bureau of Labor Statistics hourly costs to employers for professional labor. Costs for non-employee home crafter businesses may be less, depending upon their "opportunity costs" for their own labor, although some professional expertise and equipment will likely be required to ensure that redesigned products meet the performance requirements, particularly for firmness and seam strength. Ongoing annual third-party testing costs are estimated at $650 to $1,150 per model.

The impact is likely to be significant for most small firms with low sales volume. Staff considers one percent of annual revenue to be a "significant" economic impact on a company, consistent with regulatory flexibility analyses used by other federal government agencies. Many small-volume hand crafters might stop selling nursing pillows. Small-volume hand crafters may not have enough sales to cover the expense of redesign and testing, and small-volume importers might not be able to find compliant suppliers. However, even relatively small-volume suppliers with sales under 1,000 units per year might be able to reduce the impact of the proposed rule by raising prices to cover costs of testing and redesign. A retail price increase of less than $5 could cover all testing costs and a substantial portion of the redesign costs, even for a very small supplier.

Consumers may not experience a significant loss of consumer utility as small-volume sellers exit online marketplaces, because the products currently in stores, and the best-selling online-only products, are likely to still be available, with redesign, because the suppliers of these products have sufficient sales volume to render the impact of redesign and testing not significant; that is, less than one percent of annual revenue. The selection in brick-and-mortar stores is already limited to the products of only nine companies. Also, many of the best-selling products online are from the same small group of firms that sell in stores. The best-selling online-only products are from companies that are small by the Small Business Administration (SBA) size standards but have sufficient sales volume to spread the cost of compliance over thousands of units and are unlikely to exit the market. Staff observes that nursing pillows are available used in some cases from secondary marketplaces such as eBay and that replacement covers are available also on such marketplaces.

Product redesign could increase the wholesale or retail price of nursing pillows by a few dollars, but likely not a significant amount, given that the materials and production methods are likely to remain roughly similar. Warning labels, registration forms, and instruction manuals could add a small amount to the cost of the product: $1 or less, or 2 percent of the retail price of a $50 item. If companies decide to pass the ongoing cost of testing onto consumers, the price increase could be relatively modest, perhaps under $1 at retail, which when added to the additional $1 cost of the warning labels and instruction manuals would total $2, or 4 percent of the price of a $50 item. Even a $5 price increase to cover redesign, testing, and labeling costs for a small-volume seller would represent only a 10 percent increase in price. The overall market for nursing pillows is relatively inelastic, meaning that an increase or decrease in price will not have a proportional increase or decrease in demand, because parents who need a nursing pillow will likely not postpone that purchase.[21] However, if parents find the redesigned pillows to be less useful than substitutes such as slings or regular adult bedding pillows, there could be a decline in total sales of nursing pillows because of the proposed rule.

VIII. Compliance Recall Information

Staff of CPSC's Office of Compliance (EXC) has not identified any recalls involving nursing pillows from January 1, 2010, through December 31, 2022.

[21] In addition, in the case the price goes down, demand is also inelastic because a parent who demands one nursing pillow does not necessarily want three or four.

IX. Other Recommended Amendments

A. Product Registration Rule Amendment

In addition to requiring the Commission to issue safety standards for durable infant or toddler products, section 104 of the CPSIA directed the Commission to issue a rule requiring that manufacturers of durable infant or toddler products establish a program for consumer registration of those products. The Commission issued the product registration card rule, 16 C.F.R. part 1130, in 2009. Staff's draft proposed rule would add nursing pillows to the list of durable infant or toddler products requiring a program for consumer registration.

B. Notice of Requirements

Section 14(a) of the Consumer Product Safety Act (CPSA) requires that any children's product subject to a consumer product safety rule under the CPSA must be certified as complying with all applicable CPSC-enforced requirements. The children's product certification must be based on testing conducted by a CPSC-accepted third-party conformity assessment body (test laboratory). The CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third-party test laboratories to determine compliance with a children's product safety rule. A proposed rule for nursing pillows, if issued as a final rule, would be a children's product safety rule that requires issuing an NOR.

The Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, at 16 C.F.R. part 1112. All new children's product safety rules, such as the proposed rule for nursing pillows, require an amendment to part 1112 to create an NOR. Therefore, staff recommends an amendment to part 1112 to include nursing pillows in the list of children's product safety rules for which CPSC has issued NORs.

X. Recommended Effective Date

The Administrative Procedure Act generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C § 553(d). Staff recommends a 180-day, or 6-month, effective date. Barring evidence to the contrary, staff generally considers 6 months to be sufficient for suppliers to come into compliance with a new standard, and this amount of time is typical for other CPSIA section 104 rules. Six months is also the period that JPMA typically allows for products in their certification program to shift to a new standard once that new standard is published. Therefore, juvenile product manufacturers are accustomed to adjusting to new standards within this time. Staff invites comments, particularly from small businesses, that provide specific data on the amount of time they will need to come into compliance.

XI. Staff Conclusion and Recommendations

Staff recommends that the Commission issue a proposed rule for nursing pillows that includes the requirements discussed in Section VI, which can be summarized as follows:

- Add a "nursing pillow" definition.
- Include certain general requirements and associated test methods that are consistent with the draft voluntary standard for infant feeding supports, but with:

  - an expanded requirement to prevent the removal of not just protective components, but other components such as zipper pulls; and
  - an additional warning permanence requirement to prevent free-hanging labels that could be easily removed.
- Include performance requirements and associated test methods that:
  - prohibit infant restraints;
  - add requirements for the strength of seams and caregiver attachments;
  - add firmness requirements that apply to the infant support surfaces of the nursing pillow, as well as the inner wall of the nursing pillow opening; and
  - add an infant containment provision that reduces the likelihood that consumers will use nursing pillows for infant lounging and sleep and reduces the risk of infant head entrapment in the openings of these products.
- Include warning and instructional requirements that include a strongly worded on-product warning.

Staff also recommends an effective date of 6 months after publication of the final rule to allow time for nursing pillow manufacturers to bring their products into compliance and to arrange for third-party testing. Laboratories will need to apply for accreditation specifically for this rule before they can provide third-party testing to verify conformity with the final rule. The draft proposed rule provided with this briefing package includes these recommended provisions.

TAB A: Overview of Nursing Pillow Fatalities and Nonfatal Incidents from January 1, 2010, to December 31, 2022 (EPHA Staff Memorandum)

United States
Consumer Product Safety Commission

Memorandum

TO: Timothy P. Smith, Nursing Pillows Rulemaking Project Manager, Division of Human Factors, Directorate for Engineering Sciences

DATE: March 7, 2023

THROUGH: Steve Hanway, Associate Executive Director, Directorate for Epidemiology

FROM: Stephanie Bragg, Mathematical Statistician, Division of Hazard Analysis

SUBJECT: Overview of Nursing Pillow Fatalities and Nonfatal Incidents from January 1, 2010, to December 31, 2022

I. Introduction

This memorandum characterizes the number of incidents and concerns and the hazard patterns associated with nursing pillows, as reported to CPSC staff. The fatalities and nonfatal incidents were reported to have occurred between January 1, 2010, and December 31, 2022.

II. Incident Data

Staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA), searched the Consumer Product Safety Risk Management System (CPSRMS) and the National Electronic Injury Surveillance System (NEISS) databases for reports to CPSC involving nursing pillows. The fatalities and nonfatal incidents were reported to have occurred between January 1, 2010, and December 31, 2022. Because the data from NEISS did not meet the minimum criteria for computing an estimate,[1] staff was unable to provide a separate national estimate of the number of emergency department-treated injuries to infants involving nursing pillows. However, the NEISS injury cases were included with the rest of the incident data described in this memorandum.

CPSC staff performed multiple searches consisting of a combination of product codes and narrative or manufacturer/model keyword searches to find all nursing pillow incidents. The first data search included all reports with the product code that includes nursing pillows (code 4050 *Pillows excl. water pillows*). The second data search looked for specific keywords in the narrative field across all product codes. Subsequent searches included several infant-related product

[1] Per NEISS standards, an estimate must be 1,200 or greater, the sample size must be 20 or greater, and the coefficient of variation must be 33 percent or smaller.

codes[2] and searched the manufacturer/model fields for several keywords and known manufacturer names. The data were extracted in January 2023. Upon careful review of the data from these searches, CPSC staff from the Directorates for Epidemiology, Health Sciences, Economic Analysis, Engineering Sciences, and Laboratory Sciences selected the final in-scope set of data. An event was considered to be in-scope if the product involved was identified as a nursing or feeding pillow and determined to have played a contributing role in the incident. An event was also included as in-scope only if the infant was up to 12 months of age, or age was unknown. With the exception of incidents occurring at U.S. military bases in foreign countries, all incidents occurring outside of the U.S. were also excluded. To prevent any double-counting, when multiple reports of the same incident were identified, staff consolidated and counted them as one incident. Examples of incidents considered out of scope included cases where it could not be determined if the incident product was a nursing pillow rather than an infant lounger pillow or other infant support cushion, and cases where it was determined the nursing pillow's presence was incidental and not involved in the incident. The final, in-scope incidents were characterized as fatal or nonfatal.

The CPSRMS data are anecdotal in nature. The data are not a census nor a statistical sample of all nursing pillow-related incidents in the U.S. during the given timeframe. Moreover, the reporting is ongoing; as new reports are received, the numbers presented in this analysis may change. However, the counts presented here are at least a minimum of what has occurred throughout the nation between 2010 and 2022.

III. Results

CPSC staff has identified 154 fatal incidents and 88 nonfatal incidents from January 1, 2010, to December 31, 2022. Of the 88 nonfatal incidents, 64 resulted in an injury and 24 reported no injury. The incidents without injury included concerns of a strong smell from the nursing pillow and other concerns with the nursing pillow such as product integrity that did not necessarily involve an actual incident.

In 92 percent (142 of 154) of the fatalities, the nursing pillow was used for sleep for the infant. In a few of the remaining 12 fatalities, the nursing pillow was most likely also used for sleep, but it was not explicitly stated in the incident source documents.

In 5 percent of the fatalities (7 of 154), the nursing pillow was specifically identified as being used for nursing or feeding at the time of the incident. In four of these seven incidents, the nursing pillow was used for both sleep and nursing/feeding, as the infant was initially nursed or fed and then fell asleep on the product. In the other three incidents, the caregiver fell asleep while nursing or feeding, and it was not specifically noted that the nursing pillow was used for sleep for the infant.

Table 1 provides the distribution of incidents by year for fatalities, injuries, and non-injuries.

[2] Code 1513 *Playpens and play yards*, code 1529 *Portable cribs*, code 1537 *Bassinets or cradles*, code 1542 *Baby mattresses or pads*, code 1543 *Cribs, nonportable*, code 1545 *Cribs, not specified*, code 1552 *Cribs, nonportable or not specified*, code 1562 *Other soft baby carriers*, code 4002 *Bedding, not specified*, code 4010 *Mattresses, not specified*, code 4082 *Toddler beds*, and code 9101 *No clerical coding - retailer report*

Table 1: Reported Incidents and Injury Severity by Year, January 1, 2010 – December 31, 2022

Year	Fatalities	Injuries	No Injury	Total
2010	7	3	2	**12**
2011	5	0	1	**6**
2012	7	1	1	**9**
2013	5	0	6	**11**
2014	4	2	3	**9**
2015	10	3	0	**13**
2016	6	3	1	**10**
2017	10	5	0	**15**
2018	16	2	0	**18**
2019	17	5	0	**22**
2020	38	14	2	**54**
2021*	21	14	1	**36**
2022*	8	12	7	**27**
Total	**154**	**64**	**24**	**242**

Source: CPSRMS and NEISS
Reporting is ongoing for these databases, especially for 2021-2022.
*Fatality counts should be considered incomplete for the years 2021-2022, due to a time lag in reporting to CPSC.

CPSC staff notes that over half of the fatalities of which CPSC staff is aware were reported to have occurred since 2019. However, because the reported data are anecdotal, fluctuations in the numbers of reported incidents could simply reflect changes in reporting rather than an actual change in incident frequency. As new reports come in, these numbers may increase. Table 2 shows breakdowns by age in months for fatalities, injuries, and non-injuries.

Table 2: Reported Incidents and Injury Severity by Age, January 1, 2010 – December 31, 2022

Age	Fatalities	Injuries	No Injury	Total
1 month	44	7	0	**51**
2 months	36	4	0	**40**
3 months	30	5	0	**35**
4 months	15	4	1	**20**
5 months	10	4	0	**14**
6 months	9	1	0	**10**
7 months	6	1	0	**7**
8 months	2	1	0	**3**
9 months	1	1	0	**2**
Unknown	1	36	23	**60**
Total	**154**	**64**	**24**	**242**

Source: CPSRMS and NEISS
Reporting is ongoing for these databases, especially for 2021-2022.

Ninety-four percent (144 of the 154) of the reported fatalities involving nursing pillows were to infants 6 months old or younger, and 71 percent (110 out of 154) were to infants 3 months old or younger. Over two-thirds of the nonfatal incidents involved a victim of unknown age. It is worth noting that when an incident reports no injury, the age of the victim is often coded as “unknown.” Almost all of the non-injury incidents had an unknown age.

Table 3 presents age and gender for fatalities and injuries. Males comprised the majority of both the fatalities and nonfatal injuries, when gender was known.

Table 3: Reported Fatalities and Injuries by Age and Gender, January 1, 2010 – December 31, 2022

Age	Fatalities		Injuries			Total
	Male	Female	Male	Female	Unknown	
1 month	25	19	5	1	1	**51**
2 months	22	14	2	2	0	**40**
3 months	18	12	1	4	0	**35**
4 months	12	3	3	1	0	**19**
5 months	5	5	2	1	1	**14**
6 months	5	4	1	0	0	**10**
7 months	5	1	1	0	0	**7**
8 months	1	1	1	0	0	**3**
9 months	1	0	0	1	0	**2**
Unknown	0	1	2	5	29	**37**
Total	**94**	**60**	**18**	**15**	**31**	**218**

Source: CPSRMS and NEISS
Reporting is ongoing for these databases, especially for 2021-2022.

IV. Hazard Patterns

A. Fatal Incidents

Generally, the medical examiner reported the cause of death in the fatal incidents as asphyxia, suffocation, overlay, sudden unexpected infant death (SUID), sudden infant death syndrome (SIDS), or unknown. In many of the deaths, the infants were sharing a sleep surface, and/or the sleep area was identified as “unsafe sleep”. CPSC staff, through group consensus consisting of team members in the Directorates for Epidemiology, Health Sciences, Economic Analysis, Engineering Sciences, and Laboratory Sciences, categorized the fatalities into hazard scenarios based on the best available account information on the position of the child when found.

Table 4 shows the distribution of the 154 reported fatalities by hazard scenario.

Table 4: Reported Fatalities by Hazard Scenario, January 1, 2010 – December 31, 2022

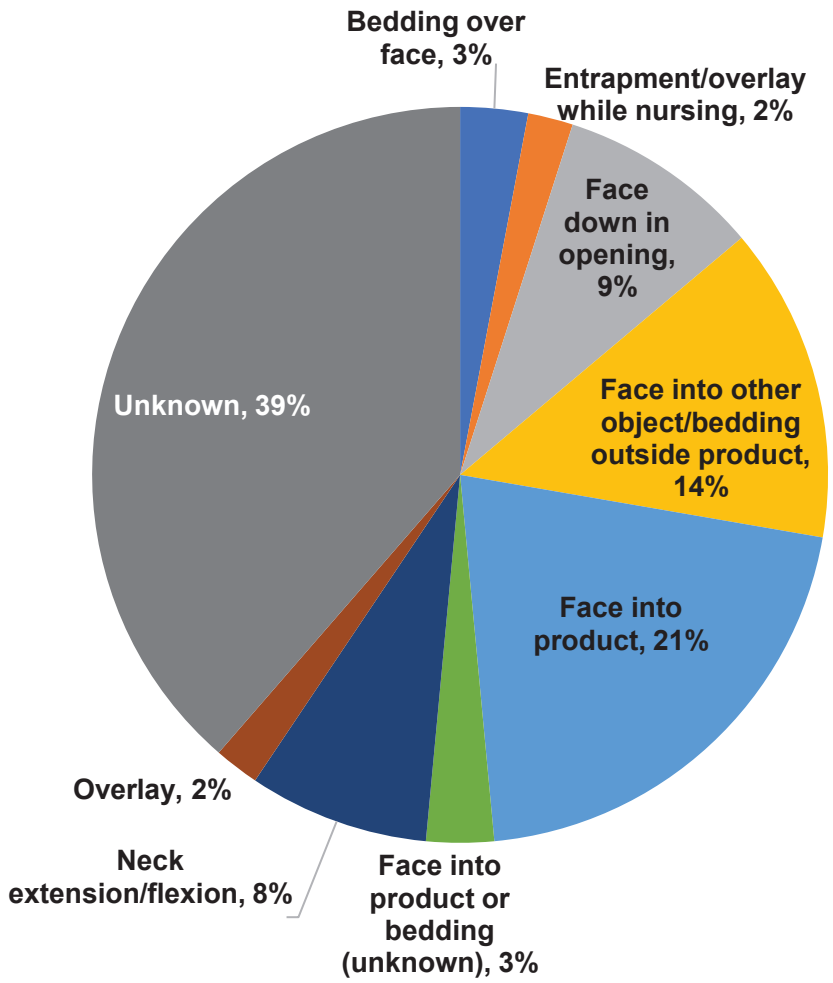
Hazard Scenario	Fatalities	Percent*
Face into product	32	21
Face into other object/bedding outside product	21	14
Face down in opening	14	9
Neck extension/flexion	13	8
Bedding over face	4	3
Face into product or bedding (unknown)	4	3
Entrapment/overlay while nursing	3	2
Overlay	3	2
Unknown	60	39
Total	**154**	**100**

Source: CPSRMS
Reporting is ongoing, especially for 2021-2022.
*Percentages may not sum to 100 due to rounding.

1. **Face into product:** In 21 percent (32 of 154) of the reported fatalities, the infant was found with their face into the nursing pillow product, typically after turning or rolling over.
2. **Face into other object/bedding outside of nursing pillow:** In 14 percent (21 of 154) of the reported fatalities, the infant was found with their face against another object or bedding outside of the nursing pillow product, typically as a result of rolling off or out of the product.
3. **Face down in opening:** In 9 percent (14 of 154) of the reported fatalities, the child was found face down in the opening of the nursing pillow, with the pillow surrounding the head, and the face into the mattress or other surface beneath the product.
4. **Neck hyperextension/hyperflexion:** In 8 percent (13 of 154) of the reported fatalities, the infant was found in contact with the nursing pillow, with their neck hyperflexed and the head pressed against their chest, or their neck hyperextended and the head tilted backward over the top of the product.
5. **Bedding over face:** In 3 percent (4 of 154) of the reported fatalities, the infant was found with bedding over or covering their head/face.
6. **Face into product or bedding (unknown):** In 3 percent (4 of 154) of the reported fatalities, it was indeterminate if the infant was found with their face into the nursing pillow product or other bedding.
7. **Entrapment/overlay while nursing:** In 2 percent (3 of 154) of the reported fatalities, the infant was entrapped or overlaid by the caregiver when the caregiver fell asleep while breastfeeding.
8. **Overlay:** In 2 percent (3 of 154) of the reported fatalities, the infant was found with a caregiver, with whom they were co-sleeping, overlaying the infant.
9. **Unknown:** In 39 percent (60 of 154) of the reported fatalities, the hazard scenario was unknown or could not be determined.

Figure 1 shows the percentage breakdown of the reported fatalities by hazard scenario.

Figure 1: Reported Fatalities by Hazard Scenario, January 1, 2010 – December 31, 2022



Source: CPSRMS
Reporting is ongoing, especially for 2021-2022.
Percentages may not sum to 100 due to rounding.

Table 5 displays fatal incidents by the location in which the nursing pillow and infant were placed. Forty percent (62 of 154) of the fatalities involved the infant being placed in an infant sleep product such as a bassinet, crib, or portable playpen/crib, while another forty percent (61 of 154) involved the infant being placed in an adult bed or mattress.

Table 5: Reported Fatalities by Pillow/Infant Placement, January 1, 2010 – December 31, 2022

Pillow/Infant Placement	Fatalities	Percent*
Infant sleep product	**62**	**40**
Bassinet	29	19
Crib	20	13
Portable playpen/crib	13	8
Adult sleep product	**61**	**40**
Adult bed	58	38
Adult mattress	3	2
Couch	**18**	**12**
Recliner chair	**1**	**1**
Unknown size mattress	**1**	**1**
Unknown	**11**	**7**
Total	**154**	**100**

Source: CPSRMS
Reporting is ongoing, especially for 2021-2022.
*Percentages may not sum to 100 due to rounding.

B. Nonfatal Incidents

Of the 88 nonfatal incidents, 64 resulted in an injury and 24 reported no injury. Of the 64 injuries, 19 were known to have been treated and released from the emergency department. All 19 of these injuries involved the infant falling or rolling out of the nursing pillow. An additional 3 injuries, one involving a burn, one due to a fall, and one due to cardiopulmonary arrest after the infant was laying on the nursing pillow, resulted in hospital admission. The remaining 42 injuries where the level of care was not known included falls, near suffocation, near strangulation, choking, and skin irritation or allergy.

Twenty-four incident reports indicated that no injury had occurred or provided no information about any injury. However, many of the descriptions indicated the potential for a serious injury or even death. As staff noted earlier, some of these incidents without injury were consumer complaints or concerns about the product that did not involve an actual incident.

Table 6 summarizes the hazard patterns for the nursing pillow-related nonfatal incidents.

Table 6: Reported Nonfatal Incidents by Hazard Pattern, January 1, 2010 – December 31, 2022

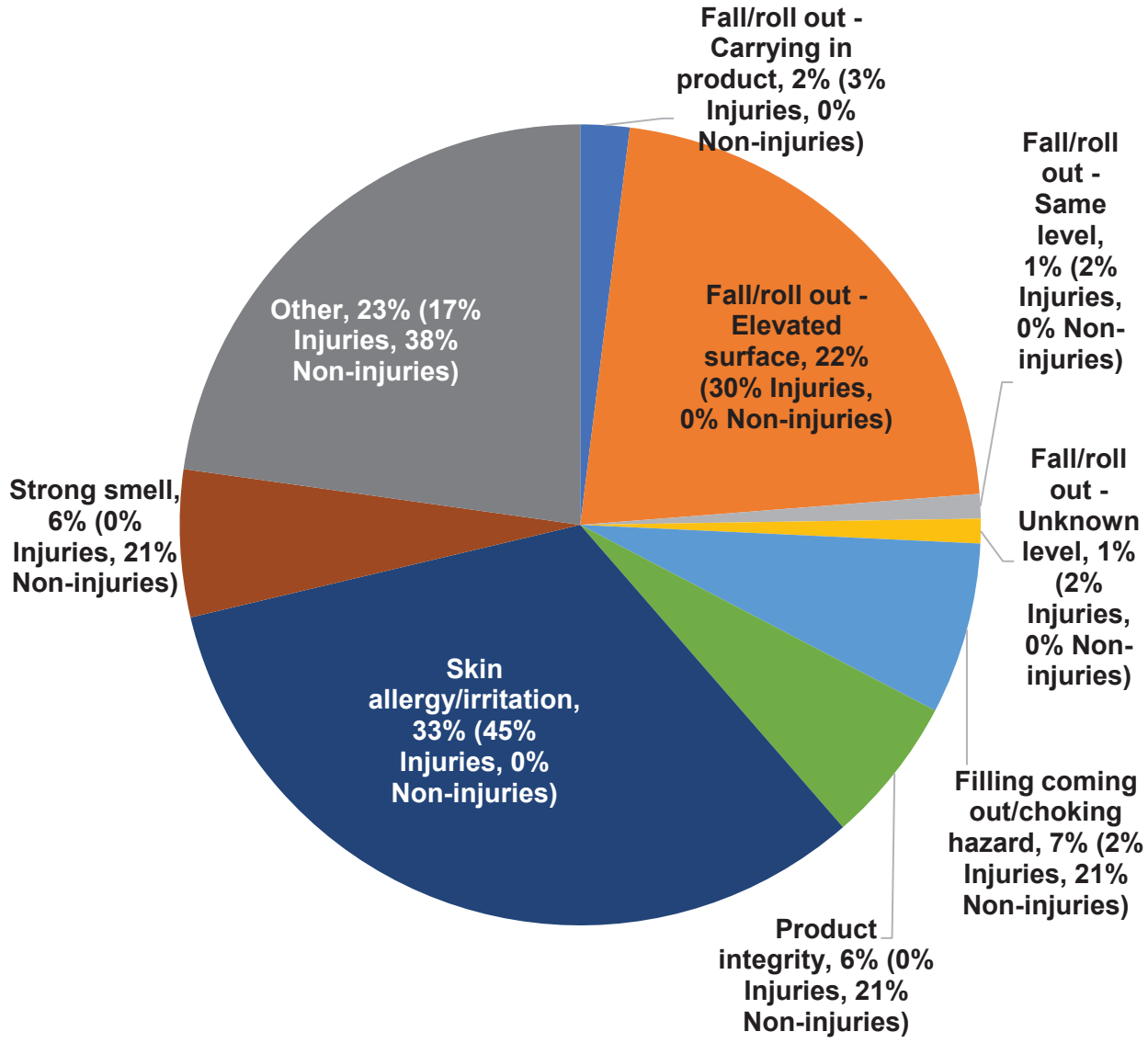
Hazard	Nonfatal Incidents	Percent*
Skin allergy/irritation	**29**	**33**
Fall/roll out	**23**	**26**
Elevated surface	19	22
Carrying in product	2	2
Same level	1	1
Unknown level	1	1
Filling coming out/choking hazard	**6**	**7**
Product integrity	**5**	**6**
Strong smell	**5**	**6**
Other	**20**	**23**
Total	**88**	**100**

Source: CPSRMS and NEISS
Reporting is ongoing for these databases, especially for 2021-2022.
*Percentages may not sum to 100 due to rounding.

1. **Skin allergy/irritation:** In 33 percent (29 of 88) of the nonfatal incidents, the infant developed a skin irritation or allergic reaction to the nursing pillow.
2. **Fall/roll out:** In 26 percent (23 of 88) of the nonfatal incidents**,** the infant either fell or rolled out of the nursing pillow. This category is further divided into levels the infant fell or rolled from.
    a. **Elevated surface:** In 22 percent (19 of 88) of the nonfatal incidents, the infant either fell or rolled out of the nursing pillow from an elevated surface, such as a couch or bed.
    b. **Carrying in product:** In 2 percent (2 of 88) of the nonfatal incidents, the infant either fell or rolled out of the nursing pillow while a caregiver was carrying the infant in the product.
    c. **Same level:** In 1 percent (1 of 88) of the nonfatal incidents, the infant either fell or rolled out of the nursing pillow onto the same level surface as the product.
    d. **Unknown level:** In 1 percent (1 of 88) of the nonfatal incidents, the infant either fell or rolled out of the nursing pillow from an unknown level.
3. **Filling coming out/choking hazard:** In 7 percent (6 of 88) of the nonfatal incidents, filling came out of the nursing pillow, causing choking or presenting a choking hazard.
4. **Product integrity:** In 6 percent (5 of 88) of the nonfatal incidents, a consumer noted issues with product integrity, posing a potential hazard. These included holes in the product, the seam of the product opening, and a crack in the product's clip.
5. **Strong smell:** In 6 percent (5 of 88) of the nonfatal incidents, the consumer was concerned with a strong smell coming from the product.
6. **Other:** The remaining 23 percent (20 of 88) of the nonfatal incidents involved other hazard patterns, such as burn, entanglement, scratch, neck sprain, near-strangulation, and near-suffocation.

Figure 2 shows the percentage breakdown of the reported nonfatal incidents by hazard pattern. Separate percentages are also shown by injuries and non-injuries.

Figure 2: Reported Nonfatal Incidents by Hazard Pattern, January 1, 2010 – December 31, 2022



Source: CPSRMS and NEISS
Reporting is ongoing for these databases, especially for 2021-2022.
Percentages may not sum to 100 due to rounding.

Table 7 displays nonfatal injuries by the location in which the nursing pillow and infant were placed. In 66 percent (42 of 64) of the nonfatal injuries, the infant placement was unknown.

Table 7: Reported Nonfatal Injuries by Pillow/Infant Placement, January 1, 2010 – December 31, 2022

Pillow/Infant Placement	Injuries	Percent*
Couch	8	13
Adult bed^	5	8
Bed, unknown type	3	5
Infant being carried in product	2	3
Table	2	3
Bathroom counter	1	2
Rocking Chair**	1	2
Unknown	42	66
Total	**64**	**100**

Source: CPSRMS and NEISS
Reporting is ongoing for these databases, especially for 2021-2022.
*Percentages may not sum to 100 due to rounding.
^In one incident, the caregiver was breastfeeding while in an adult bed.
**Infant was placed on the caregiver's lap while in the rocking chair.

TAB B: Staff Recommended Performance Requirements for the Draft Proposed Rule for Nursing Pillows (LSM Staff Memorandum)

United States
Consumer Product Safety Commission

Memorandum

TO: Timothy P. Smith, Nursing Pillows Rulemaking Project Manager, Division of Human Factors, Directorate for Engineering Sciences

DATE: June 26, 2023

THROUGH: Andrew Stadnik, Associate Executive Director
Directorate for Laboratory Sciences

Michael Nelson, Director,
Division of Mechanical Engineering

FROM: Mark Eilbert, Mechanical Engineer,
Mechanical Engineering, Directorate for Laboratory Sciences

SUBJECT: Staff Recommended Performance Requirements for the Draft Proposed Rule for Nursing Pillows

---

I. Introduction

This memorandum describes nursing pillow firmness requirements and test methods proposed by the Directorate for Laboratory Sciences, Division of Mechanical Engineering (LSM), to reduce the risk of suffocation and other hazards associated with nursing pillows.

Nursing pillows support an infant while breastfeeding or bottle feeding. Products can have C-, U-, or crescent-like shapes or recesses to fit the caregiver's body. While nursing, the infant is supported on the top surface of the product, with the caregiver providing stable support. Some products with a crescent-shaped recess can support a reclined or propped infant, although this is not the primary use of the product. The ASTM subcommittee, with input from CPSC staff, has drafted firmness requirements and test methods for the top surface and the inner wall of this recess. LSM staff proposes nursing pillow firmness requirements based partially on this task group work.

Through the voluntary standards development process, CPSC staff and the ASTM F15.16 Infant Feeding Supports Performance Requirements task group developed draft performance requirements for nursing pillows, including firmness requirements and test methods for both the top intended use surface and the interior "crescent" surface to reduce the likelihood that an infant could suffocate from the product conforming to the infant's face. This memorandum describes the process CPSC staff and contractors engaged by the Commission used in developing general and performance requirements for nursing pillows, including the use of nursing pillows in sample product testing.

U.S. Consumer Product Safety Commission
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Bethesda, MD 20814
cpsc.gov

National Product Testing & Evaluation Center
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Rockville, MD 20850

II. Background

In June 2022, Boise State University (BSU), under contract with CPSC, published a report on their development of a test method and performance requirement for the firmness of infant pillow products, including nursing pillows. According to BSU, a sufficiently firm product surface will not occlude breathing and cause suffocation of an infant due to the three-dimensional anatomy of the infant's face and the infant's arousal response, which can lead to the repositioning of the face away from restricted breathing. Less firm products can contribute to suffocation as the product surfaces conform to the infant's face and the infant lacks the necessary physical response to sufficiently turn their head. For a nursing pillow firmness test, the tasks for BSU included defining a requirement and test method that assesses the sufficient firmness to address suffocation of the infant's face.

BSU tested crib mattress products, which represent a safe level of firmness, and applied those findings to assess a new firmness test for nursing pillows. The AS/NZS 8811.1[1] safety standard applies to horizontal or nearly horizontal infant sleep surfaces such as crib mattresses. The Federal Safety Standard for Crib Mattresses[2] incorporates a test method similar to that in AS/NZS 8811.1. However, no standard test method was available to BSU to evaluate the firmness of nursing pillows, which have smaller geometries and curved surfaces, as compared to mattresses. BSU developed a firmness test method that, when applied to crib mattresses known to comply with AS/NZS 8811.1, could also be applied to nursing pillows to determine a safe firmness level. The AS/NZS 8811.1 standard requires that the probe, with a mass of 5.20 kg (11.4 lb) and diameter of 203 mm (8 in.), may not deflect more than a gauge distance of 15 mm (0.59 in.) when applied to a mattress surface. The test had been developed from a study of infant deaths in cribs. BSU confirmed through testing to the AS/NZS 8811.1 test requirements that a typical selection of crib mattresses complied with AS/NZS 8811.1 and therefore had a safe level of firmness. To determine a safe firmness for nursing pillows, BSU developed a new test method that could apply to both mattresses and nursing pillows. BSU based the probe design on anthropometric measurements of an infant's face and based the force applied on the firmness test method in a related infant product standard.[3] BSU fabricated a 3-in. (7.6 cm) hemispheric probe (Figure 1) to represent the shape and size of an infant's face. BSU did not specify a length for the probe. The applied force was 10 N (2.2 lb), which BSU describes as approximately the weight of an infant's head. The test method included steps to zero the deflection at the start of testing, a time period to allow the force reading to stabilize, and specifications for locations and number of trials. The BSU test method recorded the force and deflection when the probe was applied vertically downward into the crib mattress:

1. Position the probe to apply a 0.1 N (0.02 lb) force and set the deflection to 0.0 in.
2. Position the probe at 1 in. (2.54 cm), wait for the force reading to stabilize,[4] and measure the deflection force.
3. Allow time between each of three trials for product to settle.

[1] AS/NZS 8811.1:2013 Methods of testing infant products Method 1: Sleep surfaces—Test for firmness
[2] Safety Standard for Crib Mattresses incorporates ASTM F2933 – 21, Standard Consumer Safety Specification for Crib Mattresses, and adds 6.3 Mattress Firmness, a test method similar to AS/NZS 8811.1:2013, effective 8/15/2022.
[3] British Standard BS 4578:1970, Test for Hardness of, and for Air Flow Through Infant Pillows (BS 4578:1970)
[4] A stabilization time is not specified in the BSU report. However, during follow-up conversations between staff and BSU, BSU stated that the time was approximately 1 minute.

4. Test at three locations: maximum thickness, minimum thickness, and a location of interest.

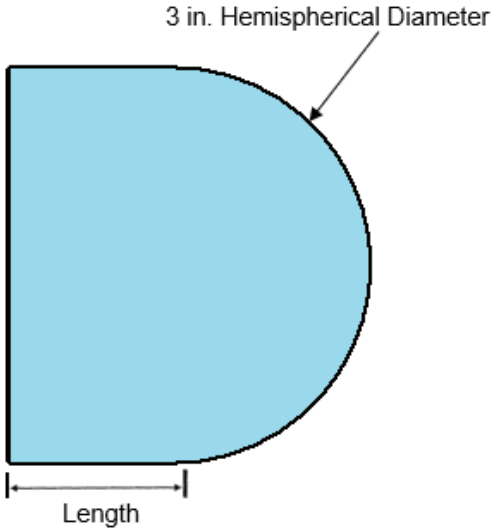

Figure 1. 3-in. Head probe

BSU reported that all test mattresses required more than a 10 N force to deflect 1.0 in. using the 3-in probe. The sufficiently safe maximum deflection into the surface by the infant probe was therefore 1.0 in. BSU tested a sampling of nursing pillows to this test method (Figure 2, samples a. through h.). Results in the report indicate that two of six nursing pillows complied with forces above 10 N at 1.0 in. deflection. The resulting recommendation was that for infant feeding supports, including nursing pillows, "the force required for this 1-in. displacement should be >10 N to pass the firmness test." The BSU testing was conducted with a vertical test fixture applied to generally horizontal product surfaces. Nevertheless, the test method can be adapted to other test orientations.

Figure 2. Nursing Pillow Samples

III. Discussion

CPSC staff adopted, with modifications, the BSU firmness requirement and test method, and incorporated draft language from the Performance Requirements task group of the ASTM F15.16 Infant Feeding Supports subcommittee to develop firmness requirements and test methods for the draft proposed rule for nursing pillows. CPSC staff discussed two nursing pillow firmness requirements with the ASTM F15.16 Infant Feeding Support Performance Requirements task

group in meetings from November 2022 to March 2023. One firmness requirement applied to the top, intended use surface of the nursing pillow, a generally horizontal surface. The other firmness requirement applied to the inner surface of the nursing pillow opening, a generally vertical surface. Additionally, the ASTM draft standard has performance requirements for infant restraint, fabric/mesh integrity, and occupancy containment. In a letter to the ASTM subcommittee,[5] staff made suggestions for improvement to the draft voluntary standard for infant feeding supports, which was included in ASTM Ballot F15.16 (23-01).

A. Discussions of Staff Proposals for Requirements and Test Methods

i. Firmness

CPSC staff fabricated test fixtures and conducted testing on a sampling of nursing pillows (Figure 2) to evaluate the BSU test method. Staff made the fixtures adjustable such that the probe can be oriented perpendicular to either the intended use surface or the inner side of the opening of a nursing pillow. Staff evaluated the BSU test method (Figure 3) in which a 3-in. hemispherical probe is lowered vertically down to apply a 0 to 10 N force to the intended use surface of a nursing pillow, such that the force can be measured at the point that the deflection equals 1.0 in. If the measured force is 10 N or less at the 1.0 in. deflection, then the test location fails the test. If a 1.0 in. deflection is not reached due to the firmness of the product, the probe can be advanced further in a similar manner until the force exceeds 10 N and the deflection is less than or equal to 1.0 in., in which case the test location passes the test.

[5] https://www.cpsc.gov/s3fs-public/CPSC-Staff-Letter-in-Response-to-Ballot-F15-16-23-01-Item-1.pdf

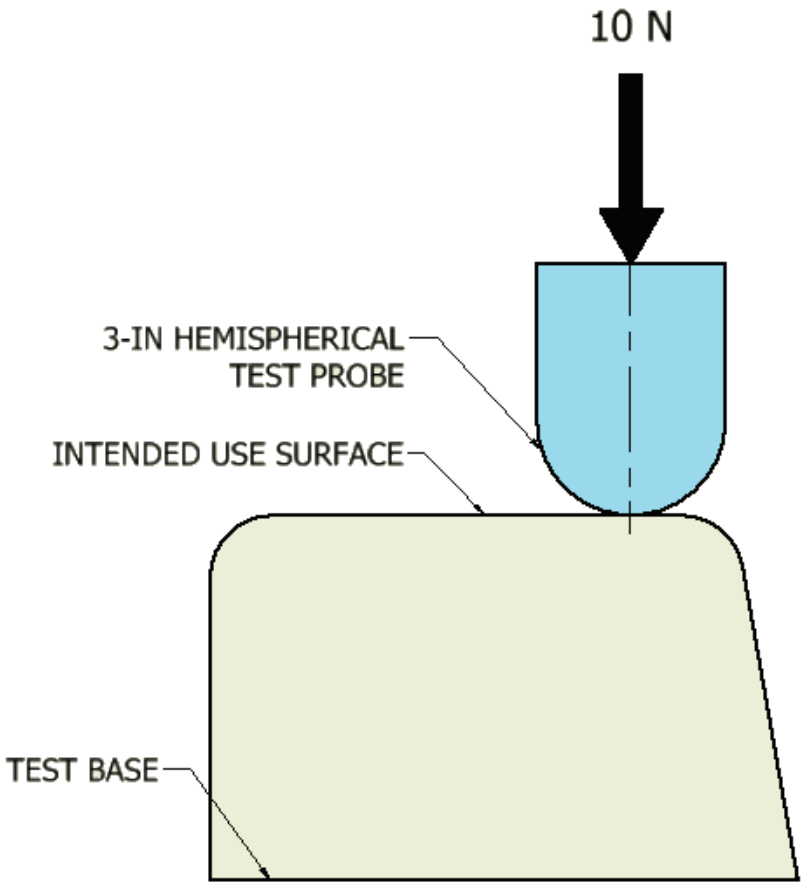

Figure 3. Test Fixture Configuration for Intended Use Side Firmness

Figure 4 depicts the results of two exemplary tests that show passing and failing the recommended firmness test. Testing begins at a nominally zero deflection and force. Testing continues until either the 1.0 in. deflection is reached before the force exceeds 10 N (red failure), or the 10 N force is exceeded before the 1.0 in. deflection is reached (bright green pass).

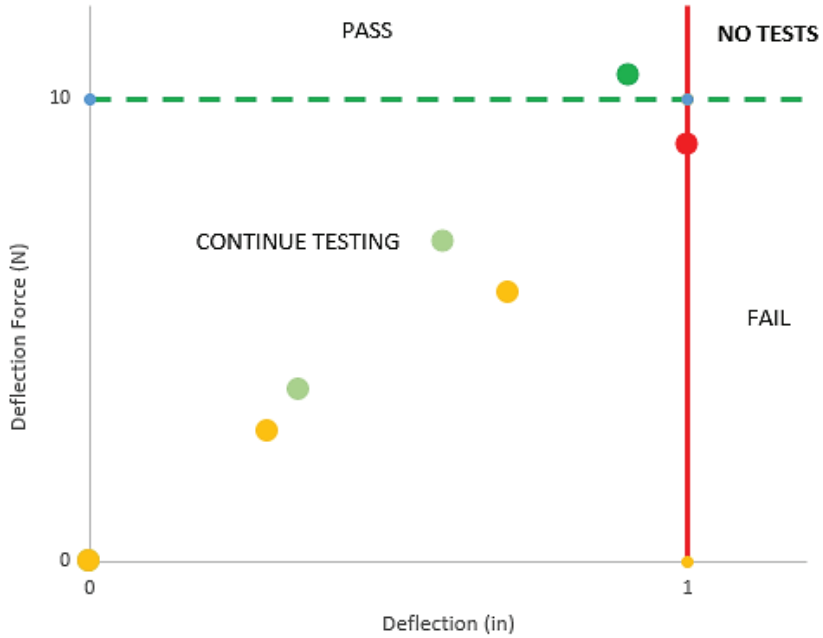

Figure 4. General Firmness Test, Force versus Deflection

As previously discussed, the BSU firmness requirement and test method are based on anthropometric dimensions of an infant's head and comparative testing with crib mattresses, which are considered products with safe firmness. Staff recommends the BSU firmness test, with modifications that add certain procedural steps to improve the nursing pillow firmness test method. In the BSU test method, the force is allowed to stabilize for approximately 1 minute prior to measuring the final force at the 1.0 in. deflection. Through nursing pillow testing, staff determined that a 30-s. stabilization period is sufficient to bring changes in the force measurement, which is still slightly decreasing after 30 s., to within a target resolution of 0.05 N (0.01 lb) at the deflection of 1.00 in. (2.54 cm), measured to a resolution of 0.03 in. (0.08 cm). Staff assesses these force and deflection resolutions are reasonable given the nature of measuring force and distance with a soft product such as the nursing pillow. In other procedural steps, staff recommends that the firmness test method include a rate of approach for the probe of 1 in. per 10 s. and a waiting period between successive tests of 5 minutes at the same location or if adjacent locations are within 3 in. The total duration of a test would combine the total time of the rate of approach (10 s.) and the stability period (30 s.), resulting in 40 s. The purpose for the approach rate and stabilization and waiting periods is to improve repeatability and reproducibility.

The ASTM draft performance requirement for nursing pillow firmness requires that the deflection of the intended use surface be less than 1.0 in. (2.54 cm) when a 3-in. diameter hemispherical probe is applied in increments of deflection until a force of 10 N (2.24 lb) has been reached. The size of the increments is selected by the test laboratory. Each increment of deflection is followed by a total 15-s. period to allow the force to stabilize. The basic test setup is similar to BSU (Figure 3), but the adjusted variable in the ASTM test method (deflection) is the same variable (deflection) that determines compliance, in contrast to having an independent variable (deflection) that determines the dependent variable (force), as in the BSU test. In the ASTM method, the size of the increments determines the final resolution of the deflection at 1.0 in. Staff assesses that allowing a choice for the increment of deflection, as opposed to a continuous

deflection, will vary the resolution of the deflection measurement, and may result in inconsistent laboratory test results. In the CPSC staff letter to the subcommittee, staff suggested that the test method could be improved by requiring a force of greater than 10 N when the deflection has reached 1.0 in., which is the basic BSU test method.

The ASTM draft firmness test method specifies locations on the “intended use side” and on the inner wall of the nursing pillow. However, the orientation for the firmness test is not specified for the inner wall. The inner wall is inside the opening to the nursing pillow that fits against the caregiver during use, but also could be used by the caregiver as a support for the infant. The inner wall firmness test is intended to address a suffocation hazard in which an infant’s face contacts the inner wall after sliding down into the opening or after being propped up in the inner opening by a caregiver. In several incidents, an infant has suffocated within the nursing pillow. Staff recommends this inner wall test, with modifications. Staff recommends that the inner wall firmness be tested with the product on a horizontal test surface and with the test fixture oriented to apply a horizontal deflection to the inner wall and measure a horizontal force (Figure 5).

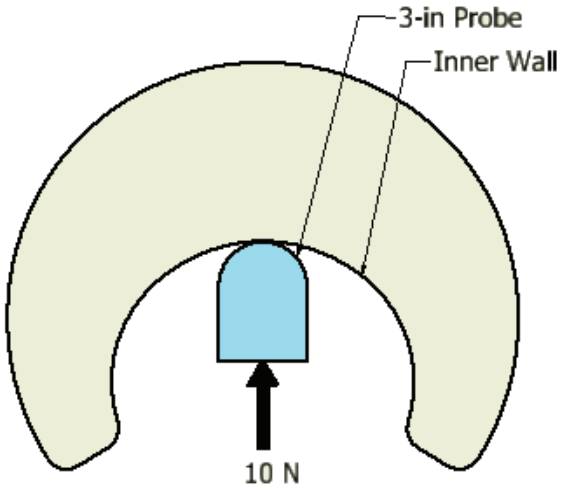

Figure 5. Test Fixture Configuration for Inner Wall Firmness Test, Top View

The test locations that the ASTM subcommittee specified are “maximum thickness, minimum thickness, and other most onerous location”. Staff assesses that a “most onerous” location allows some latitude in selecting test locations to test potentially hazardous locations, which is especially important with products as varied as nursing pillows. Staff proposes to replace the “minimum thickness” test location with an additional “onerous” location, because areas with minimal thickness are generally less likely to conform than thicker areas to the infant’s face, and therefore, less likely to pose the same suffocation hazard. If the location of minimum thickness is judged to be an onerous location, that location can be selected as one of the three test locations. Some products are reversible and can be used as intended on either side. Staff recommends the test method specify testing at three locations (maximum thickness and two most onerous locations) on each intended use side of the product.

The start of the deflection test is described as the point where “the probe first touches the surface” of the product. A subjective visual determination for contact is likely to lead to

inconsistencies in measurements. Staff recommends that the requirement should instead use an objective measurement by setting the zero point for displacement when the probe achieves a force measurement of 0.1 N (0.022 lb). This is consistent with the approach taken by Boise State University.

The ASTM F15.16 Infant Feeding Supports Performance subcommittee uses the term “intended use surface” to indicate the manufacturer’s recommended surface to support the infant for the intended use of the product. Staff recommends the term “infant support surface” to indicate any surface intended by the manufacturer to be used for infant support during nursing or feeding. An example is a symmetrical product with similar surfaces on the top and bottom of the nursing pillow.

ii. Infant Containment

The infant entrapment hazard pertains to the infant’s head becoming entrapped within the crescent-shaped opening of a nursing pillow. Entrapment scenarios include an infant that slides into this opening from an infant support position and a caregiver that props an infant in the opening of a nursing pillow product. Both scenarios can result in the infant being unable to free themselves from a position that can cause suffocation.

As discussed in the Directorate for Engineering Sciences, Division of Human Factors memorandum, staff also recommends reducing the amount of support available for infant propping or lounging when not nursing, and reducing the extent to which nursing pillows would be perceived by caregivers as being intended for such propping or lounging, by controlling opening width and depth into the product. Infants that are placed to lounge in a nursing pillow before the age they can sit up by themselves are at risk for head entrapment or for rolling out of position within or out of the product. Staff assesses that nursing pillows with openings less than approximately 9 in. are smaller than most caregivers’ waist sizes and could be used for propping an infant. In addition, openings smaller than about 9 in. could entrap or limit the movement of an infant’s head. Staff recommended that the ASTM Infant Feeding Supports Performance Requirements task group consider using a large head probe to assess the entrapment potential of nursing pillow openings, and members of the task group proposed using the 9-in. diameter head probe that is used for testing completely bounded openings in ASTM F2388 – 21, Standard Consumer Safety Specification for Baby Changing Products for Domestic Use. Staff assesses that the 9-in. head probe (Figure 6) is a suitable size and shape to gauge a safe opening in a nursing pillow. To inhibit the perception that the nursing pillow opening could be used for lounging, staff assessed from their own sample study (nursing pillows shown in Figure 2) that “nursing-lounger” pillows were much more likely to be involved in incidents than “nursing-only” pillows. The nursing-only pillows all had opening depths less than 9 in. and therefore staff associates a 9-in. depth with a safer opening than the nursing-lounger pillows, which all had depths greater than 9 in. Human Factors staff recommends a maximum opening depth in nursing pillows of 9 in. and an opening size (e.g., width) that the 9-in. head probe can pass through without contact.

The ASTM performance requirement for occupant containment uses the 9-in. head probe (Figure 6) to indicate whether an opening in the product can surround and restrict the movement of an infant’s head. The opening must be wide enough to allow complete passage of the probe without touching the side walls. The test method has two parts:

(1) The probe is placed adjacent to the opening and moved forward until it contacts the inner wall at the deepest point. The probe may make no other contact with the sidewalls, and

(2) The probe is passed through the opening with a 25 lb (111 N) force applied parallel to the base of the probe. The product meets the requirement if there is no further contact with the side walls of the product.

The ASTM draft language is ambiguous as to whether these two parts are intended to be conducted as one test or whether these are two tests. Since this test method determines compliance to the requirement, staff recommends a test based on the simplest interpretation: the probe, whose shape represents the extent of infant head entrapment, must not make contact with any part of the opening, starting initially inside the opening where the infant is placed down and moving through the opening to the outside of the product. Staff does not find the 25 lb force is necessary or consistent with the requirement. Such a high force would seem to test whether the probe can be forced through the opening, which is different from the requirement that simple contact may not be made.

Illustrations in Figures 7 and 8 and images in Figures 9 and 10 show sample testing of nursing pillows passing and failing the infant containment test, consistent with staff's recommendation. Figure 8 indicates that the inner wall of the caregiver opening (dashed arc) fails the infant containment provision because it is smaller than, and therefore contacts, the 9-in. head probe. Figure 10 indicates that the caregiver opening fails the infant containment depth requirement because the opening extends out past (red dashed line) the 9-in. head probe.

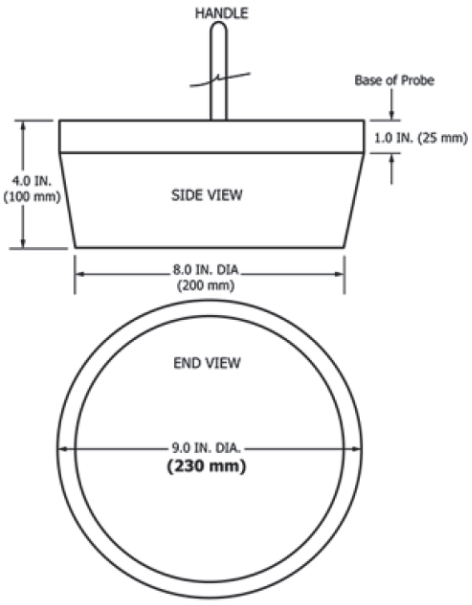

Figure 6. 9-in. Head Probe

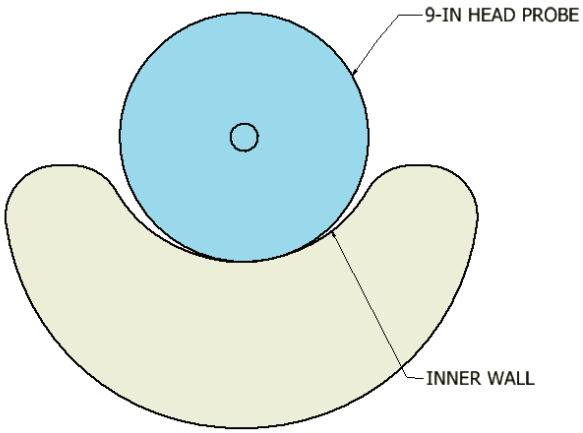

Figure 7. Infant Containment, Passing Test

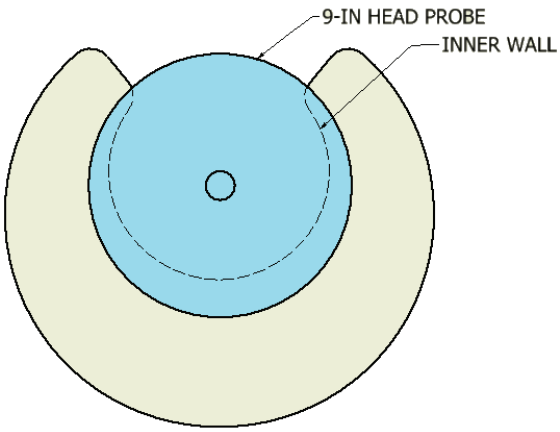

Figure 8. Infant Containment, Failing Test

Figure 9. Infant Containment, Sample 380 Passing Test

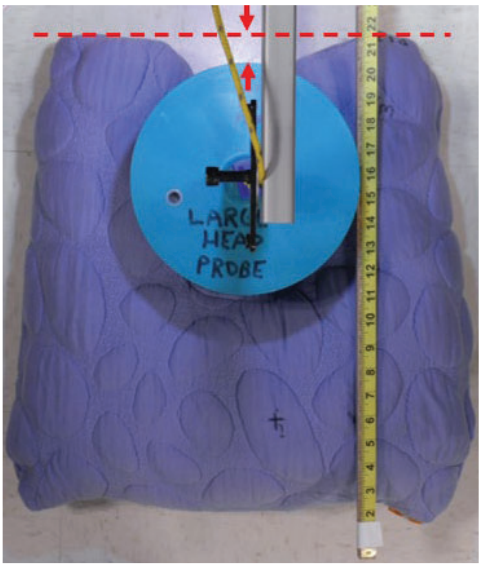

Figure 10. Infant Containment, Sample 330 Failing Test

Some nursing-only pillows include caregiver attachments (*e.g.*, a belt or strap intended to secure the product to the caregiver) that span in front of the opening subject to this infant containment provision. The ASTM test does not address the presence of these attachments. Caregiver attachments can change the shape of a nursing pillow that could affect the opening dimensions that pertain to infant containment, for example they draw the nursing pillow ends inward when worn. However, caregiver attachments themselves do not typically provide infant support. Staff recommends that nursing pillows should be tested for contact with the 9-in. head probe for infant containment with and without the caregiver attachments secured, but contact of a caregiver attachment, which cannot support an infant, should be ignored. The intent is to apply the 9-in. head probe test to configurations of the product that depend on the caregiver attachment but exclude contact of the probe with the caregiver attachment itself. Examples of infant containment tests with a caregiver attachment secured are shown in Figure 11. Contact with the 9-in. head probe on the side that constrains the probe within the opening is not allowed, indicated with the dashed red arcs in the figures. Both Products A and B are required to have

the caregiver attachment straps adjusted to their minimum adjustable lengths. Contact with the straps is not considered in the containment assessment. Product A passes the infant containment test with the caregiver attachment secured because the inside surfaces of the nursing pillow do not contact the side of the probe that faces to the outside of the opening (dashed red arc). Product B fails the test because the strap has pulled the sides inward which contact the side of the probe, thus constraining the probe within the opening. As illustrated in Figure 11, the use of a caregiver attachment strap can reduce the inside opening of the nursing pillow and represents a worst-case condition for entrapment of the infant's head, which the 9-in. head probe diameter represents.

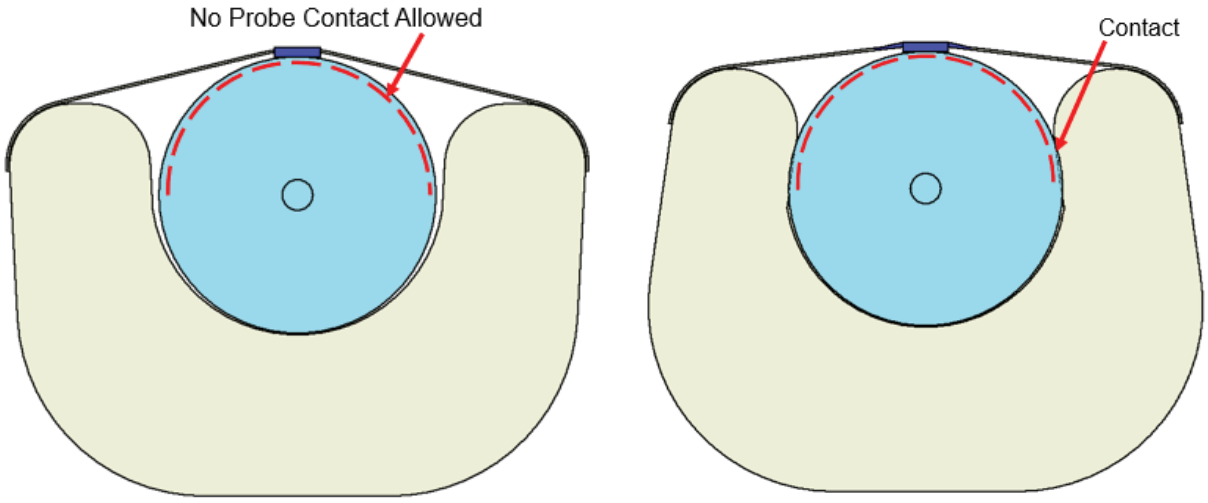

Figure 11. Example Infant Containment Tests with Caregiver Attachments

iii. Infant Restraints

The ASTM performance requirements include a section entitled "Infant Restraint" that prohibits "any restraint system." CPSC staff assesses that infant restraints are unnecessary because caregivers are supposed to be actively attending to the infant during use, and the presence of restraints could suggest to consumers that infants could be left unattended in the product. Staff agrees that nursing pillows should not include infant restraint systems.

iv. Seam Strength

Nursing pillows provide feeding support for an infant with some products marketed for ages up to 18 months. Support for the product is intended to be on the caregiver's lap. The seams of the nursing pillows secure the filling material that, if released, can be swallowed by the infant. Staff is aware of incidents involving seams opening and incidents in which infants accessed, and in some cases choked on, filling materials. ASTM F963 − 17 *Standard Consumer Safety Specification for Toy Safety*,[6] has requirements that seams withstand a tension force of 10 lb (45 N) for an age category for intended infants of 0-18 months old and 15 lb (67 N) for 18–36-month-

[6] Incorporated by reference in 16 C.F.R. part 1250—*Safety Standard Mandating ASTM F963 For Toys*

old infants. As discussed in the Directorate for Economic Analysis memorandum, nursing pillows are considered durable infant products and are often used for siblings, or found on the resale market, indicating a particular nursing pillow may be in use for several years. Because nursing pillows are durable infant products, the required force for testing the strength of seams should be at least as great or greater than that for toy products. Staff recommends that nursing pillow seams be tested with a tension force of 15 lb applied with ¾ in. diameter clamping fixtures, based on the ASTM F963 tension test force for 18-month-old infants and using the specified clamping fixture.

v. Removal of Components

Components include elements that provide a function to the product, such as zipper pulls and buttons, or provide protection to the infant from hazards. Removal of components can expose the infant to sharp points or edges or to choking hazards, including from the component itself. The draft ASTM voluntary standard's general requirements include a section entitled "Protective Components" that requires protective components may not be removed when subject to a "Removal of Protective Components Test." Staff assesses that, in addition to protective components, components on nursing pillows can include other possibly detachable parts, such as zipper tabs and buttons. If detached these parts can expose the infant to hazards such as choking, sharp points, and sharp edges. Staff recommends that nursing pillows have requirements for removal of components that are graspable by an infant and that present hazards if removed.

vi. Caregiver Attachment Strength

Caregiver attachments, including straps, buckles or latches are common features that free the hands of the caregiver to tend to the infant on the nursing pillow. The usage that caregiver attachments experience is from a generally sedentary activity in which the caregiver provides feeding while seated. However, more of the weight of the infant may bear on the attachments depending on the particular activity of the caregiver. For example, the caregiver may briefly raise themselves to reposition their body such that the full weight of the infant bears on the attachment straps. The attachments bear this loading while the nursing pillow is in daily intermittent use over several months of feeding, potentially for multiple infants over time. Further, as discussed in the Directorate for Economic Analysis memorandum, nursing pillows are often found on the resale market and may be in use for several years. To address a fall hazard from the failure of caregiver attachments, staff recommends that attachments should have a strength requirement and a performance test. ASTM F2907-19 *Standard Consumer Safety Specification for Sling Carriers* has a requirement that the sling carrier shall not fail after a one-minute application of a static load equal to three times the manufacturer's recommended maximum weight, or 60 lb (27.2 kg), whichever is greater. Because nursing pillows caregiver attachments do not experience the continual stress inherent with sling carriers and the height of any fall hazard is generally lower, staff assesses that a reasonable test loading for nursing pillow caregiver attachments should equal the recommended weight for the product, or 20 lb, whichever is greater. Staff recommends that each strap or similar element of a nursing pillow attachment system should be subject to a static load equal to the recommended weight for the product, or 20 lb, whichever is greater, and that the secured buckle, latch, or other attachment means should be subject to the same loading.

B. Recommended Requirements and Test Methods

Staff recommends the basic firmness requirement and test method developed by BSU, as modified by staff, the ASTM firmness test methods for occupant support surfaces and inner walls, and the occupant containment requirement and test method, as modified by staff, and the ASTM requirement for infant restraint. Staff recommends staff's proposed requirements and test methods for seam strength, removal of components, and caregiver attachment strength, which are derived from existing standards. Staff's recommended general and performance requirements and test methods for nursing pillows appear in Tab F, Recommended Regulatory Text for the Draft Proposed Rule.

IV. Testing

A. Firmness Test Results, Infant Support Surface

The firmness results from staff-conducted testing of the infant support surface are shown in Table 1. Infant support surface firmness was measured as the force to deflect the surface 1.00 in. (2.54 cm) using the 3-in. head probe oriented vertically, according to the staff recommended method for the manufacturer's infant support surface, and as depicted in Figure 3. A force greater than 10.0 N (2.24 lb) complies with the firmness requirement. Results show that eight of the nine samples failed to comply with the firmness requirement. Sample 370 passed at 10.05 N (2.26 lb). Sample 380 met the force requirement, exceeding 20.9 N (4.70 lb), on the one of the two infant support surfaces that were designated by the manufacturer. For both samples 350 and 390, one of the measured forces was greater than 10.0 N.

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Table 1. Sample Firmness Results, Manufacturer's Infant Support Surface (ISS)

Sample	Maximum Force (N)	Minimum Force (N)	Deflection Set to (in.)	All Infant Support Surfaces Compliance	Comment
		10.0	1.00		Requirement: > 10.0 N at 1.00 in. deflection
210	2.35	1.80	1.00	Not Met	
330	5.27	4.10	1.00	Not Met	
340	5.68	5.18	1.00	Not Met	
350	20.80	7.84	1.00	Not Met	Center section is stiffer
360	2.64	1.38	1.00	Not Met	
370	35.58	10.05	1.00	Met	
380	9.29	7.84	1.00	Not Met	Softer side
380	27.70	20.90	1.00		Firmer side
390	11.12	6.90	1.00	Not Met	
395	4.59	2.92	1.00	Not Met	Softer side
395	7.90	2.18	1.00		Firmer side

Firmness Test Results, Inner Wall

The firmness results are shown in Table 2. Inner wall firmness was measured as the force to deflect the surface 1.00 in. using the 3-in. head probe oriented horizontally, according to the staff recommended method, and as depicted in Figure 5. A force greater than 10.0 N complies with the firmness requirement. Results show that of the samples for which the test applies, seven of the eight samples failed to comply with the firmness requirement. Sample 370 passed at 18.58 N (4.18 lb).

Table 2. Sample Firmness Results, Inner Wall

Sample	Maximum Force (N)	Minimum Force (N)	Deflection Set to (in.)	Inner Wall Compliance	Comment
		10.0	1.00		Requirement: > 10.0 N at 1.00 in. deflection
210	n/a	n/a		n/a	OSS is the only test surface
330	4.57	2.77	1.00	Not Met	
340	5.28	2.92	1.00	Not Met	
350	9.90	6.17	1.00	Not Met	

360	2.88	0.89	1.00	Not Met	
370	21.80	18.58	1.00	Met	
380	6.13	2.28	1.00	Not Met	
390	7.38	3.65	1.00	Not Met	
395	4.52	1.88	1.00	Not Met	

Infant Containment Results

The infant containment results are shown Table 3. Infant containment was determined with the 9-in. head probe, according to the staff recommended method, and as depicted in Figures 7, 8, and 11. A sample complied with the requirement if the probe could move from within the caregiver opening, which staff defines as the surface of the product that fits against the torso of the caregiver during use, to the outside without contacting the inner sides. The test is conducted with any caregiver attachments latched and then again unlatched. Results show that of the samples for which the test applies, five of the eight samples failed to comply. The infant containment test did not apply to sample 210 because it had no internal opening. Samples 360 and 395 did not comply when the caregiver attachment was latched because pulling the caregiver attachment straps reduced the size of the caregiver opening.

Table 3. Sample Infant Containment Results

With and Without Latching of Caregiver Attachment

Sample	No Contact in Opening without Latching	No Contact in Opening with Latching	Overall Compliance	Comment
210	n/a	n/a	n/a	No inside Opening
330	Not Met	n/a	Not Met	
340	Not Met	n/a	Not Met	
350	Met	n/a	Met	
360	Met	Not Met	Not Met	
370	Met	Met	Met	
380	Met	Met	Met	
390	Not Met	n/a	Not Met	
395	Met	Not Met	Not Met	

V. Conclusion

LSM proposes firmness requirements for the draft proposed rule for nursing pillows, based on the contract report from BSU, and general and performance requirements that are based on draft requirements developed by CPSC staff and the ASTM Infant Feeding Supports Performance Requirements task group. BSU developed a firmness test to reduce infant suffocation in products, including nursing pillows. Staff concludes that the recommended firmness, infant containment, seam strength, removal of components, caregiver attachments, and infant restraint requirements, and their associated test methods, reduce suffocation and other hazards associated with the use of nursing pillows.

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TAB C: Human Factors Review of Incident Data and Recommended Requirements for Nursing Pillows (ESHF Staff Memorandum)

United States
Consumer Product Safety Commission

Memorandum

TO: The Nursing Pillows Rulemaking Project File **DATE:** June 26, 2023

THROUGH: Mark E. Kumagai, Associate Executive Director,
Directorate for Engineering Sciences

Rana Balci-Sinha, Ph.D., Director,
Division of Human Factors, Directorate for Engineering Sciences

FROM: Timothy P. Smith, Senior Human Factors Engineer,
Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Human Factors Review of Incident Data and Recommended Requirements for Nursing Pillows

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I. Background

This memorandum, prepared by staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF), reviews the available incident data involving nursing pillows, discusses human factors-related issues pertaining to performance requirements considered and being recommended by CPSC staff, and recommends warning and instructional requirements that research suggests are likely to reduce the risk of injury and death associated with the use of nursing pillows.

II. Discussion

Nursing pillows are infant products intended to position and support an infant during breastfeeding or bottle feeding with a caregiver. These products generally rest upon or are "worn" by the caregiver while seated or partially reclined, and are often C-, U-, or crescent-shaped to fit closely around the caregiver's torso. Besides providing a support surface for infants, nursing pillows also provide support to the caregiver by raising the infant to the desired height for nursing, thereby reducing strain on the caregiver,[1] and by providing an intermediate surface between the infant and the caregiver to reduce physical pressures on the caregiver. This latter function is especially helpful in cases where the caregiver has abdominal stitches resulting from a caesarean section.[2] Some products include a belt or similar feature to secure the product to the caregiver's body. Used nursing pillows are available from secondary marketplaces such as eBay, and sales of used nursing pillows suggest that consumers perceive nursing pillows as

[1] For example, reducing the extent to which the caregiver must engage their stomach muscles.
[2] See, for example, https://www.askdrsears.com/topics/feeding-eating/breastfeeding/rightstart-techniques/breastfeeding-after-cesarean-section/.

having a future useful life beyond the initial infant user.[3] Moreover, sales of used nursing pillows on commercial second-hand sites likely underestimates the prevalence of consumers reusing nursing pillows, because some consumers are likely retaining and reusing nursing pillows for future children of their own rather than selling the products on secondary marketplaces.

Although some nursing pillows are intended solely as a support for nursing or feeding, many also have secondary uses, such as for propping, "tummy time," or as a sitting support. For example, some products can be used for tummy time, with the infant propped up so their chest is on the product, to assist developing infants in strengthening their neck or back muscles. Many nursing pillows also function as a sitting or lounging aid for infants who have not yet developed the core strength to maintain a sitting position on their own. In these cases, the infant generally is propped up within the crescent-shaped opening, where the caregiver's body would be located when the product is used for nursing, and the ends of the product curve around and envelop the infant to provide side, or lateral, support. To some extent, there is a distinction between the lounging and sitting aid functions; younger infants would tend to be in a more reclined, supine position on these products relative to older infants, who would be more capable of staying upright in a seated position, with some support. Some products that originally were marketed as being designed for secondary uses like propping no longer promote such use, and instead focus on the nursing or feeding function. Some products still are marketed for lounging and even sleep.

A. Review of Incident Data

i. Fatal incidents

As staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA), discusses in Tab A, staff has identified 154 fatal incidents, reported to CPSC during the 13-year period of January 1, 2010, to December 31, 2022, involving nursing pillows. All victims for which the age is known were 9 months old or younger. Almost all (94 percent) of these victims were 6 months old or younger, with nearly three-quarters (71 percent) no older than 3 months.

The incidents generally are unwitnessed by the caregiver and commonly involve the infant being found with their face, or airways, in direct contact with the nursing pillow or another item in the immediate environment. Staff found the following scenarios to be among the most common in these incidents:

- The victim was found with their face pressed into the nursing pillow (at least 32 incidents).
- The victim was found with their face pressed into another object or soft bedding outside the perimeter of the nursing pillow (at least 21 incidents).
- The victim was found face-down within the perimeter of the product but into the mattress or bedding[4] (at least 14 incidents).

These cases typically involve the infant changing position relative to the position in which they were placed on the product, suggesting that the infant turned or rolled over—in some cases rolling completely off the product—and therefore, wound up in a compromised position.

[3] For example, at 13:45 on June 13, 2023, ESHF staff performed a simple search in eBay using the phrase "nursing pillow," with the results filtered to include only items in "used" condition and to show only "sold listings." The search resulted in 145 listings—primarily nursing pillows, but also including nursing pillow covers—dated between March 15, 2023, and June 12, 2023.

[4] The nursing pillows in these incidents were C- or U-shaped, and the victim was found face-down in the C- or U-shaped opening, with the nursing pillow surrounding the head.

This finding is consistent with the developmental milestones and skills one would expect from the infant users of these products. As noted earlier, 71 percent of all reported fatalities were to infants younger than 4 months, and infants at this age are actively reaching for objects and trying to turn over. For example, Bayley (1969) reports the average ages at which infants reach for objects[5] and can turn from supine to their side while on a flat surface as 4.1 months and 4.4 months, respectively, but also reports that about 5 percent of infants could perform these actions as young as about 2 months. Because the age at which infants attain, or even attempt, these milestones is highly variable, caregivers might not expect an infant who is propped on these products to be capable of repositioning themselves in a way that puts them at risk, as reflected by the statements provided by some consumers suggesting that the infant had not previously, or had only recently, demonstrated that they could perform the types of actions that might have led to their final position.[6]

Consumers who do anticipate the possibility of their infant turning or rolling might view a product that supports or partially envelops the infant as "containing" or limiting the movement of the infant.[7] However, it is reasonable to conclude that characteristics of nursing pillows that also function as loungers might have assisted infants who otherwise had not yet fully reached the necessary developmental level in carrying out these turning or rolling actions. For example, a support surface that positions the infant at an incline could make it easier for an infant who otherwise would not be capable of rolling over to do so (see Mannen, et al., 2022), and a support surface that is soft and conforming might have sufficient "give" to allow an infant who begins to roll to continue rolling over to prone earlier than expected. Young infants have limited control over their torso muscles and generally lack the strength and motor control to reverse their actions or to get themselves out of a compromised position.

Another common infant position associated with cases of asphyxia involved the infant being found in contact with the nursing pillow, but with the neck hyperflexed (*i.e.*, head pressed down towards the chest; 12 cases) or hyperextended (head tilted backwards; 1 case), presumably causing the airways to close. Like the incident previously discussed, these incidents most likely involved the infant shifting position is some way that caused them to slide partially off the product. In the cases involving neck hyperflexion, the infant's neck typically was held in the flexed position by the nursing pillow, which was pressed against the back of the infant's head.

A common thread among asphyxia incidents was use of the nursing pillow for sleep. In nearly all fatal incidents (142 of 154 fatal incidents, or 92 percent), the incident occurred while the product was being used for sleep. Although nursing pillows generally warn against using the products for sleep, it is foreseeable that consumers will use nursing pillows with a lounging function for sleep, if only because infants who are lounging or resting on the product are likely to fall asleep. Consumers are especially likely to be motivated to use the products in this way for infants who are trying to sleep while suffering from reflux or from breathing difficulties resulting from

[5] In the specific task examined, the child was reaching for a cube.
[6] For example, in one incident (INDP 120109CAA2257), the 2-month-old infant reportedly had not been able to fully roll over prior to the incident. In another incident (INDP 131115CCC2130), the 3-month-old infant was just learning to turn their head and could roll from their side to supine, but the incident involved the infant rolling from supine to prone. In another incident (INDP 210714HCC3290), the 2-month-old infant could not yet roll over but could kick.
[7] Some reported fatalities involve similar consumer behavior. For example, INDP 220921HCC1537 reports that the consumer used the product to prevent the baby from rolling or turning. INDP 120109CAA2257 reports that the infant was positioned with their head on the product to prevent the head from moving side to side. Staff also is aware of a nonfatal fall-related incident (INDP 210225CEP9081) where the consumer placed the infant in the product to "cradle" it and stated that she thought the product would keep the infant from falling off the surface on which the product was placed.

congestion or colds. Such circumstances are likely to motivate consumers to find some way to place the infant to sleep on an incline, possibly with the encouragement of a doctor. Several incidents were consistent with this and involved consumers using these products to prop up the infant during sleep because they were congested or otherwise had breathing problems.[8]

When used for sleep, these products are likely to be placed within or atop another sleep-related product such as a bed, crib, or bassinet, and this is reflected in the incident data. Most reported fatalities for which staff could determine the placement of the product (124 of 143 reported fatalities, or 87 percent) involved the product being used in or on a sleep-related product. For example, the nursing pillow was used in an infant sleep product such as a crib, portable playpen, or bassinet in 43 percent of these cases (62 of 143), in an adult bed or on an adult mattress in another 43 percent (61 of 143) of these cases, and on an unknown-size mattress in one case.[9]

Very few incidents (7) occurred while the product was being used for feeding, and only three incidents occurred while the product was being used specifically for nursing, or breastfeeding. In these three cases, the caregiver fell asleep during or soon after nursing the infant, resulting in entrapment or overlay. The remaining four incidents involved an infant who was feeding from a bottle, unattended, while in the product.

It is notable that all reported fatalities for which the product could be identified involved a nursing pillow that appeared to have been designed with, or intended or marketed for, a secondary function of lounging or propping. None of the reported fatalities are known to have involved a nursing pillow that was designed or intended solely for nursing or feeding.

ii. Nonfatal incidents

EPHA staff also identified 88 nursing pillow-related nonfatal incidents and consumer concerns, reported to CPSC over the same 13-year period. Staff identified numerous incidents (23) involving falls, with most (19) involving the infant falling from an elevated surface on which the product was placed for lounging or propping. The most common elevated surfaces involved in these falls were couches (7) and beds (6), and these were also among the most common surfaces on which nursing pillows were used, when the surface could be identified.[10] Two fall-related incidents involved the infant being carried while in the product. In nearly all fall-related cases, the infant was left in the product unattended. In contrast to the fatal incidents, few (3) of the nonfatal incidents involved the product being used for sleep.[11]

Thus, it appears that nursing pillows rarely pose a risk to infants while being actively used for nursing or feeding, and that the primary use pattern that leads to injury or fatality is the use of these products for lounging, or more concerningly, for sleep. Nursing pillows that pose the

[8] See, for example, INDP 120913CCC1959, 211119CAA3177, 200917CCC1944, 200923CCC2895, 140421HCC3524, 130222CCC3442, 200924CAA1962, 180321CCC3602, and 210520CBB1001, all of which involved an infant who was suffering from congestion or a cold either at the time or recently. In the case of INDP 200923CCC2895, a doctor reportedly recommended propping up the infant with something to assist in breathing.
[9] Nearly all other cases for which staff could determine the placement of the product involved use of the nursing pillow on a couch, love seat, or sofa (18 of 143, or 13 percent).
[10] Among those nonfatal incidents for which the location of the nursing pillow was identified, the most common surfaces were couches (8), beds (8), and counters or tables (3 combined).
[11] Staff is uncertain why most nonfatal incidents did not involve sleep, as many of these cases had limited details. However, most nonfatal incidents and concerns were consumer complaints rather than incidents. In addition, as noted, many fall-related incidents involved unattended use on an elevated surface, and many consumers may be unlikely to place their infant to sleep on a nursing pillow on an elevated surface when they are not present.

greatest risk, therefore, are those that are intended, marketed, or designed for infant propping or lounging without the presence of the caregiver.

B. Performance Requirements

As staff noted above, all known fatalities and most injuries[12] associated with nursing pillows for which the product could be identified involved nursing pillows that have a secondary lounging function. Infant loungers, including nursing pillows that function as loungers, are included under the scope of the separate CPSC Infant Support Cushions rulemaking project, and therefore, the draft proposed rule for infant support cushions includes several performance requirements related to nursing pillows' use for lounging. The focus of the draft proposed rule for nursing pillows is on requirements related to the use of these products for nursing or feeding, and requirements intended to discourage the use of these products for propping or lounging.

Although ASTM International has not yet published a voluntary standard for nursing pillows, an ASTM Infant Feeding Supports subcommittee has been established and that subcommittee is in the process of developing a voluntary standard for "infant feeding supports," which the standard defines as including nursing pillows.[13] Like the draft proposed rule, the focus of the draft voluntary standard being developed by the subcommittee is on requirements related to the use of these products while nursing or feeding.

As part of the voluntary standards development process, CPSC staff and the ASTM subcommittee developed firmness requirements for both the intended infant support surface and the interior surface of the C- or U-shaped openings in many of these products. These firmness requirements should effectively reduce the risk of asphyxia, or suffocation, from the product conforming to an infant's face.

CPSC staff and the ASTM Infant Feeding Supports subcommittee also investigated possible performance requirements that would discourage consumers' use of nursing pillows and other infant feeding supports for lounging. The following subsections discuss two requirements considered by staff and the subcommittee.

i. Infant Containment Provision

As staff noted earlier, virtually all fatalities and injuries involving nursing pillows appear to involve products that also are, or had been, marketed for lounging. One obvious characteristic of nursing pillows that include a lounging function, when compared against nursing pillows that are intended solely for nursing, is the presence of substantially more lateral support for an infant who is placed within the crescent-like opening of these products. This is illustrated in Figure 1; for each nursing pillow example shown, the red outline and shading indicates the degree to which the product extends forward from the rearmost portion of the opening (the dashed line), not factoring in any belts or other features intended to secure the product to the caregiver (*i.e.*, caregiver

[12] Most injuries associated with nursing pillows that are intended solely for nursing were consumer complaints about skin irritation or allergic reactions to the product.
[13] On March 20, 2023, ASTM issued ballot F15.16 (23-01), which included a preliminary draft of the Infant Feeding Supports voluntary standard. The draft standard defines an infant feeding support as a "product that is intended to position and support an infant (the occupant) close to a caregiver's body, and to reduce strain and pressure on the caregiver's body, while breastfeeding or bottle feeding." Although not part of the formal definition, this term includes a discussion that states the following: "These products are commonly U-shaped in appearance, and generally rest upon, wrap around, or are worn by a caregiver in a seated or reclined position. These products are commonly known as nursing pillows."

attachments). This highlighted portion can be viewed as the amount of lateral support offered by each product for an infant placed within this space.

Nursing pillows with substantial side support, or that essentially envelop the infant, enable infants who otherwise would be unable to support themselves to be propped up and supported for lounging within or against these products, whereas nursing pillows with more limited side support are unlikely to do so. As staff noted in its review of the incidents, most reported fatalities involved infants no older than 3 months. Although the age at which infants can sit upright without support varies, infants generally do not reach this milestone until at least 4 months of age, and closer to 6 or 7 months of age, on average.[14] Thus, infants younger than this generally would be unable to support and maintain themselves in a sitting or semi-reclined position without substantial external support. For this reason, staff recommends an "infant containment" provision with the following two elements, meant to reduce the amount of support available for independent infant propping or lounging and to reduce the extent to which nursing pillows would be perceived by caregivers as being intended for these uses: opening size and opening depth.

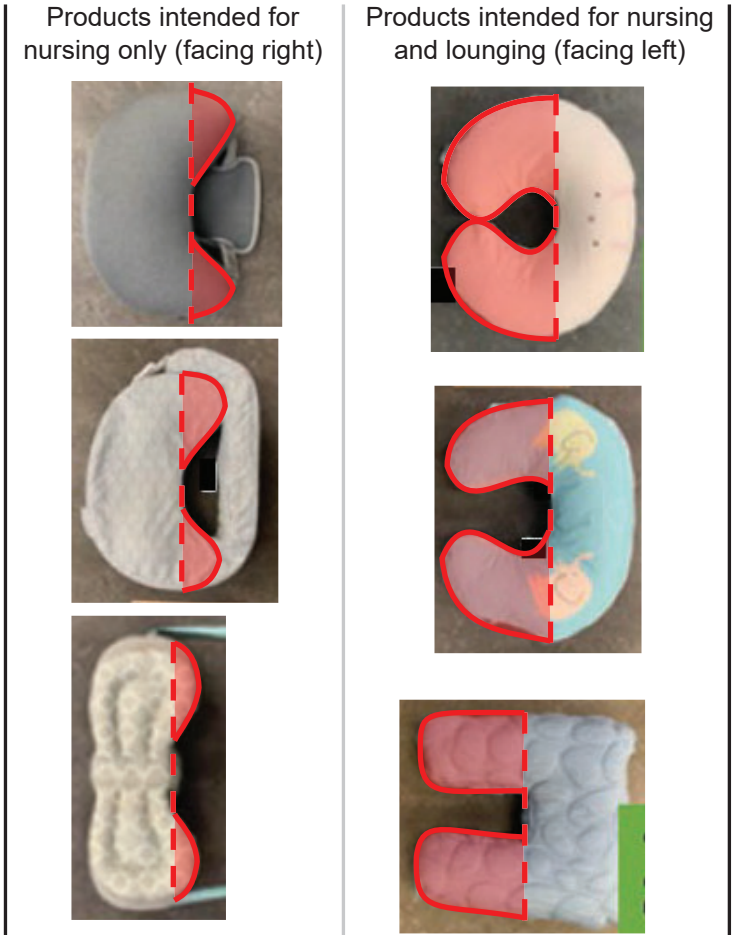


FIGURE 1. Lateral support (portion of products in red) provided by sample nursing pillows.

Opening Size

ESHF staff recognizes that many nursing pillows have a crescent-like opening for functional reasons, as these products generally are "worn" by the caregiver and are intended to fit around a caregiver's body. However, the variance in opening size among products on the market suggests that products with very small openings or especially long side "arms" that envelop or partially enclose the opening, like the products shown on the right in Figure 1, are not necessary to maintain the utility of the product. Moreover, many of these latter products include openings of a size and shape that seem designed with the specific intention of supporting a small infant, not primarily to fit a caregiver's body. For example, the lowermost product in the right column of Figure 1 is very narrow—staff estimates the width of the opening to be about 5 inches—and

[14] According to Bayley (1969), about 5 percent of infants can sit alone momentarily as young as 4 months, but cannot sit alone steadily, without support, until about age 5 months. The average age for sitting along steadily, without support, is about 6.6 months, and the average age for doing so while engaged in other actions that take the infant's attention away from the sitting process is about 6.9 months.

rectangular, and does not resemble the size or shape of a caregiver's waist. Although the openings in the other two products in the righthand column are rounded, staff estimates the opening in the top-right nursing pillow to be about 6 inches in diameter and the opening in the middle-right product to be about 7 ½ inches in diameter. These opening sizes are likely to be smaller than the waist size of even the smallest-waisted adult user of these products. Anthropometric data show that the 5th percentile waist circumference of a young adult female is about 27.5 inches, which would correspond to a diameter of about 8.8 inches.[15] Staff recognizes that a person's waist is not a perfect circle; however, this measurement roughly approximates the size and shape of an opening that would fit the smallest waists of young adult women. Given that at least 95 percent of all adult females have larger waists than this, and that many users of nursing pillows are likely to be using the product within days or months of having been pregnant, and thus would be even less likely to have waists this small,[16] staff considers a nursing pillow with a crescent-shaped opening smaller than this as being designed and intended to support an infant who is placed within the opening. In contrast, staff found that nursing pillows intended solely for nursing, examples of which appear in the lefthand column of Figure 1, tend to have crescent-like openings with a larger arc, or radius, that would more closely match the expected shape and size of a caregiver's body.

Also relevant to the issue of opening size, the available incident data also show that numerous nursing pillow-related fatalities (at least 14) involved the infant being found face-down within the opening, with the nursing pillow surrounding the infant's head. Openings that are small or narrow can restrict an infant's head movements, particularly among young infants who are involved in these incidents and have limited strength and muscular control. In fact, in one reported fatality (INDP 120109CAA2257), a consumer deliberately placed the infant's head in the opening of the nursing pillow to keep the infant from turning their head side to side. For nursing pillows with smaller openings, an infant who winds up face-down into soft bedding or the other surface below the opening may be unable to turn or free their head to expose their airways to fresh air. Thus, staff considered using a large head probe to assess the potential for head entrapment in nursing pillow openings. ASTM F833 – 21, *Standard Consumer Safety Performance Specification for Carriages and Strollers*, employs an 8-inch diameter spherical head probe to address head entrapments in certain completely bounded external openings (section 6.10). The 8-inch measurement upon which the head probe is based represents the 95th percentile tip-of-chin to back-of-head dimension of a large infant and was developed to address the fatality of a 6-month-old child (ASTM F833 – 21, sections X1.3 & X1.10).[17] These ages are consistent with the range of infants for which nursing pillows are intended, and staff preliminarily concluded that applying a similar probe to the opening of nursing pillows should identify those products whose openings are small enough to potentially restrict an infant's head movements, thereby placing them at

[15] The 5th percentile waist circumference of adult females measures about 73.3 cm, or 28.9 inches (Fryar, et al., 2021). However, that population includes older adults who are unlikely to wear one of these products for nursing. Focusing instead on young adult females—women in their 20s—the 5th percentile waist circumference measures 69.9 cm, or 27.5 inches. This dimension equates to a circle with a diameter of 8.8 inches. PeopleSize (1998 as cited in Peebles & Norris, 1998) estimates the 5th percentile underbust circumference of an adult female to be about 679.8 mm, or 26.8 inches, which equates to a circle with a diameter of 8.5 inches. Note that PeopleSize estimates are based on ratio scaling aggregated data and are not direct measurements.

[16] This also ignores male users of the product, who have larger waist sizes relative to women, on average.

[17] The Annex to the voluntary standard states that this measurement represents the 95th percentile dimension of a 13-month-old child. However, according to Schneider et al. (1986), the 95th percentile measurement for infants 10-12 months is 7.9 inches, and the next set of measurements is for infants 13-18 months (the 95th percentile value for these infants is 8.1 inches); thus, staff is unsure from where the reported 95th percentile measurement for 13-month-olds was obtained.

risk.[18] However, ASTM F2388 – 21, *Standard Consumer Safety Specification for Baby Changing Products for Domestic Use*, uses a larger, 9-inch head probe to address head entrapments (section 7.5). This head probe, shown in Figure 2, is cylindrical rather than spherical, with a 9-inch diameter base that begins to taper after 1 inch to a final diameter of 8 inches. Unlike an 8-inch spherical probe, which is only 8 inches in diameter around its center (by definition, at a height of 4 inches), the 9-inch probe's more cylindrical shape limits the opening size for nursing pillows to 8 inches or greater along its entire height, and closer to 9 inches where an infant would potentially be propped up on the product. The use of this head probe to test for entrapment potential also would bring the opening size more in line with the minimum opening size staff identified earlier, to accommodate the caregiver's body. Staff worked with the ASTM Infant Feeding Supports Performance Requirements task group on the development of such a requirement, and the Infant Feeding Supports subcommittee included an "occupant containment" performance requirement using the 9-inch probe in the draft voluntary standard that was balloted.[12]

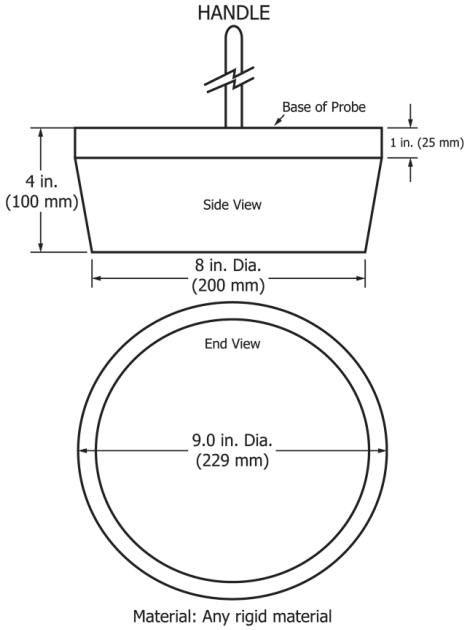


FIGURE 2. Proposed 9-inch probe for use in head entrapment testing.

Staff of CPSC's Directorate for Laboratory Sciences, Division of Mechanical Engineering (LSM) performed the occupant containment and head entrapment test under consideration, using the 9-inch head probe, on sample nursing pillows and found that this test fails products with smaller openings that are intended secondarily for lounging. This is illustrated in Figure 3, which shows how the nursing pillows that offer greater lateral support and are intended for lounging (on right) constrain the probe and result in points of contact on opposing sides of the probe. In contrast, the products marketed solely for nursing have infant support surfaces that only contact the probe on one side. Thus, this requirement and test method, using the 9-inch probe, accomplishes two tasks: it reduces the potential for infant head entrapment within the crescent-like opening of a nursing pillow, and it reduces the degree to which a nursing pillow can envelop or support a young infant for lounging by increasing the opening to a size that is more appropriate for an adult user, rather than an infant.

[18] For example, one could place the head probe into the opening of the product so it makes contact with the rearmost portion of the opening. If, when in this position, the probe can contact any two opposing portions of the product, not including portions that are intended to secure the product to the caregiver, then the product might pose a head entrapment hazard to young infants.

Opening Depth

Despite the promising findings related to opening size, ESHF staff remained concerned that increasing the size of the opening, alone, was insufficient to address the use of crescent-shaped nursing pillows for propping young infants for lounging or sleeping. This was indirectly acknowledged by the ASTM Infant Feeding Supports Performance Requirements task group, who, in response to comments on the ballot containing the draft voluntary standard, changed the name of the occupant containment provision in the draft voluntary standard to "occupant entrapment," on the basis that the requirement was intended primarily to prevent infant entrapments.[19]

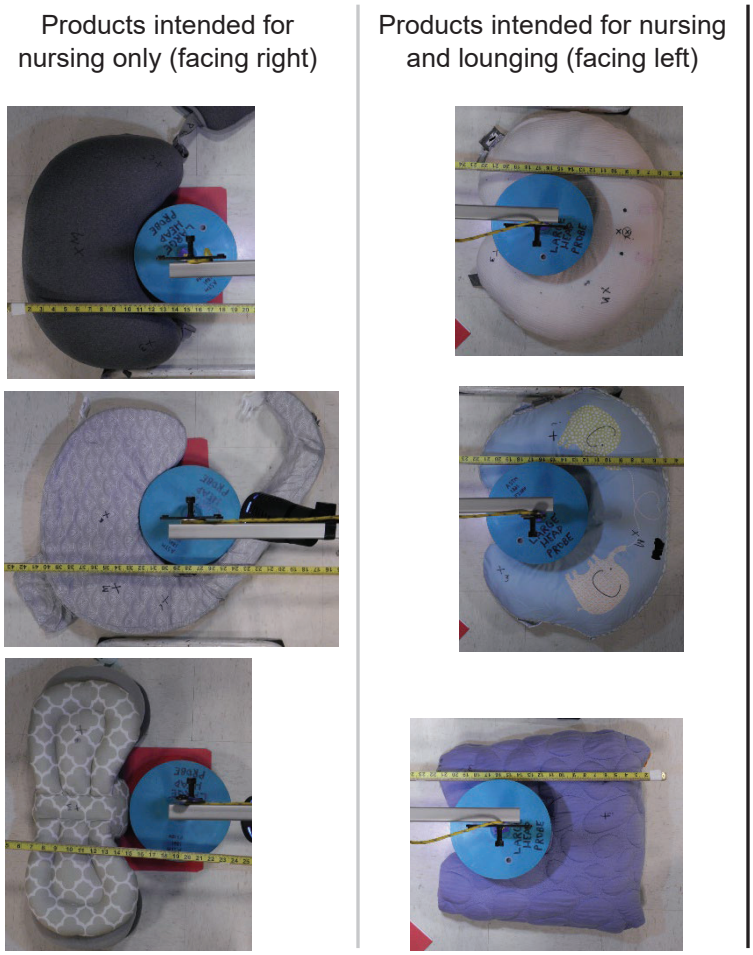


FIGURE 3. Application of 9-inch probe to sample nursing pillows.

Although assessing opening size reduces the degree to which a nursing pillow can surround an infant, this requirement alone still would permit nursing pillows with a 9-inch-wide opening to have very long side arms that could provide lateral support to young infants and be perceived by the caregiver as being intended for propping and lounging.

Staff's examination and testing of nursing pillow samples found that using the 9-inch probe as the criteria for assessing the length of the side supports, or the depth of the nursing pillow opening, also distinguished nursing pillows marketed solely for nursing from products intended for both nursing and propping or lounging. Specifically, all nursing pillows marketed solely for nursing had infant support surfaces that did not extend past the opposite end of the 9-inch probe, when the probe was positioned against the rearmost portion of the opening. In contrast, the infant support surfaces for nursing pillows that also are intended for lounging *did* extend past the opposite end of the probe. Although opening depth is related to, and could be viewed as another measure of, opening "size," staff considers opening depth to be distinct characteristic. A 9-inch opening depth requirement would complement the opening size requirement by further reducing the potential for lateral support and infant lounging, based on the dimensions of existing nursing pillows that are intended solely for nursing, for which there are no known fatalities. In addition,

[19] https://www.cpsc.gov/s3fs-public/2023-05-30-ASTM-F15-16-Infant-Feeding-Supports-Performance-Requirements-Task-Group-Meeting-Log.pdf

nursing pillows that meet such a requirement are likely to provide most caregivers with ample arm and elbow support to maintain the utility of the product.[20]

Testing With and Without Caregiver Attachment Secured

Lastly, staff recommends that products with a caregiver attachment—that is, a belt or other feature intended to secure the nursing pillow to the caregiver and not intended to support the infant—be required to pass the two elements of the infant containment provision both with and without the caregiver attachment secured. Staff concludes that such a requirement is necessary to address nursing pillows whose caregiver attachment converts the product into a more traditional dual-use nursing pillow-lounger shape. An example of such a product is shown in Figure 4.

FIGURE 4. Sample nursing pillow without (left) and with (above) caregiver attachment secured.

For the reasons described above, ESHF staff recommends that the draft proposed rule incorporate an infant containment performance requirement that assesses crescent-like openings in nursing pillows using a 9-inch probe, as described. Staff concludes that this requirement should reduce the likelihood that consumers will use these products for infant lounging and should effectively address the potential for head entrapments in nursing pillow openings.

ii. Angular Requirement

Staff considered an additional requirement to discourage use of nursing pillows for lounging, based on an observation by Boise State University (BSU) in their "Pillows Product Characterization and Testing" report to CPSC (Mannen et al., 2022). BSU's report notes that some products that are marketed solely for nursing include features like sharper corners, which do not easily facilitate lounging, and the report includes the following statement (p. 107):

> Nursing pillows which are firm and feature sharper corners rather than cylindrical sides are likely the safest option for babies, as there is no reasonable way to use this product as a lounger, limiting the dangers associated with sagittal plane positioning in nursing pillows.

[20] PeopleSize (1998 as cited in Peebles & Norris, 1998) estimates the mean lower abdominal depth of an adult female to be about 279.6 mm, or 11.0 inches, and the 95th percentile lower abdominal depth to be about 410.4 mm, or 16.2 inches. Thus, a nursing pillow meeting a 9-inch opening depth requirement could allow the sides of the product, when worn, to extend more than half of the caregiver's full abdominal depth, even among caregivers with the largest abdominal depths.

CPSC staff considered a possible "angular" requirement to address this issue and recommended that the ASTM Infant Feeding Supports Performance Requirements task group (TG) also consider such a requirement. The TG discussed a possible requirement that used a test device similar to the prototype sagittal-plane test devices developed by BSU and discussed in the BSU report. Specifically, the TG discussed a requirement whereby a sagittal-plane test device is placed on the product, with the head segment on the intended infant support surface and the body segments in the product's crescent-like opening; the requirement would establish a maximum angle between the top two segments of the device. This angle, besides measuring the angle between the two surfaces, also represents the head/neck flexion or extension angle, and this concept is illustrated in Figure 5.

The TG had multiple concerns about such a requirement and test. First, the TG was unsure how to determine the "correct" test position for the device when placed on the product, as not all products have a clear demarcation between the two surfaces, and different placements of the device on the product would likely yield different angles. Thus, the TG was unsure how to ensure the consistency of this placement during testing and among different test labs. BSU's testing of various products using the sagittal-plane test devices also found that the devices could be placed on and in the products in various ways, and BSU stated that consistent placement of the devices on the products was difficult (p. 104). BSU stated in its report that further research was needed to determine acceptable body positions as well as worst-case positions for testing (p. 105).

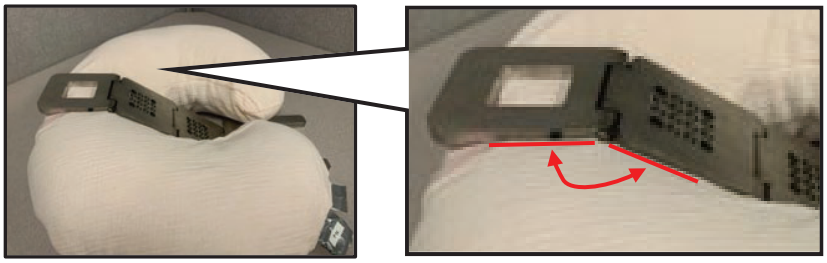


FIGURE 5. Prototype sagittal-plane test device applied to sample nursing pillow. Red indicates the angle to be measured.

The TG also was unsure what threshold angle would be appropriate as pass-fail criteria for such a requirement. CPSC staff has similar concerns, because one intent of an angular requirement would be to persuade consumers by its very appearance that the product would not be capable of being used for infant lounging, suggesting that one would have to determine the threshold angle that creates this perception to a sufficient degree. This raises doubts, or at least uncertainty, about the effectiveness of such a requirement. Moreover, even if an angular requirement were somewhat effective in discouraging lounging, staff must weigh its hypothetical effectiveness against the possible increased risk to infants whose caregivers still choose to use the product for infant lounging. The BSU report states that sagittal-plane testing of nursing pillows that also function as loungers resulted in "concerning" and "extreme" neck flexion angles when the devices were placed in a slumped position on the product (p. 102). A nursing pillow that is firm and has sharper edges to be more "angular" would likely yield similarly extreme, and possibly more extreme, neck flexion angles under the same conditions. In addition, such a product would likely result in a more acute neck extension for an infant placed in the product for lounging, with their head on the intended infant support surface, and this could pose a greater risk of suffocation by neck hyperextension relative to a product that is not designed to meet such a requirement.

Thus, although ESHF staff agrees that nursing pillows with sharper edges might, in principle, discourage some consumers from using the product for infant lounging, staff concludes that it is

premature to include an angular performance requirement in the draft proposed rule, particularly given the potential for increasing the positional asphyxia risk by neck hyperflexion or hyperextension if infants are placed in these products for lounging, contrary to the products' intended use.[21] Staff recommends seeking public comments on this issue; specifically, information on the potential effectiveness of an angular requirement, the potential risks associated with such a requirement, and whether an alternative requirement could further discourage consumers from using nursing pillows for infant lounging without concurrently increasing risks to those infants whose caregivers still choose to use the product in this way, relative to nursing pillows that do not meet the requirement.

C. Warning and Instructional Requirements

Safety and warnings literature consistently identify a classic hierarchy of approaches that should be followed to control hazards. Warning about hazards is viewed universally as less effective at eliminating or reducing exposure to hazards than either designing the hazard out of a product or guarding the consumer from the hazard; therefore, the use of warnings is lower in the hazard-control hierarchy than the other two approaches.[22] Warnings are less effective because they rely on educating consumers about the hazard, and then persuading consumers to alter their behavior in some way to avoid the hazard. To be effective, warnings also depend on consumers behaving consistently, regardless of situational or contextual factors that influence precautionary behavior, such as fatigue, stress, or social influences. Thus, one should view warnings as a measure that supplements, rather than replaces, redesign or guarding efforts, unless these higher-level, hazard-control efforts are not feasible. As a supplementary safety measure, in concert with staff's proposed performance requirements, warnings can be useful to inform consumers about residual nursing pillow hazards and steps consumers can take to avoid these hazards.

The draft ASTM voluntary standard for Infant Feeding Supports includes marking and labeling requirements, which include requirements for warnings that must appear on nursing pillows and other infant feeding supports covered by the standard. The following shows the draft standard's required warning statements that must appear on all infant feeding supports—and therefore, nursing pillows—formatted to be consistent with the warning design requirements that also are specified in the draft standard:

[21] Staff also reminds the reader that nursing pillows intended, marketed, or designed to support an infant or any portion of an infant up to 12 months old for lounging, rest, or sleep would be subject to the additional requirements of the Infant Support Cushions rule.
[22] See Laughery and Wogalter (2011), Vredenburgh and Zackowitz (2005), Wogalter (2006), and Wogalter and Laughery (2005).

⚠WARNING

USING THIS PRODUCT FOR INFANT SLEEP OR NAPS CAN KILL.

Babies can turn, scoot, or roll over without warning and CAN SUFFOCATE in only a few minutes when airway is blocked.

- **Use only with an awake baby.** If baby falls asleep after feeding, move baby to a firm, flat sleep surface such as a bare crib or bassinet.
- **NEVER leave or prop baby alone in this product.** Do not use in sleep products like cribs, bassinets, or play yards.
- **KEEP baby in arms reach during use.** Stop using if you feel yourself falling asleep.
- **KEEP baby's face visible and airway clear.**

Babies have been injured from FALLS.

- Do not use to prop up baby on beds, sofas, or other raised surfaces.
- Never carry or move product with baby in it.

The draft standard requires the warnings to be "permanent" and "conspicuous," which the draft standard defines as, "label that is visible, when the infant feeding support is in a manufacturer's recommended use position, to a person sitting near the infant feeding support at any position around the infant feeding support."

The draft voluntary standard also includes requirements for package warnings that warn against sleep and using the nursing pillow in sleep products, and must address the manufacturer's recommended weight, height, age, developmental level, or combination thereof, of the infant. In addition, the package cannot include warnings, statements, or graphics that indicate or imply that the infant may be left in the product without an adult caregiver in attendance.

Lastly, the draft voluntary standard includes requirements for instructional literature to accompany products covered by the standard. These requirements state that the instructional literature that accompanies infant feeding supports must include the warnings on the product, as well as the following additional warnings:

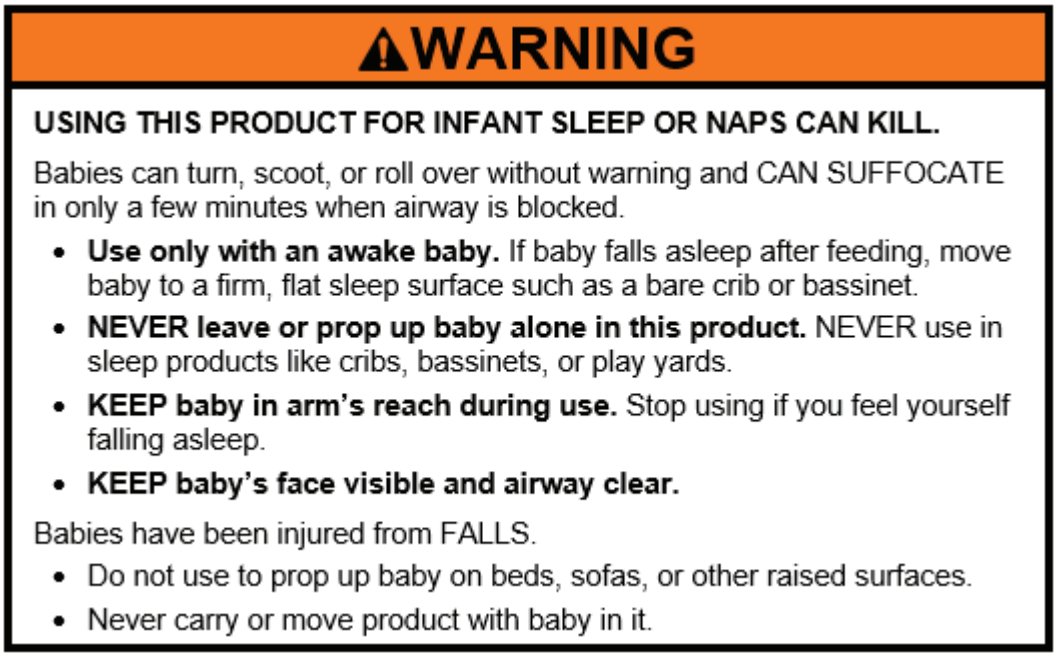
- Read all instructions before using this product.
- Keep instructions for future use.
- Do not use this product if it is damaged or broken.

The instructions also must indicate the manufacturer's recommended maximum weight, height, age, developmental level, or combination thereof, of the infant. If the product is not intended for use by a child for a specific reason (*e.g.*, a disability that would prevent safe use of the product), the instructions must state this limitation.

i. On-Product Warning Requirements

ESHF staff, and other CPSC staff, worked with the ASTM Infant Feeding Supports subcommittee to develop the on-product marking requirements in the draft standard, and supports the use of these warning content and format requirements in the draft proposed rule, with minor changes to

the content, as discussed in the subsection that follows. Staff's recommended warning for the draft proposed rule is as follows:



ESHF staff also recommends that the proposed rule include:

- a requirement for the warning to be conspicuous, and a definition of "conspicuous" that clarifies the required placement of the warning on the product, in terms of when the warning must be visible to the consumer; and

- warning permanence requirements and test methods that are consistent with other ASTM juvenile products standards.

The following subsections describe staff's rationale for the proposed warning requirements.

Warning Content

The primary U.S. voluntary consensus standard for product safety signs and labels, ANSI Z535.4, *Product Safety Signs and Labels*, and other literature and guidelines on warnings (*e.g.*, Robinson, 2009; Wogalter, 2006; Wogalter, Laughery, & Mayhorn, 2012), consistently recommend that on-product warnings include content that addresses the following three elements:[23]

- a description of the hazard
- information about the consequences of exposure to the hazard
- instructions regarding appropriate hazard-avoidance behaviors

As mentioned in staff's review of the incident data, the primary hazards associated with the use of nursing pillows are asphyxia, or suffocation, and to a lesser extent, falls. Nearly all fatal

[23] All three elements may not be necessary in some cases, such as if certain information is open and obvious or can be readily inferred by consumers; however, people often overestimate the obviousness of such information to consumers.

incidents involved infants sleeping in or on the product. These incidents generally resulted in the infant's airways being covered or blocked, whether by the nursing pillow itself or by other products or bedding in the immediate environment. Common scenarios leading to suffocation involve the infant turning, shifting position, or rolling over, in some cases rolling off or out of the product. Staff's proposed warning content pertaining to the hazard and its consequences directly address these issues. Specifically:

- The warning begins with the statement, "USING THIS PRODUCT FOR INFANT SLEEP OR NAPS CAN KILL." This statement immediately communicates to consumers the potential deadly consequences of using nursing pillows for sleep, which is the primary use pattern that has resulted in fatalities with these products. Many nursing pillows, including products that have been involved in fatal incidents, already include warning statements that identify the potential for suffocation and that using the products for sleep have resulted in death. However, the continued use of nursing pillows for sleep suggests that existing messaging is not sufficient and that beginning the warning with an explicit, succinct, and strongly worded description of the usage pattern that often leads to death, printed in all-uppercase lettering, is necessary. The reference not only to "sleep" but to "naps" prevents consumers from concluding that the hazard only applies to cases where the product is used for overnight sleep.
- The warning further explains the hazard and potential consequences with the statement, "Babies can turn, scoot, or roll over without warning and CAN SUFFOCATE in only a few minutes when airway is blocked." Staff concludes this statement is needed to clarify how infants are dying ("CAN SUFFOCATE") and to communicate not only the mechanism by which infants are suffocating, but the unpredictability and speed with which such incidents can occur. Information about the imminence of the suffocation hazard is often lacking in the warnings on existing products and may not be obvious to consumers. The features of staff's proposed warning should provide consumers with a better understanding of the speed with which suffocation can occur when infants are left unattended in these products and may increase consumers' motivation to comply with the warning message.[24]
- The warning includes a statement that alerts consumers that "Babies have been injured from FALLS." Falls are among the most common incidents resulting in injury, and staff concludes that warning statements pertaining to this hazard are necessary. Nevertheless, this hazard generally is less severe and less common than the suffocation hazard; thus, staff has positioned the associated warning messages below the suffocation-related information. A description of the additional fall-related warning content appears below.

CPSC staff and members of the ASTM Infant Feeding Supports subcommittee discussed the key actions that consumers should take, or avoid, to prevent suffocation when using a nursing pillow. Based on the available incident data, key actions include not using the product for sleep, not leaving the infant unattended in the product, and keeping the infant's face unobstructed. Staff's proposed warning content addresses these and other issues:

- The warning emphasizes the importance of using nursing pillows only with infants who are awake. Warnings that accompany products that are not intended for sleep, including nursing pillows, often tell consumers not to use the product for sleep, and the initial statement of staff's proposed warning ("USING THIS PRODUCT FOR INFANT SLEEP OR NAPS CAN KILL") already strongly indicates that consumers should not use the product this way. However, given that this is the primary suffocation avoidance behavior

[24] For example, the imminence of a hazard tends to increase the perceived threat associated with that hazard (Gass & Seiter, 1999), which is more likely to lead to compliance with the warning.

that consumers can take, explicitly addressing this behavior after the hazard description is important. Staff has written this statement in a more positive, or affirmative, form—that is, "Use only with an awake baby"—to further reinforce the message that the infant should be *awake* during use and to remove all doubt about whether consumers could make exceptions for napping, as opposed to overnight sleep. Recognizing that consumers are likely to be presented with scenarios where the infant falls asleep during use, a follow-up sentence reinforces the safe-sleep message that consumers should move the infant to a firm, flat sleep surface if the infant falls asleep after feeding. This language is generally consistent with language developed by the ASTM Ad Hoc Language task group.[25]

- The warning includes statements that explicitly address leaving the infant unattended in the product. Specifically, the warning tells consumers never to leave the infant alone in the product, never to prop the baby alone in the product, and to keep the infant within arm's reach during use. Staff's proposed warning uses the more accurate phrase "arm's reach," rather than "arms reach," which appears in the draft voluntary standard. As staff noted in its review of the incident data, reported fatalities with nursing pillows often involved consumers using the product to prop up the infant within a sleep product, and common sleep products involved in these incidents include cribs, portable playpens or play yards, and bassinets. Thus, the warning includes a statement warning against using nursing pillows in sleep products in general, with cribs, bassinets, and play yards called out as specific examples. Staff's proposed warning differs slightly from that in the draft proposed rule by stating that consumers should never "prop up," rather than just "prop," the baby alone,[26] and that consumers should "NEVER" use the product in sleep products, rather than telling consumers "Do not" do so. Beds were another common sleep-related product in which nursing pillows were used; however, an adult bed is a common location in which caregivers are likely to use the product as intended, unlike the other sleep products identified in the warning. The warning also includes a statement instructing consumers to stop using the product if the consumer feels *themselves* falling asleep. Although nearly all fatalities involved infant sleep and involved the nursing pillow being used for lounging or sleeping, the three fatalities that occurred while the product was being used for nursing involved the caregiver inadvertently falling asleep, resulting in the caregiver entrapping or overlaying the infant.
- Lastly, the warning includes a clear and concise statement telling consumers to keep the infant's face visible and airway clear to encourage consumers to be vigilant about not allowing soft bedding to cover an infant's face.

Nonfatal injuries from falls most frequently involved placing or propping the infant in the product atop an elevated surface. Thus, the primary hazard-avoidance statement related to falls instructs consumers to not prop up the infant on beds, sofas, or other raised surfaces. Bed and sofas, or couches, are identified explicitly because they are the most common elevated surfaces involved in these types of falls. Two additional fall-related incidents involved the infant being carried while still in the product; thus, the section of the warning pertaining to falls ends by telling consumers never to carry or move the product while the baby is in the product.

[25] The ASTM Ad Hoc Language task group was formed to develop standardized language across ASTM juvenile products standards. This task group is discussed more in the next, *Warning Format*, subsection. The latest version of the Ad Hoc-approved recommended language is published in the "Committee Documents" section of the Committee F15 ASTM website.

[26] The portion of the warning related to the fall hazard also refers to propping up the infant, so this revision ensures that consumers are receiving the message with consistent language.

Warning Format

When assessing the adequacy of a warning, one must consider not only the content of a warning, but also its design or "form" (Laughery & Wogalter, 2006; Madden, 1999; Madden, 2006). ESHF staff supports the warning format requirements that appear in the draft ASTM Infant Feeding Supports voluntary standard, as these requirements will result in permanent, conspicuous, and consistently formatted on-product warning labels that address many warning format issues related to capturing consumer attention, improving readability, and increasing hazard perception and avoidance behavior.

Specifically, the draft ASTM Infant Feeding Supports voluntary standard includes warning format requirements that are consistent with the recommendations of the ASTM Ad Hoc Language task group. Since 2016, ASTM juvenile products standards have begun adopting warning format requirements that are consistent with the recommendations of this task group, which ASTM formed to develop standardized language across ASTM juvenile products standards and which has developed recommendations for warning format to be applied to these products. The author of this memorandum is a member of the Ad Hoc Language task group and serves as the CPSC staff representative on the ANSI Z535 Committee on Safety Signs and Colors, which publishes the Z535 series of voluntary standards, including ANSI Z535.4, *Product Safety Signs and Labels*.[27] ESHF staff collaborated with the other members of the ASTM Ad Hoc Language task group to develop recommendations for warning format that are based primarily on the requirements of ANSI Z535.4, while also accounting for the wide range and unique nature of durable nursery products, the concerns raised by industry representatives, and historical ESHF staff recommendations associated with durable nursery product rulemaking projects. These recommendations include requirements for the following:

- content that is "easy to read and understand," not contradicted elsewhere on the product, and in English, at a minimum;
- conformance to the following sections of ANSI Z535.4 – 2011, *Product Safety Signs and Labels*:
    - ANSI Z535.4, sections 6.1–6.4, which include requirements related to safety alert symbol use, signal word selection, and warning panel format, arrangement, and shape;
    - ANSI Z535.4, sections 7.2–7.6.3, which include color requirements for each panel; and
    - ANSI Z535.4, section 8.1, which addresses letter style;
- minimum text size and text alignment; and
- the use of bullets, lists, outline, and paragraph form for hazard-avoidance statements.

The Ad Hoc Language task group recommendations also include recommended text for general labeling issues, such as labeling permanency, and content related to manufacturer contact

[27] ESHF staff consistently uses this standard—the primary U.S. voluntary consensus standard for the design, application, use, and placement of on-product warning labels—when developing or assessing the adequacy of warning labels. Literature on the design and evaluation of on-product warnings frequently cites ANSI Z535.4 as the minimum set of requirements that products containing such labels that are sold in the United States should meet (*e.g.*, Vredenburgh & Zackowitz, 2005; Wogalter & Laughery, 2005). Hellier and Edworthy (2006) and Peckham (2006) report that this conclusion has been reaffirmed by the U.S. courts, who have accepted the ANSI Z535 series of standards in general, and the ANSI Z535.4 standard in particular, as the benchmark against which warning labels are evaluated for adequacy, because these standards are seen as the state of the art (also see Laughery & Wogalter, 2006).[27] Furthermore, the scope of ANSI Z535.4 is broad enough to encompass nearly all products, including children's products and toys (see Kalsher & Wogalter, 2008; Rice, 2012).

information and date of manufacture. As staff pointed out earlier, the latest version of the Ad Hoc-approved recommended language is published in the "Committee Documents" section of the Committee F15 ASTM website.[24]

Warning Placement

The draft ASTM Infant Feeding Supports voluntary standard requires the on-product warning for in-scope products to be "conspicuous." Numerous ASTM juvenile products standards specify the placement of product warnings by including a requirement for warnings to be conspicuous, which is defined separately in each standard in terms of when the warning must be visible to the consumer. The draft voluntary standard defines this term as follows:

> label that is visible, when the infant feeding support is in a manufacturer's recommended use position, to a person sitting near the infant feeding support at any position around the infant feeding support.

ESHF staff finds this definition of conspicuous inadequate for the draft proposed rule because it is too broad and would allow the warning to be placed on a side of the product that is not readily visible to the caregiver who is using the product (*e.g.*, the side opposite the interior crescent-shaped surface). Additionally, the definition treats the term conspicuous as a noun (in this case, a label) rather than an adjective (*e.g.*, the characteristics of the warning or other item to which it is applied), which is how this term typically is defined.

ANSI Z535.4 provides general guidance on the placement of warnings by stating that warnings must be placed so they are "readily visible to the intended viewer" and will "alert the viewer to the hazard in time to take appropriate action" (section 9.1).[28] This guidance is consistent with the guidance typically offered in human factors and warnings literature. The warning content for nursing pillows is directed not to *any* consumer, but to the consumer who would be interacting with and placing the infant in the product. Thus, ESHF staff recommends the following definition of "conspicuous" for the draft proposed rule:

> visible, when the nursing pillow is in each manufacturer's recommended use position, to a person while placing an infant into or onto the nursing pillow.

Warning Permanence

The draft voluntary standard requires warning labels for infant feeding supports to be "permanent." The draft standard includes warning label permanence requirements in the *General Requirements* section and specifies that warning labels must be permanent when tested in accordance with specific test methods that appear in the *Test Methods* section. ESHF staff supports these requirements and test methods, which are consistent with the general approach taken across ASTM juvenile products standards. Thus, ESHF staff recommends that the draft proposed rule for nursing pillows include permanency-related requirements and test methods that are consistent with the draft voluntary standard requirements.

In addition, staff concludes that it is important to include an additional warning-permanency requirement that would address so-called "free-hanging" labels that are common to nursing pillows; that is, labels that attach to the product at only one end of the label. Warning labels that

[28] However, warnings must not be presented so far ahead that the consumer might forget the message when exposed to the hazard.

are attached in this way are more likely to be torn or ripped off, or otherwise altered by the consumer, which would eliminate the potential safety benefit of the warning for future users of the product. Given their importance, the required warnings must be as permanent as possible and discourage easy removal. Thus, staff recommends that the draft proposed rule include the following additional requirement:[29]

> 5.8.4 Warning labels that are attached to the fabric of nursing pillows with seams shall remain in contact with the fabric around the entire perimeter of the label, when the product is in all manufacturer-recommended use positions, when tested in accordance with 7.1.3.

A similar requirement appears in the ASTM voluntary standard for infant bedding (F1917 – 20e1), as well as in the CPSC final rule for sling carriers (16 C.F.R. part 1228).

ii. Package Warning Requirements

The draft ASTM Infant Feeding Supports voluntary standard includes basic warning requirements for the packaging that accompanies nursing pillows. These requirements are based largely on the ASTM Ad Hoc Language task group's recommended requirements for package warnings, and ESHF staff worked with the ASTM Ad Hoc Language task group to develop these requirements. The requirements in the draft voluntary standard include warning statements about not using the product for sleep or in sleep products like cribs, bassinets, or play yards; information about the manufacturer's recommended weight, height, age, or developmental stage, at a minimum; and a prohibition against other warnings, statements, or graphics that indicate or imply that an infant can be left in the product without an adult caregiver present. The package warnings also are required to have formatting similar to the on-product warnings. Staff recommends the use of the draft ASTM requirements in CPSC's proposed rule.

iii. Instructional Literature Requirements

The draft ASTM Infant Feeding Supports voluntary standard includes requirements for instructional literature to accompany nursing pillows. These requirements are based on the ASTM Ad Hoc Language task group recommended requirements for instructional literature and for the formatting of warnings in instructional literature, and ESHF staff worked with the ASTM Ad Hoc Language task group to develop these requirements. The requirements generally specify that the accompanying instructions must meet the following:

- be easy to read and understand and be in the English language, at a minimum;
- include information regarding specific tasks associated with the product such as assembly, maintenance, cleaning, and use, where applicable;
- address the same warning and safety-related statements that must appear on the product, with similar formatting requirements, but without the need to be in color; and
- not include any instructions that contradict or create confusion about the meaning of the required information, or otherwise mislead the consumer.

[29] Section numbering reflects the relevant numbering in the draft voluntary standard for infant feeding supports and may not reflect the numbering employed in the draft proposed rule for nursing pillows.

The ASTM Infant Feeding Supports subcommittee included in the draft voluntary standard the following additional warnings and related statements that must be addressed in the instructional literature that accompanies these products:

- statements about reading all instructions before using the product and keeping the instructions for future use;
- a warning to not use the product if it is damaged or broken; and
- information about the manufacturer's recommended maximum weight, height, age, developmental level, or combination thereof, of the infant intended to be supported by the product, and if the product is not intended for specific children (*e.g.*, children with a disability that would prevent safe use of the product) a description of this limitation.

The draft Instructional Literature section also refers the reader to ANSI Z535.6, *Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials*, for additional guidance on the design of warnings for instructional literature.

ESHF staff worked with the ASTM Infant Feeding Supports subcommittee to develop the draft instructional literature requirements for these products and recommends the use of these requirements in the draft proposed rule for nursing pillows.

III. Conclusions

ESHF staff recommends that the draft proposed rule incorporate an infant containment performance requirement that assesses crescent-like openings in nursing pillows using a 9-inch probe, as described in this memorandum. Staff concludes that this requirement reduces the risk of head entrapments in crescent-like nursing pillow openings, would eliminate certain designs of nursing pillows known to be used for lounging and sleeping, and would reduce the likelihood that consumers will use nursing pillows for infant lounging by reducing the amount of support for young infants who might be placed within the nursing pillow opening. Staff has considered an "angular" requirement that, in principle, might discourage some consumers from using the product for infant lounging. However, staff has concerns that such a requirement could increase the positional asphyxia risk if infants are placed in these products for lounging, contrary to the products' intended use. Staff recommends seeking public comments on this issue.

ESHF staff also proposes warning and instructional requirements for the draft proposed rule for nursing pillows that are generally consistent with the draft requirements developed by the ASTM Infant Feeding Supports subcommittee. Staff worked with the subcommittee to develop these requirements and staff concludes that these requirements reduce the risk of injury and death associated with nursing pillows. The requirements include a strongly worded on-product warning, with particular focus on the deadly suffocation hazard associated with using nursing pillows for sleep, as well as requirements for the format, placement, and permanence of these warnings, requirements for package warnings, and requirements for instructional literature that must accompany nursing pillows.

IV. References

American National Standards Institute. (2011, reaffirmed 2017). *ANSI Z535.4. American national standard: Product safety signs and labels*. Rosslyn, VA: National Electrical Manufacturers Association.

American National Standards Institute. (2011, reaffirmed 2017). *ANSI Z535.6. American national standard: Product safety information in product manuals, instructions, and other collateral materials*. Rosslyn, VA: National Electrical Manufacturers Association.

Bayley, N. (1969). *Manual for the Bayley Scales of Infant Development*. New York: The Psychological Corporation.

Fryar, C. D., Carroll, M. D., Gu, Q., Afful, J., & Ogden, C. L. (2021). *Anthropometric Reference Data for Children and Adults: United States, 2015-2018*. Vital and Health Statistics, 3(46). Hyattsville, MD: National Center for Health Statistics. Available: https://www.cdc.gov/nchs/data/series/sr_03/sr03-046-508.pdf.

Gass, R. H., & Seiter, J. S. (1999). *Persuasion, social influence, and compliance gaining*. Boston: Allyn & Bacon.

Hellier, E., & Edworthy, J. (2006). Signal Words. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 407–417). Mahwah, NJ: Lawrence Erlbaum Associates.

Kalsher, M. J., & Wogalter, M. S. (2008). Warnings: Hazard Control Methods for Caregivers and Children. In R. Lueder & V. J. B. Rice (Eds.), *Ergonomics for Children: Designing Products and Places for Toddlers to Teens* (pp. 509–539). New York: Taylor & Francis.

Laughery, Sr., K. R., & Wogalter, M. S. (2006). The Warning Expert in Civil Litigation. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 605–615). Mahwah, NJ: Lawrence Erlbaum Associates.

Laughery, K. R. & Wogalter, M. S. (2011). Hazard Control Hierarchy and Its Utility in Safety Decisions about Consumer Products. In W. Karwowski, M. M. Soares, & N. A. Stanton (Eds.), *Human Factors and Ergonomics in Consumer Product Design: Uses and Applications* (pp. 33–39). Boca Raton, FL: CRC.

Madden, M. S. (1999). The Law Relating to Warnings. In M. S. Wogalter, D. M. DeJoy, & K. R. Laughery (Eds.), *Warnings and Risk Communication* (pp. 315–330). Philadelphia: Taylor & Francis.

Madden, M. S. (2006). The Duty to Warn in Products Liability. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 583–588). Mahwah, NJ: Lawrence Erlbaum Associates.

Mannen, E. M., Davis, W., Goldrod, S., Lujan, T., Siddicky, S. F., Whitaker, B., & Carroll, J. (2022). *Pillows Product Characterization and Testing*. Prepared for the U.S. Consumer Product Safety Commission under contract no. 61320620D0002, task order no. 61320621F1015. Available: https://www.cpsc.gov/content/Pillows-Product-Characterization-and-Testing.

Peckham, G. M. (2006). An Overview of the ANSI Z535 Standards for Safety Signs, Labels, and Tags. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 437–443). Mahwah, NJ: Lawrence Erlbaum Associates.

Peebles, L., & Norris, B. (1998). *ADULTDATA: The Handbook of Adult Anthropometric and Strength Measurements – Data for Design Safety*. London: Department of Trade and Industry.

Rice, V. J. B. (2012). Designing for Children. In G. Salvendy (Ed.), *Handbook of Human Factors and Ergonomics* (4th ed.) (pp. 1472 - 1483). Hoboken, NJ: Wiley.

Robinson, P. A. (2009). *Writing and Designing Manuals and Warnings* (4th ed.). Boca Raton, FL: CRC.

Schneider, L.W., Lehman, R.J., Pflug, M.A, & Owings, C.L. (1986). *Size and Shape of the Head and Neck From Birth to Four Years*. (Report No. UMTRI-86-2, Contract No. CPSC-C-83-1250). Prepared for the U.S. Consumer Product Safety Commission, Washington, DC.

Vredenburgh, A. G., & Zackowitz, I. B. (2005). Human Factors Issues to be Considered by Product Liability Experts. In Y. I. Noy & W. Karwowski (Eds.), *Handbook of Human Factors in Litigation* (Chapter 26). Boca Raton, FL: CRC Press.

Wogalter, M. S. (2006). Purposes and Scope of Warnings. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 3–9). Mahwah, NJ: Lawrence Erlbaum Associates.

Wogalter, M. S., & Laughery, K. R. (2005). Effectiveness of Consumer Product Warnings: Design and Forensic Considerations. In Y. I. Noy & W. Karwowski (Eds.), *Handbook of Human Factors in Litigation* (Chapter 31). Boca Raton, FL: CRC Press.

Wogalter, M. S., Laughery, Sr., K. R., & Mayhorn, C. B. (2012). Warnings and Hazard Communications. In G. Salvendy (Ed.), *Handbook of Human Factors and Ergonomics* (4th ed.; pp. 868–894). Hoboken, NJ: Wiley.

TAB D: Health Sciences Data Analysis of Nursing Pillow Fatalities from January 1, 2010, to December 31, 2022 (HS Staff Memorandum)

United States
Consumer Product Safety Commission

Memorandum

TO: Timothy P. Smith, Nursing Pillows Rulemaking Project Manager,
Division of Human Factors, Directorate for Engineering Sciences

DATE: June 26, 2023

THROUGH: Mary Kelleher, Associate Executive Director
Directorate for Health Sciences

Stefanie Marques, Ph.D.,
Division Director of Pharmacology and Physiology

FROM: Suad Wanna-Nakamura, Ph.D., Physiologist
Division of Pharmacology and Physiology
Directorate for Health Sciences

SUBJECT: Health Sciences Data Analysis of Nursing Pillow Fatalities from January 1, 2010, to December 31, 2022

I. Introduction

This memorandum provides a Health Sciences (HS) assessment of data on fatal incidents that are associated with nursing pillows, with the objective of revealing hazard patterns and mechanisms of injury and death. The memorandum also includes an updated summary on the changes in the classification of sudden infant death syndrome (SIDS) as they relate to the circumstances of death and the interpretation sleep settings investigation and autopsy findings by the medical examiners (ME).

II. Discussion

HS staff reviewed the data regarding fatal incidents of infants where an apparent involvement with a nursing pillow had been reported. HS staff reviewed the data to assess the contribution of the nursing pillow in the deaths and to determine whether there were specific product characteristics that could have played a role. While the primary function of a nursing pillow is as a support aid while nursing, the vast majority of incident data showed that the product was used for infant sleeping.

A search of CPSC databases for infant deaths involving nursing pillows identified 154 in-scope fatal incidents (Directorate for Epidemiology, Division of Hazard Analysis (EPHA), Tab A) in the period between January 1, 2010 – December 31, 2022. The infant victims ranged in age from 2 days to 9 months, which included seven newborns between the ages of 2-17 days. Ninety-four percent of the fatalities (144 of the 154) involving nursing pillows were infants 6 months old or younger, and 81 percent (125 of the 154) were 4 months old or younger, an age bracket that is particularly vulnerable to suffocation and sudden infant death syndrome (SIDS)

HS staff reviewed the fatality reports for all 154 fatal incidents. That examination revealed only 3 cases where the fatality occurred while the product was being used for nursing. When used as instructed the nursing pillow wraps around the mother's waist and serves as a support platform while the infant is nursing. In the 3 nursing incidents, however, the mother is reported to have fallen asleep while nursing. In 4 other incidents, the product was used during bottle feeding, in some cases to support the baby bottle, while the infant was left unattended in a crib, playpen, or adult bed. In 142 of the 154 incidents, the fatality occurred when the infant was sleeping in the product and without caregivers watching the infants sleep. There is no evidence any of the 142 fatalities occurred while the infant was nursing or feeding.

The infant and nursing pillow were found in a variety of infant sleep settings that included, portable playpens (13), cribs (20), and bassinets (29). There were also incidents involving non-infant sleep settings that included adult beds and mattresses (61), couches (18) and a recliner chair (1). These infants reportedly were napping or sleeping for extended periods, up to 9 hours, without caregivers watching the infant sleep. There were also cases where infants were sharing the sleep surface with a parent and/or sibling on an adult bed or sofa (60), a situation where the possibility of overlay can be a significant risk. Finally, the presence of extraneous bedding was reported in many of the cases, which posed an additional risk factor that may have contributed to the suffocation of the infant.

In all of the fatal incidents, the official cause of death was categorized as asphyxia, suffocation, overlay, SIDS,[1] or Sudden Unexpected Infant Death (SUID). In cases where the infant was co-sleeping with another individual, medical examiners (MEs) were unable to definitively rule out overlay as the likely cause of the death of the victim. In these instances, the cause of death was suffocation with a note that "overlay could not be ruled out".

Despite extensive research, the etiology of SIDS remains unclear, and no exact cause has been identified. However, several physiological abnormalities and developmental delays in the brainstem have been observed that can be linked to impaired respiratory function, arousal response, premature birth plus extrinsic factors such as maternal smoking, and socioeconomic disadvantages (Getahun et. al., 2004, Kraus et. al., 1989). For example, it has been suggested that SIDS-related deaths could be a consequence of a delayed development in the arousal response such that an infant is not able to arouse themselves from a compromised and life-threatening sleep event. (Hefti et. al., 2016, Machaalani, et. al., 2009, Kinney et. al., 2003).

Determining the exact cause of death is difficult and sometimes not possible with the available information. The deaths often happen during sleep and are not witnessed. In autopsy findings, there is often a lack of specific physical markers when investigating suffocation and asphyxial deaths. MEs and coroners[2] often have to rely heavily on supplemental details of death scene investigations and or death scene reenactments, the accuracy of which are dependent on individual's recall of events during a time of panic and emotional distress. In the absence of a uniform system for terminology and classification used in coding of suffocation deaths, the same terminology can have different meanings to (MEs) and coroners. It is known that the interpretation of data surrounding asphyxial death can differ significantly between forensic experts (Byard, et al.,2007, and Sauvageau, et al., 2010).

HS staff reviewed the data of 154 deaths that were used by MEs and coroners in determining the cause of death. For 61 of the deaths, the cause of death was listed "unknown," "undetermined,"

[1] SIDS is a subset of SUID.

[2] Death certificates are usually signed by MEs, forensic pathologists, and/or coroners. In the U.S., coroners are often elected officials and, depending on the requirements of their office type (local county, regional or state level) their expertise can range from little or no formal forensic training to that of an ME (some coroners are also MEs).

"SUID" or similar, "SIDS," or asphyxia. In most of the incidents the ME/coroner reported "unsafe sleep" such as surface sharing and extra bedding, which were visible in IDI images. Three were reported as overlay.

Based on review of incident data, HS staff identified four major types of likely positional hazards associated with product use that may lead to positional asphyxia. Seven infants were reported to have underlying health risk factors and were listed as having contributed to the death. Included were SAR-Covid2, eosinophilic gastro enteritis with history of apneic episodes, sepsis due to urinary tract infection, fatty liver disease, broncho pneumonia and Congenital Pulmonary cyst and Airway Malformation.

1) Head in Center Space: An infant placed in a supine or prone position on top of the product may slip off and end up face down within the center space/or opening of the nursing pillow. In such a situation, head movement can be restricted by the raised portion of the product perimeter. in a manner that raised the risk for positional asphyxia/suffocation. An infant who is face down in the prone position can have their airways physical obstructed. In a situation where movement is restricted by the product, the infant may be unable to change position and relieve the blockage, resulting in oxygen deprivation, suffocation, and ultimately death, (DiMaio, 2001; Shapiro, 1982; and Azmack, 2006). In 14 of reported fatalities, the infant was discovered face down in the opening of the nursing pillow.

Figure 1. Center space of nursing pillow image showing where the head was located relative to the pillow, *(image source IDI)*

***2) Hyperextension*:** Neck hyperextension can result if an infant's unsupported head is tilted backwards over the top of the product while in a supine position (Figure 2). Sustained neck hyperextension where the head is below level of the infant's heart can lead to oxygen desaturation and death. There was one reported incident of neck hyper extended.

Figure 2: A doll enactment showing the position of the victim on the product with its back with body arched over the pillow, head tilted backward, and the neck hyperextended over the edge.

3) Hyperflexion: Hyperflexion in an infant can occur within the product when in a sitting position the body curled forward with the head pressed against the chest by the back of the pillow. The hyperflexion position can result in reduced airflow to the lungs and oxygen desaturation, and if sustained for a prolonged period of time, this can lead to death. (Bass et al., 2009). If there is added pressure applied to the back of the head by the product, an infant may be unable to raise its head because their neck muscles are relatively weak and thus, they will remain in the compromised position. Furthermore, infants born premature or under one-month age are the most susceptible groups to oxygen desaturation. Decreased oxygenation levels have been reported in premature infants placed in car seats (Cote et al., 2008). Staff identified 9 hyperflexion incidents.

4) Rolling off the product into a hazardous surrounding: If an infant is placed on the product and rolls off onto a surface where extraneous bedding or other soft items are located, this can lead to increased risk from suffocation through occlusion of the mouth and nose by the items (Figure 3).

Figure 3: Nursing pillow use in adult beds *(image source incident IDIs)*

In at least 21 of the 154 fatal incidents, the infant rolled off the nursing pillow and was found with their face against bedding or another object outside of the nursing pillow. Occlusion of the nose and mouth by a pillow or other bedding can lead to suffocation. Clutter and extra bedding were visible in most of the incidents especially in adult beds (Figure 3), where 58 incidents happened, and in cribs and bassinets (Figure 4).

Figure 4. Examples of cluttered cribs, play yards and bassinets, where the nursing pillow was positioned (*Image source incident IDIs*).

In reviewing the fatal incident data, staff made the following observations regarding product placement on adult beds, where the infant was sharing the surface with one or more occupant.

***Bed Sharing*:** Placing infants in adult beds exposes them to potentially fatal hazards with a high-risk for overlay with or without the presence of nursing pillow (Fleming et.al., 2015, Tappin 2005 and Wanna-Nakamura, et.al., 1999), *Mechanical asphyxia or suffocation caused by overlaying cannot be determined with certainty*." Because of the lack of pathological markers in asphyxia at autopsy or at best minimal, the diagnosis is extremely difficult, and findings rely heavily on the death scene investigations of infant's death sleep settings. This uncertainty could apply to overlay cases classification to suffocation cases.

III. Conclusion

Based on the review of the in-depth investigations of the fatal incidents, the primary contributing factor that led to infant fatality seems to be products that are designed in a manner that puts infants at risk of suffocation when infants fall asleep in the product without caregivers watching the infants sleep. Fatalities also occurred when used on an adult bed with bed sharing or in a confined space such as a crib or bassinet cluttered with extra bedding. Of the 154 deaths from 2010 through 2022,142 involved an infant sleeping in the product. The product design can be a contributing factor to injury if it facilitates the movement and rollover of an infant from one position to another that puts them at risk, such as from a supine to prone position. Even from a supine position, an infant sliding down to the center of the product could increase the chances for a situation that leads to neck hyperflexion or face down positioning. If an infant's head is tilted backward over the edge of the product, neck hyperextension can occur. Finally, if there is pressure applied to the back of the head by a component of the product, an infant is likely to remain in this compromised position because the neck muscles are generally too weak to support raising the head.

IV. References

Azmak D. Asphyxial deaths: a retrospective study and review of the literature. Am J Forensic Med Pathol 2006;27(2):134–44investigation, 4th ed., Springfield, IL: Charles C Thomas, 2006:436–59.

Blair P, Ward Platt MP, Smith IJ, Fleming PJ. Sudden Infant Death Syndrome and sleeping position in pre-term and low birthweight infants: An opportunity for targeted intervention. Arch Dis Child 2006; 91:101-6.

Blair P, Ward Platt MP, Smith IJ, Fleming PJ. Sudden Infant Death Syndrome and sleeping position in pre-term and low birthweight infants: An opportunity for targeted intervention. Arch Dis Child 2006; 91:101-6.

Byard RW, Jensen LL. (2007) Fatal asphyxial episodes in the very young: classification and diagnostic issues. Forensic Sci Med Pathol. (2007) 3:177-81.

Filiano JJ, Kinney HC. A perspective on neuropathologic findings in victims of the sudden infant death syndrome: the triple-risk model. Biol Neonate. 1994;65:194–7.

Fleming P, Pease A., Blair P. (2015). Bed-sharing and unexpected infant deaths. What is the relationship? *Paediatric Respiratory Reviews, 16(1)*, 62–67.

Hefti MM, Kinney, HC, Cryan, JB, Haas, EA, Chadwock, AE, Crandall, LA, Trachtenberg, FL, Armstrong, DD, Grafe, M, Krous, HF. Sudden unexpected death in early childhood: general observations in a series of 151 cases: Part 1 of the investigations of the San Diego SUDC Research Project. *Forensic Sci Med Pathol*. 2016; 12(1): 4–13.

Kinney HC, Myers MM, Belliveau RA, et al. Subtle autonomic and respiratory dysfunction in sudden infant death syndrome associated with serotonergic brainstem abnormalities: a case report. J Neuropathol Exp Neurol. 2005;64:689–94.

Krous HF, Beckworth JB, Byard RW, et al., (2004) Sudden Infant Death Syndrome and Unclassified Sudden Infant Deaths: A Definitional and Diagnostic Approach. *Pediatrics 2004;114: 234–238.*

Machaalani R, Waters KA. Neuronal cell death in the sudden infant death syndrome brainstem and associations with risk factors. Brain. 2008;131:218–28. https://www.ncbi.nlm.nih.gov/pubmed/18084013.

Matshes EW Lew EO (2017) An approach to the classification of apparent asphyxial infant deaths *Acad Forensic Pathol. 7:200-211*

Nakamura S, Wind M, Danello MA. Hazards Associated with Children Placed in Adult Beds. Arch of Pediatric and Adolesc Med. 1999; 153:1019-1023.

Shapiro-Mendoza CS, Parks SE et al. (2017) Variations in the cause of death determination for sudden unexpected infant deaths. Pediatrics 140 (1). pii: e20170087 http://pediatrics.aappublications.org/content/pediatrics/140/1/e20170087.full.pdf

Sauvageau A, Boghossian E. (2010) Classification of asphyxia: the need for standardization. *J Forensic Sci. 55:1259-1267*

Tappin D, Ecob R, Brooke H. Bedsharing, roomsharing, and sudden infant death syndrome in Scotland: a case control study. *J Pediatr.* July 2005;147(1):32-37

Wanna-Nakamura S. Suffocation hazards to infants when placed to sleep on cushions and pillows. Health Sciences 2008 memo Tab D p 34/60 in US CPSC *Regulatory Alternatives to Address Boston Billows' Request for Exemption for Ban on Infant Cushions/Pillows and Other Aspects of the Open Rulemaking on Infant Cushions/Pillows.* https://docslib.org/doc/6481516/regulatory-alternatives-to-address-boston-billows-request-for. (Last accessed May 2023)

TAB E: Initial Regulatory Flexibility Analysis for the Draft Proposed Rule to Establish a Mandatory Safety Standard for Nursing Pillows (EC Staff Memorandum)

United States
Consumer Product Safety Commission

Memorandum

TO: Timothy P. Smith, Nursing Pillows Rulemaking Project Manager, Division of Human Factors, Directorate for Engineering Sciences

DATE: June 26, 2023

THROUGH: Alex Moscoso, Associate Executive Director
Directorate for Economic Analysis

José Tejeda, Supervisory Economist,
Directorate for Economic Analysis

FROM: Susan Proper, Economist
Directorate for Economic Analysis

SUBJECT: Initial Regulatory Flexibility Analysis for the Draft Proposed Rule to Establish a Mandatory Safety Standard for Nursing Pillows

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I. Introduction

CPSC staff has developed a draft Notice of Proposed Rulemaking to establish a mandatory safety standard for nursing pillows. CPSC does not have an existing mandatory standard for this product category, other than the general ban on infant pillows in 16 C.F.R. §1500.18(a)(16), which has an exemption for certain types of nursing pillows. This draft proposed rule proposes new performance requirements and warning label requirements that would apply to nursing pillows and adds nursing pillows to the list of products for which third-party testing and registration cards are required.

Section 603 of the Regulatory Flexibility Act (RFA, 5 U.S.C. §603) requires the Commission to prepare an Initial Regulatory Flexibility Analysis (IRFA) for a proposed rule, describing the impact of the proposed rule on small entities and identifying efforts by the Commission to reduce those impacts. This memorandum presents the main findings of the IRFA for the nursing pillows draft proposed rule.

As specified in the RFA, the IRFA must contain:

(1) a description of the reasons why action by the agency is being considered;
(2) a succinct statement of the objectives of, and legal basis for, the proposed rule;
(3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
(4) a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;

(5) an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule.

Staff assesses this draft proposed rule to have a significant impact on a substantial number of small entities because there is currently no existing mandatory or voluntary performance standard for nursing pillows. Therefore, the requirements would be new costs for all covered entities. In addition, there are more than 1,000 small entities in this market sector, including many very small hand-crafter businesses, of which a substantial number are likely to be impacted by more than one percent of annual revenue.

II. Reason for Agency Action

There is currently no mandatory safety standard for nursing pillows to address the hazards of infants sleeping in the products, sometimes on elevated surfaces or inside an infant sleep product. There is also no voluntary standard for nursing pillows.[1] CPSC staff identified 154 fatal incidents and 88 nonfatal incidents from January 1, 2010, to December 31, 2022, involving nursing pillows (see EPI memo, Tab A). Of the 154 fatalities involving a nursing pillow during that period, an infant was sleeping in the nursing pillow in 142 cases.

While there is a ban on certain "infant pillows,"[2] certain nursing pillows are exempted from the ban while others do not meet the scope of the ban, such as ones with a non-granular fill. Staff finds there are currently many products advertised for both nursing and "lounging," despite the hazard of propping up very young infants. The ban on "infant pillows" with the nursing pillow exemption was published in 1992. In 2020, the most recent year for which there is complete data, there were 38 fatalities and 14 injuries from nursing pillows, as discussed in the EPI memo (Tab A).

Because there is a hazard of infant death that is not addressed by an existing mandatory standard, staff recommends the publication of a draft proposed rule to establish mandatory performance requirements that address the hazards; a warning label, a customer registration card, and instructions; as well as third-party testing to demonstrate compliance. The registration card is already required for children's products by the CPSIA, and is exempt from Paperwork Reduction Act (PRA) or RFA analysis, per section 104(d)(1) of the CPSIA.

[1] There is an ASTM standard for "infant feeding supports" in development that has not yet been published.

[2] 16 CFR 1500.18(a)(16) bans "infant pillows" that have ALL of the following characteristics

(A) Has a flexible fabric covering.
(B) Is loosely filled with a granular material, including but not limited to, polystyrene beads or pellets.
(C) Is easily flattened.
(D) Is capable of conforming to the body or face of an infant.
(E) Is intended or promoted for use by children under one year of age.

16 CFR 1500.86(a)(9) has an exemption to this ban for "Boston Billow Nursing Pillow and substantially similar nursing pillows that are designed to be used only as a nursing aide for breastfeeding mothers. For example, are tubular in form, C- or crescent-shaped to fit around a nursing mother's waist, round in circumference and filled with granular material."

III. Objectives and Legal Basis of the Draft Proposed Rule

A. Objectives of Draft Proposed Rule

The objective of the draft proposed rule is to establish a mandatory safety standard for nursing pillows to address hazards from infants sleeping in the products, and also from fall hazards. The draft proposed rule addresses the hazards by requiring nursing pillows to be sufficiently firm that the product is unlikely to conform to an infant's face and occlude the airways, and to have openings that are large enough to not restrict an infant's head movements. These requirements are intended to discourage consumers from allowing infants to sleep in the product. The draft proposed rule also prohibits infant restraints. The labeling and instructions requirements warn consumers that nursing pillows should never be used for lounging, propping, or sleeping, nor should babies be unattended in the product.

B. Legal Basis of the Draft Proposed Rule

Section 104(b)(1) of the CPSIA requires the Commission to assess the effectiveness of voluntary standards for durable infant or toddler products, if such standards exist, and to adopt mandatory standards for these products. 15 U.S.C. § 2056a(b)(1). A mandatory standard must be "substantially the same as" the corresponding voluntary standard, or it may be "more stringent than" the voluntary standard, if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the product. 15 U.S.C. § 2056a(b). The Commission must continue promulgating safety standards for infant and toddler products until it "has promulgated standards for all such product categories." 15 U.S.C. § 2056a(b)(2).

One requirement for promulgation of this rule is that nursing pillows are "durable infant or toddler products." Staff observes that nursing pillows are available used in some cases from secondary marketplaces such as eBay and that replacement covers are available also on such marketplaces. For example, in June 2023, CPSC staff performed a simple search on eBay using the phrase "nursing pillow," with the results filtered to include only items in "used" condition and to show only "sold listings." The search resulted in 145 listings—about half for nursing pillows and half for nursing pillow covers—dated between March 15, 2023, and June 12, 2023. This suggests that consumers perceive nursing pillows as having a future useful life beyond the initial infant user. Moreover, sales of used nursing pillows likely underestimates the prevalence of consumers reusing nursing pillows, because some consumers are likely retaining and reusing nursing pillows for multiple children of their own rather than selling the products on secondary marketplaces. A similar search on Mercari in June 2023 for "sold" nursing pillows in "good" or "fair" condition found 513 listings, many of which were listings for pillow covers or other miscellaneous products such as loungers and breast pumps.

The CPSIA also authorizes the Commission to require manufacturers of durable nursery products to provide consumers with a postage-paid consumer registration form with each such product, and to permanently place the manufacturer name and contact information, model name and number, and the date of manufacture on each durable infant or toddler product. 15 U.S.C. 2056a(d). The draft proposed rule would add nursing pillows to the list of products for which registration cards are required.

The CPSIA also sets forth the requirements for third party testing of children's products, and for the accreditation of such testing laboratories. 15 U.S.C. § 2063. The draft proposed rule would add nursing pillows to the list of durable infant products specified in 16 C.F.R. part 1112, "Requirements Pertaining to Third Party Conformity Assessment Bodies."

C. Compliance with the Draft Proposed Rule

The draft proposed rule establishes new performance and labeling requirements. Suppliers would need to conduct third party testing to demonstrate compliance, provide the specified warning label and instructions, and provide a product registration card. These are new requirements for all suppliers, large and small. Nursing pillows are currently not required to be third-party tested to any CPSC standard, unless textile content or small parts requirements apply to a particular item. While pillows are subject to the existing mandatory standards for lead content and phthalates, most pillows are made of textile materials that are exempt from those testing requirements, as specified in 16 C.F.R. § 1253 and 1500.91.

The labeling and registration card requirements are also new. Some pillows currently on the market have warning labels, but not the specific labels or instructions required by this draft proposed rule. Suppliers would also be required to provide a product registration card, which some companies already do, but it is not currently required. The labeling and instructions requirements constitute a "paperwork" burden under the PRA. CPSC staff will submit an Information Collection Request to OMB for their approval and obtain an OMB control number for this information collection. Certificates of Conformance are already required for all children's products under OMB Control Number 3041-0159. Registration cards are exempt from PRA burden analysis under section 104(d)(1) of the CPSIA.

IV. Entities to Which This Rule Would Apply

A. The Product

The proposed rule would apply to nursing pillows, including products that are advertised for both nursing and lounging, and products that are advertised for "feeding support." Products in scope are advertised for both breast-feeding and bottle feeding.

The most common physical type for this product category is a C or U-shaped product, sometimes called a "horseshoe" or "crescent" shaped product. Other relatively common product types include a V or "boomerang" shaped product, a round pod with a recessed center to support the infant, a stack of multiple petal-shaped pillows attached to a central tubular pillow, and an E shape for twins. Less common are padded sleeve type pillows, padded sling-like pillows, and long tubular pillows.

Some products have a belt or straps that fasten the product to the caregiver, and a few have restraints that fasten the infant to the pillow. Many products come with removable fabric covers. Some products have attached small infant head support bolsters or fabric toys. Most products are stuffed with a synthetic batting or foam, although products stuffed with cotton, wool, or dried grains are available.

B. Products Out of Scope

Some adult body pillows, particularly pillows advertised to support pregnant adults, are also advertised for prone position nursing. These products are out of scope. The draft regulatory text

for this NPR defines these as “a large body pillow intended, marketed, and designed to provide support to a pregnant adult’s body during sleep or while lying down.”

Some products advertised as “self feeding pillows” are a pillow that holds a bottle near the infant’s face so that the infant can feed itself. These are out of scope, as they do not have the same infant/caregiver interaction as pillows designed for an adult to feed a child directly. These pillows are banned in the United Kingdom due to the risk of serious harm or death from choking or aspiration pneumonia prevents the product from meeting that country’s relevant regulations.[3] Similarly, wedge-shaped pillows that are marketed to leave a child alone to self-feed with a bottle are out of scope. Both of these types of products are in scope of a draft proposed rule for Infant Pillows (now Infant Support Cushions) that is in the CPSC’s FY 2023 Proposed Operating Plan.

C. The Market (Units Sold, Prices, Suppliers)

The Breastfeeding Infant Development Support Alliance recently estimated sales of new nursing pillows in the U.S. at 1.34 million units per year, using sales data from JPMA, the trade association for juvenile products.[4] The number of nursing pillows in use is likely higher than the estimated sales, because some parents may already own a pillow that was purchased for an older child, make a pillow, or buy a used pillow.

Nursing pillows are available from online general retail sites, brick and mortar baby specialty stores, online baby products sites, brick and mortar general retail stores, and online marketplaces for hand-crafted items. Prices for new nursing pillows range from under $15 to more than $100, with most products in the $25 to $65 range. The more expensive models tend to have removable covers and tend to be sold at brick and mortar stores. At an average price of around $50, and assuming sales of 1.34 million units, staff estimates annual sales of new nursing pillows to be about $67 million. Staff observes that nursing pillows are available used in some cases from secondary marketplaces such as eBay and that replacement covers are available also on such marketplaces. Prices for used nursing pillows on Mercari in June 2023 listed as “sold” ranged from $13.30 (including shipping) to $81 for listings where the listing photos appeared to be actual nursing pillows (some “nursing pillow” listings were breast pumps, loungers, or bundles of miscellaneous used baby items). Prices on eBay for sold, used listings of nursing pillows ranged from $6.74 (including shipping) to $123.21.

Nursing pillows are supplied by a large number of manufacturers and importers, including hundreds of direct foreign shippers and hand-crafters. Although there are more than a thousand businesses selling nursing pillows and pillow covers online, the models commonly sold at brick and mortar retail stores are supplied by nine companies. For instance, in the spring of 2023, nursing pillows from these nine companies were available for in-store purchase[5] at the two of the largest “big box” general retailers that sell baby products, a large home furnishing chain store, three department store chains, and the two largest specialty baby product chains. While these stores do sell other nursing pillows for “ship to store,” an individual physical store typically has fewer than four models of nursing pillows in stock that consumers can see, test the firmness, and see the safety warnings and instructions, before their purchase decision. Used pillows are

[3] https://www.gov.uk/product-safety-alerts-reports-recalls/product-safety-alert-baby-self-feeding-pillows-slash-prop-feeders-psa3
[4] https://bfidsa.org/2-5-million-times-daily-quantifying-the-importance-of-nursing-pillows/
[5] This type of market structure, where a few products have a large market share, but there are also a large number of products available with much smaller market share, is sometimes called a “long tail” market.

available on commercial online sites for used consumer goods; many charity second-hand sites do not sell used baby goods as a policy, or had none listed for sale in June 2023.

This market structure, with a small number of models available to purchase in person but a much larger number available to purchase only online or "ship to store," may limit consumers' ability to assess the safety-related characteristics of the products on offer, which would be addressed by the draft proposed rule. The products sold in stores typically have warning labels or information about intended use on the product and/or on the packaging. The thousands of products sold online, however, do not typically have pictures of any warning labels in the product listing. It is not possible to compare the firmness of different products from pictures online. Manufacturers often do not control how their products may be marketed by third party sellers online, including advertised uses, and whether the product is sold with the original packaging and instructions. One manufacturer's website warns consumers of counterfeit products sold by third parties online. Another manufacturer's discontinued product is sold by multiple third parties online. Nursing pillow covers marketed for use with specific brands are available from hundreds of sellers other than the manufacturer; the manufacturer has no control over whether these covers correctly fit the product, or add potentially hazards straps or restraints. The draft proposed rule seeks to ensure that all nursing pillows for sale, whether in stores or online, meet minimum performance and labeling requirements to address the known hazards.

D. Small Entities to Which the Proposed Rule Would Apply

This rule would apply to entities that supply nursing pillows to the U.S. market. These include manufacturers and importers, as well as foreign direct shippers[6]. There are more than 1,000 suppliers in this market, the majority of which are small.

The Small Business Administration sets size standards for what constitutes a U.S. small business for the purpose of various federal government programs[7]. The size standards are based on the number of employees or the annual revenue of the firm, and there is a specific size standard for each 6-digit North American Industry Classification Series (NAICS) category[8]. The SBA size standard for what constitutes a "small" business is typically 500 to 750 employees, depending on the industry category. Manufacturers and importers of nursing pillows could be in a wide variety of such categories, depending on their primary line of business, which often is not nursing pillows but rather some more general category of children's products or other consumer goods.

Based on staff's assessment of prominent online and brick and mortar retail sources for nursing pillows in the Spring of 2023, there appear to be more than 1,000 suppliers of nursing pillows to the U.S. market, including many small U.S. crafters, small importers, and direct foreign shippers. The current suppliers to the U.S. market include the following categories of businesses:

[6] A foreign direct shipper is an online supplier that ships from a foreign country directly to U.S. consumers. CPSC staff does not consider these to be U.S. small businesses for the purposes of the IRFA, because they have no U.S. presence.
[7] The size standards are in listed in the Code of Federal Regulations. See 13 CFR part 121.
[8] The North American Industry Classification System (NAICS) is the standard used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy. For more information, see https://www.census.gov/naics/ Some programs use 6 digit NAICS codes, which provide more specific information than programs that use more general 3 or 4 digit NAICS codes.

Type of Business	Number	U.S. presence	Small U.S. business
Small U.S. manufacturer	22	These are companies that design nursing pillows in the U.S. and ship from a U.S. address, although production may be in a foreign country. By number of employees, they meet the SBA standard for small manufacturer.[9]	Yes
Small U.S. importer	6	These are companies that do not appear to have U.S. design staff, but do ship from a U.S. address. By number of employees, they meet the SBA standard for small merchant wholesaler.[10]	Yes
U.S. non employer business	More than 500	These are small hand crafters that ship from the U.S. The number is approximate because these companies frequently enter and exit the market, and some of these companies list products online but do not appear to have any sales.[11]	Yes
Large U.S. manufacturers	3	Two large retail chains have their own "store brand" of nursing pillow. There is also one large U.S. manufacturer whose products are sold in brick and mortar stores. Each of these companies has more than 500 employees, exceeding the SBA size standards for small manufacturer.	No
Foreign companies whose products ship from U.S.	13	These are companies with a HQ outside the U.S. and whose products are sold by U.S. brick and mortar or online retailers. Most of these companies are large; some are publicly traded on foreign exchanges. Some have U.S. subsidiaries that would be a small business if considered separately.	6, if U.S. subsidiaries are considered separately
Foreign direct shippers and hand crafters	More than 300	These are companies that sell online to U.S. consumers and ship from a foreign address. This includes small foreign hand crafters and foreign companies that sell through U.S. or foreign online retail platforms. The number is approximate because these companies frequently enter and exit the market.	No

[9] The SBA regulations in 13 CFR § 121.105 specify that a U.S. small business for the purposes of SBA program eligibility is "a business entity organized for profit, with a place of business located in the United States, and which operates primarily within the United States or which makes a significant contribution to the U.S. economy through payment of taxes or use of American products, materials or labor." Consistent with this definition, staff considered a company to be a U.S. manufacturer if they have a headquarters and design products in the U.S., and market products with their own brand name, although production may take place overseas. Similarly, staff considered a U.S. company affiliated with a foreign company, such as a licensed distributor, to be a U.S. importer if they ship from a U.S. address.
[10] See SBA citation in previous footnote. Staff considered small companies that ship from a U.S. address to be a small importer if they don't appear to design products in the U.S., but are headquartered in the U.S.
[11] Based on staff assessment of sellers on a prominent site for hand crafted and vintage items that ship from the U.S.

As shown above, the majority of nursing pillow suppliers to the U.S. market are small U.S. manufacturers, importers, or non-employer businesses according to the SBA size standards for their category of business. Considering the U.S. subsidiaries of foreign companies as "importers", since they have U.S. staff and ship from the U.S., six of those meet the SBA size standards for small merchant wholesalers[12].

E. Entities to Which the Rule Would Not Apply

The proposed rule would not have any requirements or direct impacts on retailers of any size, except for the two large retailers that have "store brand" nursing pillows and are therefore also manufacturers of nursing pillows. Products manufactured or imported before the effective date of the final rule could still be sold by retailers of any size. Also, as specified in 16 C.F.R. part 1109, retailers may rely on a certificate of compliance provided by their suppliers; retailers are not required to third party test the children's products that they sell.

The proposed rule would not have any requirements for suppliers of aftermarket nursing pillow covers; that is, pillow covers marketed to fit a particular brand of nursing pillow, but neither sold nor authorized by the pillow manufacturer. There could be an indirect impact on these companies if nursing pillow manufacturers change the size and/or shape of nursing pillows to comply with the rule. There are hundreds of these suppliers, the majority of which are small businesses including hand-crafters and small importers, as well as foreign direct shippers.

V. Compliance, Reporting, Paperwork, and Recordkeeping Requirements of the Draft Proposed Rule

Suppliers would be required to meet the performance, warning label, consumer registration card, and user instruction requirements of the rule, and conduct third party testing to demonstrate compliance. This section discusses the reporting and paperwork requirements. The compliance costs are analyzed in detail in section VII.

Suppliers must demonstrate that they have met the performance requirements of the rule by providing certificates of compliance. Also, as specified in 16 C.F.R. part 1109, suppliers who are not the original manufacturer (including importers, wholesalers, and retailers) may rely on a certificate of compliance provided by their suppliers; retailers are not required to third party test the children's products that they sell. They must also provide product registration cards. Recordkeeping and compliance documentation do not require specialized expertise. CPSC's public website provides instructions and examples for how to develop the certificates of compliance and product registration cards.[13]

While some products currently have labels, all products would have to meet the specific labeling requirements and instructions specified in the draft proposed rule, which provides the text and graphics for the required labels and instructions. Therefore, specialized expertise in graphics

[12] The SBA regulations in 13 CFR § 121.103 specify SBA's rules for considering foreign and domestic affiliated companies in determining the size standard that applies to a particular company. The determinations differ by program and corporate structure.

[13] For instance, see: https://www.cpsc.gov/Testing-Certification/Childrens-Product-Certificate-CPC ; and https://www.cpsc.gov/Business--Manufacturing/Business-Education/Durable-Infant-or-Toddler-Products/FAQs-Durable-Infant-or-Toddler-Product-Consumer-Registration

design would not be required to develop the warnings and instructions. Most reporting and recordkeeping requirements in this draft proposed rule would be new for all suppliers. New packaging and instructions would be required for items not compliant with the current ASTM standard. Many items from foreign direct shippers and crafters do not come with the required labels, instructional literature, or product registration cards. The ongoing cost of the new labels, registration forms, and instruction manuals is estimated at about $1 per item for materials. The initial cost for labor of developing the labels and instruction manuals is included in the cost of redesigning models to comply with this rule, which is discussed in more detail in section VII of this memorandum. As noted earlier, the labeling and instruction requirements constitute a "paperwork" burden under the Paperwork Reduction Act (PRA). CPSC staff will ensure that this burden complies with the requirements of the PRA.

CPSC's Office of the Small Business Ombudsman provides additional online resources for small businesses to assist with the recordkeeping requirements.[14]

VI. Federal and State Rules that May Overlap with this Draft Proposed Rule

CPSC staff has not identified any other Federal rules that duplicate, overlap, or conflict with the proposed rule. As noted earlier, CPSC has an existing ban on certain types of infant pillows that exempts certain nursing pillows. Because those products are banned, there should not be any on the market that are in the scope of this draft proposed rule. Multiple states have bans on certain flame retardants in children's products, including nursing pillows, but this draft proposed rule does not set requirements on the use of flame retardants, so there is no overlap or conflict. As noted earlier, there is an NPR for infant pillows (now infant support cushions) in CPSC's FY 2023 Proposed Operating Plan; nursing pillows that also meet the definition of infant support cushions would also need to comply with the proposed infant support cushions rule.

VII. Potential Impact on Small Entities

This draft proposed rule would likely have a significant impact on a substantial number of small entities, based on the estimated costs of modifying the product to achieve compliance, and the ongoing cost of testing to demonstrate compliance. Staff considers one percent of annual revenue to be a "significant" economic impact on a company, consistent with regulatory flexibility analyses used by other federal government agencies.

A. Cost of Modifying Product

Most products on the market would require redesign to meet the requirements in the draft proposed rule, and no products on the market currently have the specific labels, customer registration forms, and warnings required by the draft proposed rule. A few products on the market may already meet the performance requirements in the draft proposed rule but would require third party testing to demonstrate compliance. Testing costs are covered in part B of this section.

Staff estimates the effort required for a one-time redesign to be 200 hours of professional staff time per model, including in-house testing of the prototypes and development of labels, customer

[14] For instance, see: https://www.cpsc.gov/Business--Manufacturing/Small-Business-Resources

registration forms, and instruction materials. This represents a total of 5 staff weeks of effort by engineering and design staff per model[15]. Using the Bureau of Labor Statistics Employer Costs of Employee Compensation as of December 2022,[16] the estimated cost per model is $12,530, at a current cost for professional labor of $62.65 per hour, rounded for the purpose of analysis to $12,500 per model. Materials costs for prototyping are estimated to be minimal, likely under $1,000, given that nursing pillows are typically made of fabric and stuffing materials. The total cost of redesign is approximately $13,500 per model ($12,500 for labor and $1,000 for materials)[17]. While some manufacturers may offer a wide selection of fabric coverings, most manufacturers offer three or fewer physically different models with different dimensions or features that might impact compliance. Thus, the cost of redesign per manufacturer is estimated at $40,500 at most; in most cases, particularly for small companies, it might be less because most companies have only one or two physically distinct models. For small crafters and other non-employee businesses, the estimated cost reflects the economic "opportunity cost" – while such a small business might not hire an engineer for redesign at $62.65 an hour, they would still need to spend approximately 200 hours redesigning their product and developing the instruction materials, which is 200 hours they would not have for other activities to support their business. Some engineering expertise would likely be required for the redesign, to ensure that the firmness requirement and seam strength requirements, in particular, are met, using a force gage and other equipment as specified in the NPR regulatory text. A small crafter's "opportunity cost" (the value of their time spent on redesign that cannot be spent on other activities) might be worth less than $62.65 an hour to them, in which case their cost of redesign would be less. For example, some handcrafted pillows are priced under $50, although some made of specialty textiles or personalization are priced at more than $200. For the lower priced end of the hand crafter market, given that it likely took more than one hour to construct and ship the product, and there was some cost for materials, some crafters apparently value their time at somewhat less than $62.65 an hour. Also, the BLS compensation rate of $62.65 per hour lowers to $42.66 per hour when only considering wages and not benefits (as many small crafters would not likely have), which would lower the redesign cost to $9,500 per model.[18]

Many manufacturers have outsourced production to foreign countries, but design their products in North America, so this estimate reflects U.S. labor and materials costs for prototype designs. While importers will not directly pay for the cost of redesign, the cost of redesign by others will almost certainly be reflected in the wholesale price.

As noted earlier, staff considers one percent of annual revenue to be a "significant" economic impact on a company, consistent with regulatory flexibility analyses conducted by other federal government agencies. Staff's cost estimate of $13,500 would be one percent of revenue for a firm with $1.35 million in revenue, which would represent sales of about 27,000 units at an average price of $50 per unit. The nine companies whose products are offered in brick and mortar stores, and five companies that sell a large volume of products online only, may achieve

[15] Staff estimate of labor effort reflects that it may require multiple prototypes and design iterations to develop a product that is compliant with the requirements in this NPR. The firmness requirement particularly may require several attempts to meet the requirement.
[16] https://www.bls.gov/news.release/archives/ecec_03172023.pdf. These costs reflect the employers' cost for salaries, wages, and benefits for civilian workers.
[17] While the materials cost for a single pillow may be only a few dollars, this estimate reflects that multiple prototypes and design iterations may be undertaken to develop a product that is compliant with the requirements in this NPR and otherwise satisfactory to the manufacturer in all respects, and that manufacturers may face relatively high materials costs for the small quantities of materials used for developing prototypes.
[18] $9,500 = $8,500 (rounded from 200 hours × $42.66 per hour) + $1,000 materials.

that level of sales. The cost of redesign would likely not be one percent of revenue for those fourteen companies, of which nine are small U.S. businesses. However, given that there are more than 1,000 suppliers in this market, with annual sales for the whole industry estimated at 1.34 million units, most models do not have sales of 27,000 units per year. Therefore, the cost is likely to be significant for a substantial number of small U.S. firms, particularly small home crafters[19].

Firms may be able to reduce the impact of the redesign costs by raising the retail price of nursing pillows, in which case the impact of the rule could be not significant, even for small suppliers, but instead would transfer the costs of compliance to consumers. The retail price increase to cover redesign costs could be relatively minor, even for relatively small volume suppliers. For example, a firm supplying 5,000 nursing pillows per year could cover the entire cost of redesign by raising the price by $2.70. Small manufacturers and small importers with several employees might have this level of sales volume, although most small crafters and single person importer businesses would not. However, small crafters and single person importers could cover at least some of their redesign costs by raising prices a few dollars. Given that the entire nursing pillow industry will be redesigning products to comply with this NPR, large companies may also raise prices to cover costs, so small businesses would not necessarily be less competitive if they raise prices to cover costs.

With an estimated 1,000 models that need to be redesigned, at $13,500 per model, the total cost for the industry could be as high as $13.5 million for redesign in the first year after the rule is published, assuming that all suppliers decide to remain in the market. It could be less, depending on actual costs of redesign for specific firms. It is possible many small volume home crafters will exit the market rather than redesign, and that some of the foreign suppliers to small importers will also exit the market rather than redesign, at least temporarily. However, since the performance requirements could be met by replacing the stuffing with a firmer type and changing the shape of the sides, which does not necessarily require specialized engineering expertise or tools for most of the prototyping process, it is possible that many of the small volume crafters would bear the expense of redesign and stay in the market. (Professional engineering expertise would likely be required for at least some of the redesign, to ensure that the firmness and seam strength requirements are met, using a force gage and other equipment as specified in the NPR regulatory text.) For small crafters and other non-employee businesses, their “opportunity cost” (the value of their time spent on redesign that cannot be spent on other activities) might be worth less than $62.65 an hour to them, in which case their cost of redesign could be less.

B. Third-Party Testing Costs

This draft proposed rule would require manufacturers of nursing pillows to comply with the rule and demonstrate compliance through third party testing. As specified in 16 C.F.R. part 1109, entities that are not manufacturers of children’s products, such as importers and wholesalers, may rely on the certificate of compliance provided by others. Staff assumes that manufacturers would pass on at least some of the cost of testing for compliance to importers and wholesalers.

Third-party testing would be a new cost for all suppliers, because nursing pillows are not currently required to be third-party tested. Several suppliers make vague reference in their products’ marketing to third-party testing. Given the lack of applicable current standards

[19] Several hundred foreign direct shippers, including small home crafter businesses, will also likely be impacted, but the RFA requires analysis of the impact on U.S. small businesses.

specifically for nursing pillows, any current third-party testing is likely for textile content, phthalates, lead, or small parts only.

Based on testing costs for other consumer products, third-party testing costs for nursing pillows is estimated at $500 to $1,000 per model. The cost of testing would depend on where the testing takes place, and whether a manufacturer's association or group adds nursing pillows to their certification program to enable volume discounts for third-party testing. The annual cost of samples for testing is estimated at around $150, bringing the overall annual cost to an estimated $650 to $1,150 per model.

The cost of testing alone could be significant for some small hand crafters. The low end of the testing cost estimate, $650, would represent one percent of annual revenue for a company generating $65,000 in annual revenue. At an average price of $50 per pillow, this would represent sales of 1,300 units a year. Many hand crafters show historical sales of less than 100 units. However, some small volume suppliers would likely be able to raise retail prices to cover at least some of the testing costs, thus reducing the impact on those suppliers. For example, a hand crafter selling 200 nursing pillows a year could cover the entire testing cost by raising the price by $3.25, while a smaller supplier could cover at least some of their costs with a modest price increase.

Small importers are less likely to find that testing costs (as reflected in increased wholesale cost from suppliers) are a significant burden. Nursing pillows are currently available on Alibaba.com[20] from about $2.50 to $10 in lots as small as 50 units, with lower prices for higher volume orders. If testing costs added ten percent to the wholesale cost, that would be less than $1 per unit, and importers could still make a profit selling the pillows for an average retail price of $50. Warning labels and instruction manuals might add another $1 or less to the retail price. However, small importers may not be able to find compliant suppliers, depending on the decisions of foreign manufacturers to redesign and test to the CPSC standard.

C. Summary of Impacts

Redesign costs would be a potentially significant cost for a substantial number of small firms for the first year that the rule is effective. Staff estimates one-time redesign costs, including costs of designing warning labels, consumer registration forms, and instruction manuals, to be $13,500 per model. The "opportunity cost" to small crafters for redesign could be less, depending on how they value their own time, and how much engineering assistance they use for testing prototypes. Staff estimates ongoing annual testing costs to be $650 to $1,150 per model.

The impact is expected to be significant for most small firms with low sales volume. Many small volume hand crafters may stop selling nursing pillows. Small-volume hand crafters may not have enough sales to cover the expense of redesign and testing, while small-volume importers may not be able to find compliant suppliers. However, even relatively small volume suppliers with sales under 1,000 units per year may be able to reduce the impact of the draft proposed rule on their companies by raising prices. A retail price increase of less than $5 could cover all the testing costs and a substantial portion of the redesign costs, even for a very small supplier.

Consumers may not experience a significant loss of consumer utility as small-volume sellers exit online marketplaces, since the selection in brick and mortar stores is already limited to the products of only nine companies. Also, many of the best-selling products online are from the

[20] Alibaba is a prominent Chinese site for wholesale consumer products.

same small group of firms that sell in stores. The best-selling online-only products are from companies that are small by the SBA size standards but have sufficient sales volume to spread the cost of compliance over thousands of units and are unlikely to exit the market. It is likely that the products currently in stores, and the best-selling online only products, would still be available, with modest redesigns. However, there may be some loss in sales of specific products as a result of this draft proposed rule, if the redesigned products are less appealing to consumers.

The redesign could increase the wholesale or retail price of the product by a few dollars, but likely not a significant amount, given that the materials and production methods are likely to remain roughly similar.[21] Warning labels, registration forms, and instruction manuals could add a small amount ($1 or less, or 2 per cent of the retail price of a $50 item) to the cost of the product. If companies decide to pass the ongoing cost of testing onto consumers, the price increase could be relatively modest, perhaps under $1 at retail, which added to the additional $1 cost of the warning labels and instruction manuals would total $2, or four percent of the price of a $50 item. Even a $5 price increase covering redesign, testing, and labeling costs for a small volume seller would represent only a 10 percent increase in price. However, if parents find the redesigned pillows to be less useful than substitutes such as slings or regular adult bedding pillows, there could be a decline in total sales of nursing pillows as a result of this rule.

VIII. Efforts to Minimize Impact, Alternatives Considered

The RFA (5 U.S.C. §603) specifies that the IRFA must contain a

> description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. Consistent with the stated objectives of applicable statutes, the analysis shall discuss significant alternatives such as-
>
> (1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;
>
> (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;
>
> (3) the use of performance rather than design standards; and
>
> (4) an exemption from coverage of the rule, or any part thereof, for such small entities.

Exempting small entities from this rule or parts of this rule would not be consistent with the applicable statutes, because this is a rule for durable infant or toddler products. 15 U.S.C. § 2063(d)(4)(C). The statute allows CPSC to provide “small batch” exemptions to testing requirements or alternative requirements for some mandatory safety standards, but not those for durable infant or toddler products. CPSC staff considered several alternatives to this rule including:

- Not establishing a safety standard for nursing pillows
- Delaying the NPR until the ASTM standard is published

[21] Although suppliers could meet the requirements of the rule by using more expensive inputs, such as upholstery grade foam and sail repair thread, we assume that rational suppliers would not choose the most expensive way to meet the requirements.

- Including an "angular" performance requirement as suggested in the Boise report
- A shorter effective date

Not establishing a mandatory standard

Not establishing a safety standard for nursing pillows would mean no new regulatory impact on small businesses, but it would also enable a continuation of the injury and death patterns from nursing pillows' known hazards. Deaths and injuries from the use of nursing pillows would continue to occur at likely similar rates as those observed by CPSC during the period 2010 through 2022[22] (see Tab A).

Delaying the draft proposed rule to allow for the publication of the ASTM voluntary standard

Delaying the draft proposed rule until the ASTM standard for infant feeding supports is published would delay the impact on small businesses but would also allow the hazard to continue for an unspecified period of time. In addition, the eventual ASTM voluntary standard may not be as protective of safety as this draft proposed rule.

Including an "angular" performance requirement

The Boise State University pillows research report to CPSC concluded that nursing pillows that are firm and feature sharper corners are likely the safest option for babies because there is no reasonable way to use these products for lounging, limiting the dangers associated with sagittal-plane positioning in the products. Staff considered an "angular" requirement to address this issue; however, the Boise report noted that more research is needed, both on the specific positions that are not hazardous, and how to test for them. Specifically, the report noted that "The sagittal plane testing devices offer a more robust quantification and visualization of infant position within pillow products compared to the hinged weight gage device. Further research is required to determine appropriate worst-case positions for testing and to set a threshold value for acceptable body positions. This device should also be considered for use in other infant product classes. More work should be done to simplify the design for easier manufacturability." Given the preliminary nature of this recommendation, staff did not have the information needed to specify a purpose-built device for testing infant positions. If staff had specified such a device, that would increase the burden on testing labs and likely increase the cost of third-party testing. If testing labs were unwilling or unable to provide testing with this new device, suppliers would not be able to comply with the rule. The NPR preamble will request public input on whether an angular performance requirement is appropriate to address the hazard, and what that requirement should be.

A shorter effective date

Staff proposes an effective date of 180 days after publication of the final rule. 180 days is consistent with other 104 rules, and with JPMA's certification program, which generally gives suppliers 180 days to comply with a new standard. A shorter effective date could provide the benefits of the rule more quickly, but it would increase the burden on small businesses to quickly redesign and test their products. A shorter effective date could result in temporary shortages of nursing pillows, because first testing labs need to set up the test fixtures specified in the draft proposed rule, then apply for accreditation, and then potentially more than 1,000 businesses

[22] As indicated earlier, CPSC observed 88 nonfatal incidents and 154 fatalities during this period; 142 of these fatalities occurred when a nursing pillow was used for sleep. Further, in 2020—the most recent year for which there is complete data—there were 38 fatalities and 14 injuries from nursing pillows.

need to have their products tested for compliance. A longer effective date would reduce the burden on small businesses by giving them more time to comply, but with a resulting delay in the hazard reduction benefits.

IX. Impact on Testing Labs

In accordance with section 14 of the CPSA, all children's products that are subject to a children's product safety rule must be tested by a third-party conformity assessment body that has been accredited by CPSC. One of the roles of these third-party conformity assessment bodies is to test products for compliance with applicable children's product safety rules. Testing laboratories that want to conduct testing must meet the Notice of Requirements (NOR) for third-party conformity testing. CPSC has codified NORs in 16 C.F.R. part 1112. This section assesses the impact a proposed amendment to include nursing pillows would have on small laboratories.

Staff assessed there should be no significant adverse impact on testing laboratories as a result of this rule. No new complex testing instruments or devices are required to test nursing pillows for compliance to this draft proposed rule. The one new testing device is a firmness probe, consisting of a relatively simple half-sphere, combined with force and deflection gauges. No laboratory is required to provide testing services. The only laboratories that are expected to provide such services are laboratories that anticipate receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

For the same reasons described above, revising the NOR to add nursing pillows to the list of products subject to part 1112 would not have a significant adverse impact on small laboratories. Most laboratories are not small U.S. businesses. Companies in the lab testing industry include companies with hundreds of locations, including labs in Asia and Europe, and thousands of employees. Therefore, the Commission could certify that the NOR for the nursing pillow mandatory standard will not have a significant impact on a substantial number of small laboratories.

X. Conclusion

The draft proposed rule is expected to have a significant impact on a substantial number of small entities. Nearly all the manufacturers and importers of nursing pillows are small businesses. The cost of redesign and testing would likely be significant for most small businesses currently in the market, except for eight small U.S. firms that do a high volume of business online and/or in physical stores. It is possible that many small-volume hand crafters and small importers would exit the market, because the cost of compliance would likely exceed one percent of annual revenue. It is also possible that some small firms would be able to cover most or all of testing and redesign costs by raising retail prices by less than $5 per item. There should be no adverse impact on testing laboratories, including small laboratories, as a result of this draft proposed rule.

Consumers are not expected to have a significant loss of utility due to the potential exit of small businesses from online marketplaces. The small group of products currently available in physical stores are likely to remain on the market, with modest redesigns, and the standard is not expected to raise prices of nursing pillows by more than $5. This draft proposed rule would ensure that all nursing pillows for sale, whether in stores or online, are required to meet minimum performance and labeling requirements to address the known hazards.

TAB F: Recommended Regulatory Text for the Draft Proposed Rule

United States
Consumer Product Safety Commission

Memorandum

TO: The Nursing Pillows Rulemaking Project File **DATE:** June 26, 2023

THROUGH: Duane E. Boniface, Assistant Executive Director, Office of Hazard Identification and Reduction

FROM: The Nursing Pillows Rulemaking Team

SUBJECT: Recommended Regulatory Text for the Draft Proposed Rule

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PART XXXX—SAFETY STANDARD FOR NURSING PILLOWS

Sec.

§ XXXX.1 Scope, Purpose, Application, and Exemptions

(a) *Scope and Purpose*. This part XXXX, a consumer product safety standard, prescribes requirements intended to reduce the risk of death and injury from hazards associated with nursing pillows, as defined in XXXX.2(f).

(b) *Application*. Except as provided in paragraph (c) of this section, all nursing pillows that are manufactured after [effective date], are subject to the requirements of this part XXXX.

(c) *Exemptions*. The following products are exempt from this part XXXX:

(1) Maternity pillows, as defined in XXXX.2(a), and

(2) Sling carriers, as defined in 16 C.F.R. part 1228.

§ XXXX.2 Definitions

(a) *Maternity pillow*, also known as a pregnancy pillow, means a large body pillow intended, marketed, and designed to provide support to a pregnant adult's body during sleep or while lying down.

(b) *Caregiver attachment* means a portion of the product intended to secure the nursing pillow to the caregiver and not intended to secure the infant to the nursing pillow. A caregiver attachment may comprise components including, but not limited to, straps, buckles, or latches.

(c) *Caregiver opening* means the surface of the nursing pillow, excluding the caregiver attachment, intended to fit against the caregiver's torso during use. This surface is typically, but not necessarily, crescent-like in shape.

(d) *Conspicuous* means visible, when the nursing pillow is in each manufacturer's recommended use position, to a person while placing an infant into or onto the nursing pillow.

(e) *Infant restraint system* means a portion of a product intended to secure or hold an infant in place on the product. These typically take the form of straps or harnesses that are secured by the caregiver.

(f) *Nursing pillow* means any product intended, marketed, or designed to position and support an infant close to a caregiver's body while breastfeeding or bottle feeding. These products rest upon, wrap around, or are worn by a caregiver in a seated or reclined position.

(g) *Infant support surface* means the manufacturer's intended support surface for the infant during nursing or feeding.

(h) *Safety alert symbol* means a symbol consisting of an exclamation mark surrounded by an equilateral triangle, or an equilateral triangle with a contrasting superimposed exclamation mark. The safety alert symbol precedes the signal word "WARNING," or other signal word, in the signal word panel of a warning.

§ XXXX.3 General Requirements

(a) *Lead in Paints*. All paint and surface coatings on the product shall comply with the requirements of 16 C.F.R. part 1303.

(b) *Small Parts*. There shall be no small parts, as defined in 16 C.F.R. part 1501, before testing or liberated as a result of testing.

(c) *Hazardous Sharp Edges or Points*. There shall be no hazardous sharp points or edges, as defined in 16 C.F.R. part 1500.48 and 16 C.F.R. part 1500.49, before or after testing.

(d) *Removal of Components*. When tested in accordance with § XXXX.5(b), any removal of components that are accessible to an infant while in the product or from any position around the product shall not present a small part, sharp point, or sharp edge as required in § XXXX.3(b) and § XXXX.3(c).

(e) Permanency of Labels and Warnings.

(1) Warning labels (whether paper or non-paper) shall be permanent when tested in accordance with § XXXX.5(c)(1) – § XXXX.5(c)(3).
(2) Warning statements applied directly onto the surface of the product by hot stamping, heat transfer, printing, wood burning, etc. shall be permanent when tested in accordance with § XXXX.5(c)(4).
(3) Non-paper labels shall not liberate small parts when tested in accordance with § XXXX.5(c)(5).
(4) Warning labels that are attached to the fabric of nursing pillows with seams shall remain in contact with the fabric around the entire perimeter of the label, when the product is in all manufacturer-recommended use positions, when tested in accordance with § XXXX.5(c)(3).

§ XXXX.4 Performance Requirements

(a) *Firmness*. When tested in accordance with § XXXX.5(d), § XXXX.5(e) and § XXXX.5(f), the force required for a 1.00-in. (2.54 cm) displacement of the 3-inch (76.2 mm) diameter hemispheric probe ("3-in. head probe," Figure 2) at any measurement location shall be greater than 10.0 N (2.24 lb).

(b) *Infant Containment*. When tested in accordance with § XXXX.5(g), the surfaces within the caregiver opening of the product shall not contact the 9-inch (230 mm) diameter head probe ("9-in. head probe," Figure 3) such that the probe is constrained within the caregiver opening and, when placed according to § XXXX.5(g)(6), the probe must extend past the caregiver opening.

(c) *Infant Restraints*. Nursing pillows shall not include any infant restraint system.

(d) *Seam Strength*. When tested in accordance with § XXXX.5(h), fabric/mesh seams and points of attachment shall not fail such that a small part, sharp point, or sharp edge is presented, as required in § XXXX.3(b) and § XXXX.3(c).

(e) *Caregiver Attachment Strength*. When tested in accordance with § XXXX.5(i), material seams, points of attachment, and attachment components shall not fail, and shall create no hazardous conditions, such as small parts or sharp edges, as required in § XXXX.3(b) and § XXXX.3(c).

§ XXXX.5 Test Methods

(a) *Test Conditions*.

(1) Condition the product for 48 hours at 23 °C +/- 2 °C (73.4 °F +/- 3.6 °F) and a relative humidity of 50 % +/- 5 %.

(2) Secure the firmness fixture to a test base such that the 3-in. head probe (Figure 2) does not deflect more than 0.01 in. (0.025 cm) under a 10 N (2.2 lb) load applied in each orientation required in the test methods.

(b) *Removal of Components Test Method*.

(1) For torque and tension tests, any suitable device may be used to grasp the component, provided that it does not interfere with the attachment elements that are stressed during the tests.

(2) *Torque Test*. Gradually apply a 4 lb-in. (0.4 N-m) torque over 5 seconds (s.) in a clockwise rotation to 180 degrees or until 4 lb-in. has been reached. Maintain for 10 s. Release and allow component to return to relaxed state. Repeat the torque test in a counterclockwise rotation.

(3) *Tension Test*. For components that can reasonably be grasped between thumb and forefinger, or teeth, apply a 15 lb (67 N) force over 5 s., in a direction to remove the component. Maintain for 10 s. A clamp such as shown in Figure 1 may be used if the gap between the back of the component and the base material is 0.04 in. (0.1 cm) or more.

Figure 1. Tension Test Adapter Clamp

(c) *Permanency of Labels and Warnings*.

(1) A paper label (excluding labels attached by a seam) shall be considered permanent if, during an attempt to remove it without the aid of tools or solvents, it cannot be removed, it tears into pieces upon removal, or such action damages the surface to which it is attached.

(2) A non-paper label (excluding labels attached by a seam) shall be considered permanent if, during an attempt to remove it without the aid of tools or solvents, it cannot be removed or such action damages the surface to which it is attached.

(3) A warning label attached by a seam shall be considered permanent if it does not detach when subjected to a 15-lbf (67-N) pull force applied in the direction most likely to cause failure using a 3⁄4-in. (1.9 cm) diameter clamp surface. Gradually apply the force within a period of 5 s. and maintain for an additional 10 s.

(4) Adhesion Test for Warnings Applied Directly onto the Surface of the Product:

(i) Apply the tape test defined in Test Method B of Test Method D3359, eliminating parallel cuts.

(ii) Perform this test once in each different location where warnings are applied.

(iii) The warning statements will be considered permanent if the printing in the area tested is still legible and attached after being subjected to this test.

(5) A non-paper label, during an attempt to remove it without the aid of tools or solvents, shall not fit entirely within the small parts cylinder defined in 16 C.F.R. part 1501 if it can be removed.

(d) *Infant Support Surface Firmness Test Method*. Perform the following steps to determine the infant support surface firmness of the product as received from the manufacturer.

(1) Conduct tests at three locations on the surface to be tested, with 3 in. (7.62 cm) or more separation: maximum thickness perpendicular to the test surface and two other locations most likely to fail.

(2) Lay the product, with the infant support surface facing up, on a test base that is horizontal, flat, firm, and smooth.

(3) Prevent movement of the product in a manner that does not affect the force or deflection measurement of the product surface under test. Provide no additional support beneath the product.

(4) Orient the axis of the 3-in. head probe (Figure 2) perpendicular to the test surface and aligned with a force gauge and parallel to a distance measurement device or gauge.

(5) Using a lead screw or similar device to control movement along a single direction, advance the probe onto the product and set the deflection to 0.0 in. when a force of 0.1 N (0.02 lb) force is reached.

(6) Continue to advance the head probe into the product at a rate not to exceed 0.1 inch per second and pause when the force exceeds 10.0 N (2.24 lb), or the deflection is equal to 1.00 in. (2.54 cm).

(7) Wait 30 s. If the deflection is less than 1.00 in. and the force is 10.0 N or less, repeat steps § XXXX.5(d)(6) and § XXXX.5(d)(7)).

(8) Record the final force and deflection amounts.

(9) Repeat the infant support surface firmness tests on any other infant support surface and in all manufacturer-intended configurations that could affect the infant support surface, such as the folding or layering of parts of the product.

(e) *Inner Wall Firmness Test Method*. For nursing pillows with a caregiver opening, perform the steps in § XXXX.5(d)(1) through § XXXX.5(d)(8) on the inner wall of the caregiver opening, and perform the following, to determine the inner wall firmness as received from the manufacturer.

(1) Repeat the inner wall firmness tests in all manufacturer-intended configurations that could affect the inner wall firmness.

(f) *Product Conditioning Firmness Test Method*. Following the firmness testing in § XXXX.5(d) and § XXXX.5(e), perform the following steps to determine the product firmness after conditioning.

(1) Launder and dry the product according to the manufacturer's instructions.

(2) Repeat § XXXX.5(d) *Infant Support Surface Firmness Test Method*.

(3) Repeat § XXXX.5(e) *Inner Wall Firmness Test Method*.

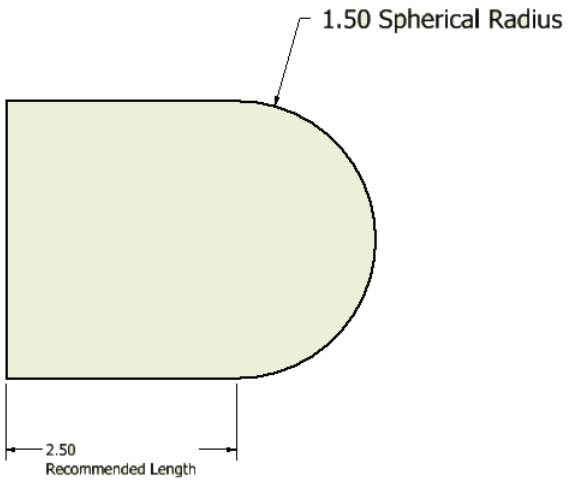

Figure 2. 3-in Head probe

(g) *Infant Containment Test Method*.

(1) Lay the product, with the infant support surface facing up, on a test base that is horizontal, flat, firm, and smooth.

(2) For nursing pillows with a caregiver attachment, adjust and latch the caregiver attachment to the minimum length allowed by the product.

(3) Place the 9-in. head probe (Figure 3) inside the caregiver opening such that the flat bottom of the probe rests on the test surface and the probe's perimeter contacts the innermost surface of the caregiver opening.

(4) If any inner surfaces of the caregiver opening contact the outwardly facing portions of the probe, or the inner surfaces interfere with placing the probe down, the caregiver opening is considered to constrain the probe. See Figure 4. Do not include in the assessment any contact with a caregiver attachment.

(5) Unlatch and move any caregiver attachment away from the caregiver opening. Conduct steps § XXXX.5(g)(3) and § XXXX.5(g)(4) in the procedure.

(6) With the probe at the position contacting the innermost surface within the caregiver opening, determine if any portion of the probe extends beyond a line projected across the outside limits of the caregiver opening.

(7) Slide the probe horizontally out of the caregiver opening to the outside of the nursing pillow. Determine if the probe is constrained by any inner surfaces of the caregiver opening contacting the outwardly facing portions of the probe. Do not include in the assessment any contact with a caregiver attachment.

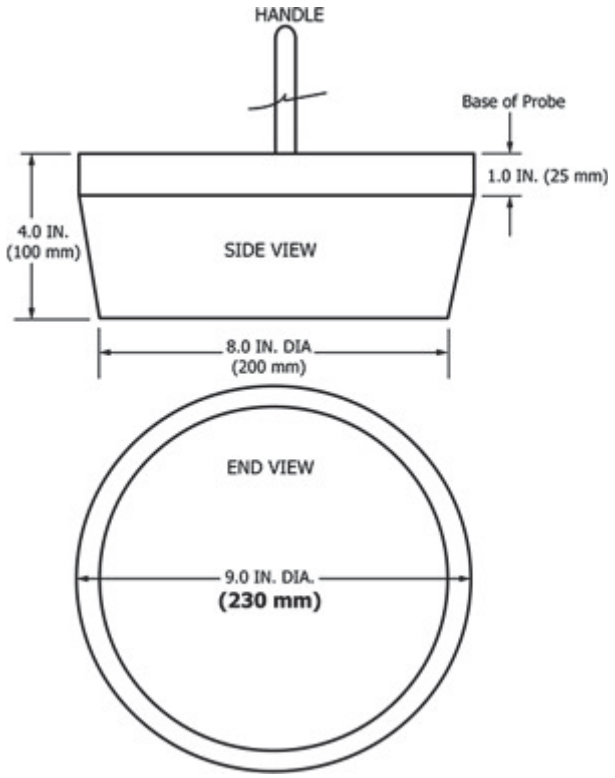

Figure 3. 9-in. head probe

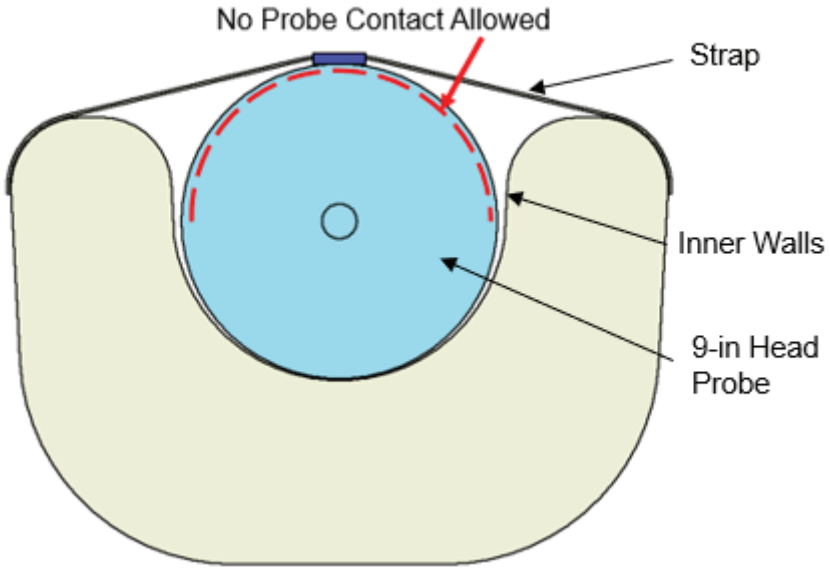

Figure 4 Infant Containment, Example

In § XXXX.5(g), the inner walls of the nursing pillow, excluding the strap, shall not constrain the 9-in. head probe in the caregiver opening, such that no contact with the outwardly facing portion (red arc) of the probe is allowed.

(h) *Seam Strength Test Method*.

(1) *Equipment*. Clamps with 0.75 in. (1.9 cm) diameter clamping surfaces capable of holding fabric and with a means to attach a force gauge. Figure 5, or equivalent.

The force gauge must have an accuracy of +/- 0.5 lb (1.1 N).

(2) Clamp the fabric of the nursing pillow on each side of the seam under test with the 0.75 in. clamping surfaces placed not less than 0.5 in. (1.2 cm) from the seam.

(3) Apply a tension of 15 lb (67 N) evenly over 5 s. and maintain for an additional 10 s.

(4) Repeat the test on every distinct seam and every 6 in. (15 cm) along each seam.

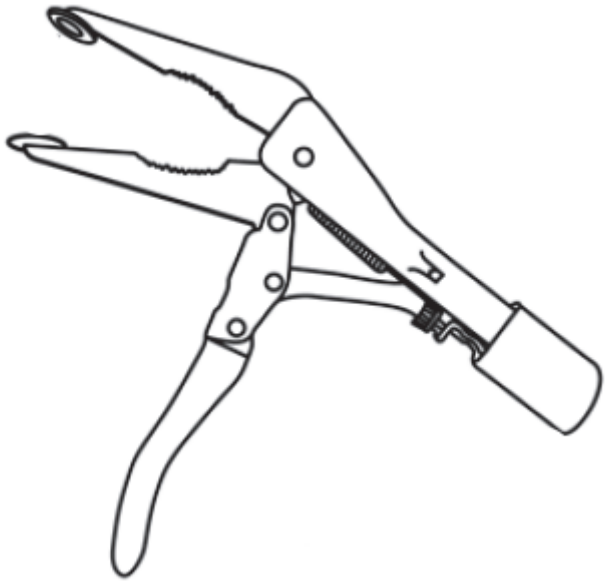

Figure 5. Seam Clamp

(i) *Caregiver Attachment Test Method.*

(1) *Equipment*. Any suitable clamping devices with means to attach a force gauge with accuracy of 0.5 lb (1.2 N) may be used. The clamping surfaces shall grasp across the entire width of the strap or attachment element.

(2) Support the nursing pillow to resist the pull forces and release the buckle or clasp of the caregiver attachment.

(3) Clamp one side of the attachment or strap of the nursing pillow not less than 0.5 in. (1.2 cm) from the attachment to the nursing pillow.

(4) Apply a tension of 20 lb (89 N) evenly over 5 s. and maintain for an additional 10 s.

(5) Repeat the test on the other side of the attachment or strap.

(6) Join the buckle or clasp of the attachment or straps.

(7) Clamp both sides of the attachment or straps across the buckle or clasp, one on each side and not less than 0.5 in. (1.2 cm) from the buckle or clasp.

(8) Apply a tension of 20 lb (89 N) evenly over 5 s. and maintain for an additional 10 s.

§ XXXX.6 Marking and Labeling

(a) Each product and its retail package shall be marked or labeled clearly and legibly to indicate the following:

(1) The name, place of business (city, state, and mailing address, including zip

code), and telephone number of the manufacturer, distributor, or seller.

(2) A code mark or other means that identifies the date (month and year as a minimum) of manufacture.

(3) The marking or labeling in § XXXX.6(a)(1) and § XXXX.6(a)(2) are not required on the retail package if they are on the product and are visible in their entirety through the retail package. When no retail packaging is used to enclose the product, the information provided on the product shall be used for determining compliance with § XXXX.6(a)(1) and § XXXX.6(a)(2). Cartons and other materials used exclusively for shipping the product are not considered retail packaging.

(b) The marking and labeling on the product shall be permanent.

(c) Any upholstery labeling required by law shall not be used to meet the requirements of this section.

(d) Warning Design for Product:

(1) The warnings shall be easy to read and understand and be in the English language at a minimum.

(2) Any marking or labeling provided in addition to those required by this section shall not contradict or confuse the meaning of the required information or be otherwise misleading to the consumer.

(3) The warnings shall be conspicuous and permanent.

(4) The warnings shall conform to ANSI Z535.4–2011, American National Standard for Product Safety Signs and Labels, sections 6.1–6.4, 7.2–7.6.3, and 8.1, with the following changes.

(i) In sections 6.2.2, 7.3, 7.5, and 8.1.2, replace “should” with “shall.”

(ii) In section 7.6.3, replace “should (when feasible)” with “shall.”

(iii) Strike the word “safety” when used immediately before a color (for example, replace “safety white” with “white”).
NOTE — For reference, ANSI Z535.1, American National Standard for Safety Colors, provides a system for specifying safety colors

(5) The safety alert symbol and the signal word “WARNING” shall be at least 0.2 in. (5 mm) high. The remainder of the text shall be in characters whose upper case shall be at least 0.1 in. (2.5 mm), except where otherwise specified.
NOTE — For improved warning readability, avoid typefaces with large height-to-width ratios, which are commonly identified as “condensed,” “compressed,” “narrow.”

(6) Message Panel Text Layout:

(i) The text shall be left-aligned, ragged-right for all but one-line text messages, which can be left-aligned or centered.
NOTE — Left-aligned means that the text is aligned along the left margin, and in the case of multiple columns of text, along the left side of each individual column. See Fig. Y in the appendix for examples of left-aligned text.

(ii) The text in each column should be arranged in list or outline format, with precautionary (hazard avoidance) statements preceded by bullet points. Multiple precautionary statements shall be separated by bullet points if paragraph formatting is used.

(7) An example warning in the format described in this section are shown in Fig. X.

(e) Warning Statements — Each product shall have warning statements to address the following at a minimum.
NOTE — “Address” means that verbiage other than what is shown can be used as long as the meaning is the same or information that is product-specific is presented.

USING THIS PRODUCT FOR INFANT SLEEP OR NAPS CAN KILL.

Babies can turn, scoot, or roll over without warning and CAN SUFFOCATE in only a few minutes when airway is blocked.

- **Use only with an awake baby.** If baby falls asleep after feeding, move baby to a firm, flat sleep surface such as a bare crib or bassinet.
- **NEVER leave or prop baby alone in this product.** Do not use in sleep products like cribs, bassinets, or play yards.
- **KEEP baby in arms reach during use.** Stop using if you feel yourself falling asleep.
- **KEEP baby's face visible and airway clear.**

Babies have been injured from FALLS.

- Do not use to prop up baby on beds, sofas, or other raised surfaces.
- Never carry or move product with baby in it.

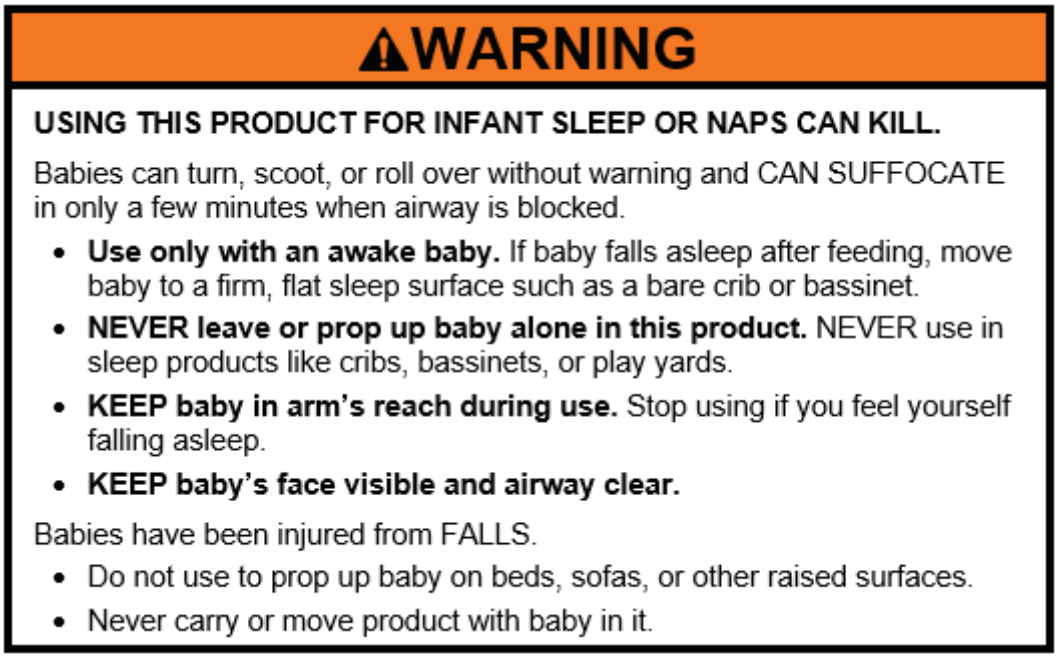

Fig. X. Example of Warning.

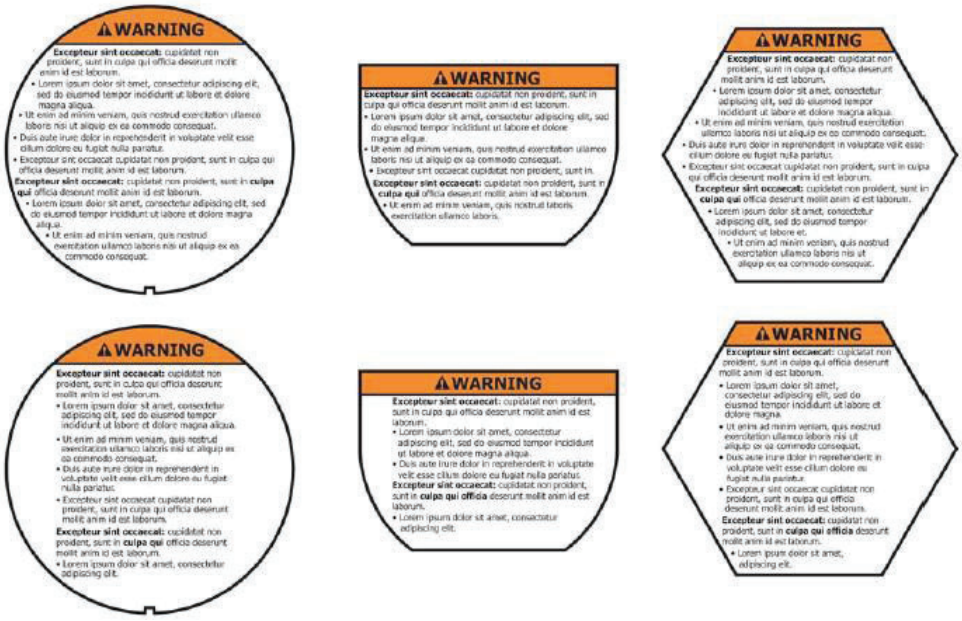

Fig. Y. Examples of Left Aligned Text.

Note—The text shown for these warnings is filler text, known as lorem ipsum, commonly used to demonstrate graphic elements.

(f) Package Warnings:
  (1) The warnings and statements are not required on the retail package if they are on the product and are visible in their entirety through the retail package. Cartons and other materials used exclusively for shipping the product are not considered retail packaging.
  (2) Warning Statements—Each product's package shall have warning statements to address the following, at a minimum, as specified in § XXXX.6(d)(1), § XXXX.6(d)(2), § XXXX.6(d)(4), § XXXX.6(d)(5), and § XXXX.6(d)(6).
    (i) Do not use for sleep.
    (ii) Do not use in sleep products like cribs, bassinets, or play yards.
  (3) Each product's retail package shall address the manufacturer's recommended weight, height, age, or developmental stage or combination thereof of the infant.
  (4) Warnings, statements, or graphic pictorials on the product and package shall not indicate or imply that the infant may be left in the product without an adult caregiver in attendance.

§ XXXX.7 Instructional Literature

(a) Instructions shall be provided with the product and shall be easy to read and understand and shall be in the English language at a minimum. These instructions shall include information on assembly, maintenance, cleaning, and use, where applicable.
(b) The instructions shall include all warnings specified in § XXXX.6(e).
(c) The instructions shall address the following additional warnings:
  (1) Read all instructions before using this product.
  (2) Keep instructions for future use.
  (3) Do not use this this product if it is damaged or broken.
  (4) Instructions shall indicate the manufacturer's recommended maximum weight,

height, age, developmental level, or combination thereof, of the infant for whom the nursing pillow is intended. If this product is not intended for use by a child for a specific reason, the instructions shall so state this limitation.

(d) The cautions and warnings in the instructions shall meet the requirements specified in § XXXX.6(d)(4), § XXXX.6(d)(5), and § XXXX.6(d)(6), except that sections 6.4 and 7.2–7.6.3 of ANSI Z535.4 – 2011, American National Standard for Product Safety Signs and Labels, need not be applied. However, the signal word and safety alert symbol shall contrast with the background of the signal word panel, and the cautions and warnings shall contrast with the background of the instructional literature.
NOTE — For example, the signal word, safety alert symbol, and the warnings may be black letters on a white background, white letters on a black background, navy blue letters on an off-white background, or some other high-contrast combination.

(e) Any instructions provided in addition to those required by this section shall not contradict or confuse the meaning of the required information or be otherwise misleading to the consumer.
NOTE — For additional guidance on the design of warnings for instructional literature, please refer to ANSI Z535.6, American National Standard: Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials.