



# Ballot Vote Sheet

**TO:** The Commission  
Alberta E. Mills, Secretary

**DATE:** April 10, 2024

**THROUGH:** Jessica L. Rich, General Counsel  
Austin C. Schlick, Executive Director

**FROM:** Daniel R. Vice, Assistant General Counsel, Regulatory Affairs  
Tayyaba W. Zeb, Attorney, Regulatory Affairs

**SUBJECT:** Notice of Availability and Request for Comment: Data Regarding Incidents Associated with Nursing Pillows

**BALLOT VOTE DUE:** April 16, 2024

The Office of the General Counsel is providing for the Commission’s consideration the attached draft notice of availability (NOA) and request for comment. The draft NOA announces the availability of and seeks comments from the public on data for fatalities and incidents associated with the Notice of Proposed Rulemaking, Safety Standard for Nursing Pillows, that addresses the risk of death and injury associated with nursing pillows (88 Fed. Reg. 65,865 (Sept. 26, 2023)). The Commission is also seeking comments on how a final rule should address nursing pillows covers.

Please indicate your vote on the following options:

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

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

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

II. Approve publication of the attached notice in the *Federal Register*, with the following 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: Draft *Federal Register* notice: Notice of Availability and Request for Comment: Data Regarding Incidents Associated with Nursing Pillows

Billing Code 6355-01-P

**CONSUMER PRODUCT SAFETY COMMISSION****16 CFR Parts 1112, 1130 and 1242****[Docket No. CPSC-2023-0037]****Notice of Availability and Request for Comments: Data Regarding Incidents Associated with Nursing Pillows****AGENCY:** Consumer Product Safety Commission.**ACTION:** Proposed rule; availability of supplemental information; request for comment.

**SUMMARY:** The U.S. Consumer Product Safety Commission (Commission or CPSC) published a notice of proposed rulemaking (NPR) in September 2023 to address the risk of death and injury associated with infant suffocations, entrapments, falls, and other hazards associated with nursing pillows. CPSC is announcing the availability of, and seeking comment on, details about incident data relevant to the rulemaking that are associated with infants and the use of nursing pillows. The Commission is also seeking comments on how a final rule should address nursing pillow covers.

**DATES:** Submit comments by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** Submit comments, identified by Docket No. CPSC-2023-0037, by any of the following methods:

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

*Mail/Hand Delivery/Courier Written Submissions:* Submit comments by mail/hand delivery/courier to: Office of the Secretary, U.S. 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](mailto:cpsc-os@cpsc.gov).

*Instructions:* All submissions must include the agency name and docket number for this notice. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: <https://www.regulations.gov>. Do not submit electronically: 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:* To read background documents or comments regarding this proposed rulemaking, go to: <https://www.regulations.gov>, insert Docket No. CPSC-2023-0037 in 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](mailto:tsmith@cpsc.gov); telephone: (301) 987-2557.

**SUPPLEMENTARY INFORMATION:**

Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) requires the Commission to promulgate consumer product safety standards for durable infant or toddler products. Under this statutory direction, in September 2023, the Commission published an NPR,

Safety Standard for Nursing Pillows, to reduce the risk of death and injury associated with nursing pillows. 88 FR 65865 (Sept. 26, 2023).

A nursing pillow is 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 Commission is considering how slipcovers (i.e., removable nursing pillow covers) should be regulated as part of nursing pillows. For instance, should the definition of "nursing pillow" specifically state that a slipcover sold as part of the nursing pillow is included within definition of a nursing pillow? Additionally, slipcovers sold with the nursing pillows can consist of those that are only intended to fit over the nursing pillow to change its look, or it can contain buckles or straps needed to attach or wear the nursing pillow. Should the Commission distinguish between slipcovers that do or do not contain functional attachments such as buckles and straps? Manufacturers of nursing pillows often sell replacement slipcovers. Should these replacement slipcovers, sold by the original manufacturer of the nursing pillow, be included within the definition of "nursing pillow"? The Commission invites public comments answering these questions and discussing how slipcovers should be regulated in the final rule.

In addition, the Commission is now making available incident reports underlying the data discussed in the NPR.<sup>1</sup> These reports have been redacted to protect personal information, confidential medical information, and other information protected from disclosure by section 6 of the CPSA. 15 U.S.C. 2055.

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<sup>1</sup> The Commission voted X-X on April XX, 2024, to publish this document.

The NPR contains information about incidents from two databases: the Consumer Product Safety Risk Management System (CPSRMS)<sup>2</sup> and the National Electronic Injury Surveillance System (NEISS).<sup>3</sup> Staff searched these databases for fatalities and incidents associated with nursing pillows and involving infants up to 12 months old (where the age was known), reported to have occurred between January 1, 2010, and December 31, 2022. For this timeframe, staff identified 154 fatal and 34 nonfatal incidents reported to CPSC. The NPR included information about the hazard patterns of fatal and nonfatal incidents, such as infants' ages, hazard scenarios, nursing pillow/infant placement, and product-specific concerns.

Relevant data from CPSRMS include incident reports from medical examiners, consumers, death certificates, and manufacturers. Some of the incident data are obtained from 124 in-depth investigations (IDIs) conducted by CPSC. Among these IDIs, 122 involved fatal incidents, and two involved nonfatal incidents. Other incident data was reported by firms to CPSC under section 15(b) of the CPSA, 15 U.S.C. 2064(b), which included 13 non-fatal incidents. CPSC also relied on incidents received from the public and state and local government agencies as well as medical examiner/coroner reports, which included 24 fatal incidents and one nonfatal incident. In addition, the data includes information obtained from eight death certificates.

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<sup>2</sup> CPSRMS includes data primarily from three groups of sources: incident reports, death certificates, and in-depth follow-up investigation reports. A large portion of CPSRMS data consists of incident reports from consumer complaints, media reports, medical examiner or coroner reports, retailer or manufacturer reports (incident reports received from a retailer or manufacturer involving a product they sell or make), safety advocacy groups, law firms, and federal, state, or local authorities, among others. It also contains death certificates that CPSC purchases from all 50 states, based on selected external cause of death codes (ICD-10). The third major component of CPSRMS is the collection of in-depth follow-up investigation reports. Based on the incident reports, death certificates, or NEISS injury reports, CPSC field staff conduct IDIs (on-site, via telephone, or online) of incidents, deaths, and injuries, which are then stored in CPSRMS.

<sup>3</sup> NEISS is the source of the injury estimates; it is a statistically valid injury surveillance system. NEISS injury data are gathered from emergency departments of about 100 hospitals, with 24-hour emergency departments and at least six beds, selected as a probability sample of all U.S. hospitals. The surveillance data gathered from the sample hospitals enable CPSC to make timely national estimates of the number of injuries associated with specific consumer products.

Data from NEISS contain incidents and injuries treated in U.S. hospital emergency departments. CPSC staff performed multiple searches consisting of a combination of product codes and narrative keyword searches to find nursing pillow incidents in NEISS. 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<sup>4</sup> in the narrative field across all product codes. Subsequent searches included several infant-related product codes<sup>5</sup> and searches in the narrative field for keywords related to known manufacturer names.<sup>6</sup> Staff then analyzed the results and determined that an event was in-scope if the product involved was identified as a nursing pillow that played a contributing role in the incident. Staff also included events as in-scope only if the infant was up to 12 months of age, or age was unknown but the incident likely involved an infant based on the description of the incident. The data were extracted in January 2023. The Commission relied on 18 records of nonfatal incidents from NEISS, associated with nursing pillows, all involving injuries resulting from falls.

The Commission invites comments on the incident data and analysis of this data in the NPR. CPSC is making available for review and comment the incident reports relied upon and discussed in the NPR, to the extent allowed by applicable law, along with the associated IDIs. To obtain access to the data, submit a request to: <https://forms.office.com/g/jrUSbYnWGx>. You will then receive a website link to access the data for this rulemaking at the email address you

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<sup>4</sup> Nurse pillo/nursi/feeding pillo/feed pillo/shape pillo/shaped pillo/support pillo/boppy/docka/dock a/atot/baby nest/flathead/flat head/pillow/pilow/feeding/bop.

<sup>5</sup> 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.

<sup>6</sup> Pilo/pillo/bop/shape/shappe/nurs/loung/docka/dock a/atot/nest/tofoan/to foan/frida/brest frien/breast frien/bamibi/bambi/balboa/mombo/lat nurs/miracl/minky/kids n such/snuggle/tillyou/till you/maman/doc a /occo/leach/cuddle/podster/nogg/tummy/choice/elephant/horsesh/horse sho/donut/circular/plush/peanut/doc-a comfy/kaki/iblin/lyu/yumo/onr/majik/cheer/lovel/humble bee/humble-bee/graco/luna lul/ergob/ergo b/Infantin/chilling home/chillinghome/blublu/twinz/twin z/lansino/Beaba/MomCozy/miracle baby/Ingenuity/Babestellar/Babymoov/Kushies/nesting pill/ecohealth pill/Sustainable Baby/zzzpal/zzz pal/Feeding Friend.

provide. Information on how to submit comments and contact information for CPSC's Office of the Secretary are in the **ADDRESSES** section of this notice.

Alberta E. Mills, Secretary  
Consumer Product Safety Commission.