- \* Consumer Federation of America \* Consumer Reports \* Kids In Danger \* Public Citizen
  - \* National Center for Health Research \* U.S. Public Interest Research Group \*

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Office of the Secretary Consumer Product Safety Commission 4330 East West Highway Bethesda, MD 20814

Joint Comments to the Consumer Product Safety Commission on the Notice of Proposed Rulemaking: "Safety Standard for Infant Support Cushions"

Docket No. CPSC-2023-0047

Consumer Federation of America, Consumer Reports, Kids In Danger, National Center for Health Research, Public Citizen, and U.S. Public Interest Research Group welcome the opportunity to comment on the notice of proposed rulemaking (NPR) by the U.S. Consumer Product Safety Commission (CPSC or Agency) on the Safety Standard for Infant Support Cushions. Our organizations strongly support the proposed rule, which addresses hazards associated with infant support cushions that put infants at an increased risk of injury or death.

For years, infant support cushions have been marketed and sold for a wide array of uses, including lounging and infant propping. Some were also marketed "for use in a crib or other infant sleep product." Putting babies to sleep for any duration in products that do not meet the requirements of the CPSC's Infant Sleep Product Rule<sup>3</sup> or another mandatory CPSC standard for infant sleep, such as the bassinet standard, runs directly counter to evidence-based safe sleeping practices established by the American Academy of Pediatrics (AAP). These expert safe sleep guidelines recommend placing a baby alone, on their back, on a firm, non-inclined surface in a safe sleep environment without soft objects or loose bedding. Despite these established safe sleep guidelines and warnings, incident data confirms that some caregivers use infant support cushions for sleep.

CPSC staff has reported at least 79 fatalities and 125 nonfatal incidents involving infant support cushions from January 1, 2010, through December 31, 2022. More than 90 percent of the fatalities involved infants six months old and younger, and a majority of the fatalities were

<sup>&</sup>lt;sup>1</sup> CPSC, "Notice of Proposed Rulemaking: Safety Standard for Infant Support Cushions" (Jan 16, 2024) (online at: <a href="www.regulations.gov/document/CPSC-2023-0047-0001">www.regulations.gov/document/CPSC-2023-0047-0001</a>).
<sup>2</sup> Id.

<sup>&</sup>lt;sup>3</sup> CPSC "Final Rule: Safety Standard for Infant Sleep Products" (Jan. 23, 2021) (online at: <a href="https://www.govinfo.gov/content/pkg/FR-2021-06-23/pdf/2021-12723.pdf">www.govinfo.gov/content/pkg/FR-2021-06-23/pdf/2021-12723.pdf</a>).

<sup>&</sup>lt;sup>4</sup> American Academy of Pediatrics, "Safe Sleep" (Aug. 21, 2023) (online at: <a href="www.aap.org/en/patient-care/safe-sleep">www.aap.org/en/patient-care/safe-sleep</a>); see also CDC, "Helping Babies Sleep Safely" (last accessed: Mar. 15, 2024) (online at: <a href="www.cdc.gov/reproductivehealth/features/baby-safe-sleep/index.html">www.cdc.gov/reproductivehealth/features/baby-safe-sleep/index.html</a>); NIH, "Safe Sleep Environment for Baby" (last accessed: Mar. 15, 2024) (online at: <a href="www.safetosleep.nichd.nih.gov/reduce-risk/safe-sleep-environment">www.safetosleep.nichd.nih.gov/reduce-risk/safe-sleep-environment</a>).

related to asphyxia or probable asphyxia.<sup>5</sup> Many of the nonfatal incidents involved the infant occupant falling from the product on an elevated surface.<sup>6</sup>

With regard to the specific information requested by the CPSC, our organizations offer the following comments:

## Scope & Definition:

The CPSC invited the public to comment on the scope of the proposed rule, including whether the "proposed definition of "infant support cushion" is sufficient to include all infant support cushions that are not subject to the Federal Hazardous Substances Act (FHSA) infant pillow ban." We support the CPSC's proposed scope and definition for this product category.

The proposed rule defines an "infant support cushion" as "an infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material, or with a gel, liquid, or gas, and which is marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position." This includes infant pillows, infant loungers, nursing pillows with a lounging function, infant props or cushions used to support an infant for activities such as "tummy time," and other similar products.

The list of products covered by the proposed infant support cushion definition is sufficiently broad and would include products AAP and other safety groups currently warn caregivers against using, including infant sleep positioners, wedges meant to incline an infant sleep surface, infant "self-feeding" pillows, and head positioner pillows. The products listed in the proposed scope of the safety standard are not necessary for the care and protection of an infant. The new requirements in the proposed rule would help to ensure that the products within the scope of this rule will either incorporate necessary changes to become safer or lose their perceived utility and be removed from the marketplace.

Some infant support cushion products may also have battery-operated features designed to vibrate and help soothe babies. We are concerned about such features and the CPSC should review the use of battery-powered movement or vibration in these products, since they seem to be intended to encourage sleep. That would obviously be inappropriate for this type of product, in addition to introducing the hazards from batteries. We recommend prohibiting soothing features such as vibration that would encourage using the products for sleep.

## Warning Labels

We support the proposed rule's requirements for warning labels, which will help inform parents and caregivers about the hazards associated with infant support cushions. While warnings alone cannot adequately reduce hazard exposure, conspicuous and clear warnings on infant support cushions can provide important safety information.

The proposed rule would require on-product warning labels to be "conspicuous," defined as "visible, when the product is in each manufacturer's recommended use position, to a person while placing an infant into or onto the product." Additionally, the warning labels must be

<sup>&</sup>lt;sup>5</sup> Supra note 1.

<sup>&</sup>lt;sup>6</sup> *Id*.

<sup>&</sup>lt;sup>7</sup> Id.

<sup>&</sup>lt;sup>8</sup> *Id.* 

permanent. The proposed rule would adopt the ASTM warning label for infant loungers and should indicate that the product should be used only on the floor, with infant face-up on its back. The example warning also clearly and correctly states that using the product for sleep or naps "CAN KILL."9

The proposed rule should also require on-product warning labels on replacement covers ensuring that critical safety information is easily and clearly accessible on infant support cushions at all times. On-product warning labels are the only way to convey safety information while the product is in use. The warning requirements are clearly stated in the rule and can be added easily to replacement covers, along with any additional warnings required for the specific product.

Manufacturers of infant support cushions should not have the ability to remove the "with baby face-up on back" language from warning labels.

The CPSC requested comments on whether manufacturers should have the flexibility to remove or change the "with baby face-up on back" language in the warning label. Our organizations do not support permitting manufacturers to remove the "with baby face-up on back" language, even for products that are currently sold for "tummy time," which is when infants spend awake time laying on their stomach to develop strength and rolling ability and to prevent flat head syndrome. This practice is an important part of the Safe to Sleep campaign, which has reduced infant sleep-related deaths. 10 In order to ensure that the warnings are clear for all infant support cushions, we recommend the CPSC require manufacturers of products used for "tummy time" to include the language "with baby face-up on back except during active tummy time with a caregiver within arm's reach," or similar language. To be clear, special pillows and mats are not needed to practice tummy time regularly - a blanket or play mat on the floor is sufficient.

Warning labels must account for all possible uses and the CPSC should ensure safety information is visible and clearly warns against using infant support cushions in any sleep environment.

Some of the products included in the scope of this new rule have traditionally been sold for use in sleep environments, including:

- head positioner pillows;
- crib pillows;
- wedge pillows for infants:
- infant sleep positioners, unless regulated by the Food and Drug Administration (FDA) as medical devices:
- stuffed toys marketed for use as an infant support cushions; and
- anti-rollover pillows with or without straps that fasten the pillow to the infant.

If these products remain on the market and meet the proposed standard, it is foreseeable that caregivers will still use them in the same way in cribs and bassinets. While this rulemaking may mitigate the risk of injury and death, these products would still be unsafe to use in sleep environments, as the warnings would indicate. If the warning is the only feature that advises against using in a sleep environment, the CPSC should consider ways to more clearly emphasize the warning against this use -- especially on products that are most likely to be used

<sup>&</sup>lt;sup>9</sup> *Id.* 

<sup>&</sup>lt;sup>10</sup> NIH, "Safe to Sleep" (last accessed: Mar. 15, 2024) (online at: <a href="www.safetosleep.nichd.nih.gov">www.safetosleep.nichd.nih.gov</a>).

in an infant's sleep environment. It is critical for these warning labels to be visible and to clearly stress the dangers associated with using these products in infant sleep products, on adult beds or on other soft surfaces.

## **Sidewall Height & Incline Angle Requirements**

We support the proposed requirement that would limit infant support cushions' sidewall height to 1.9 inches (4.8 cm). Higher sidewall heights, such as the 4-inch sidewall height limit proposed in the draft ASTM standard, would send a dangerous message to parents and caregivers that the product can safely contain an infant without constant adult supervision. Additionally, a 4-inch sidewall height can potentially be used to position an infant's head, creating a suffocation hazard.

We also support the proposed requirement that would limit any incline of the occupant support surface of an infant support cushion to less than 10 degrees. The proposal is consistent with leading research on safe infant sleep, CPSC's Safety Standard for Infant Sleep Products, and the ban on inclined infant sleepers in the Safe Sleep for Babies Act.

## **Firmness**

We support the CPSC's firmness requirements and test methods, which are consistent with the requirements for crib mattresses and with the recommendations outlined in a June 2022 CPSC-commissioned Boise State University report titled "Pillows Product Characterization and Testing" (BSU Report). According to the BSU Report, products that lack firmness are more likely to conform around an infant's nose and mouth and to present a suffocation hazard. The CPSC's proposed test method for firmness, in conjunction with the proposed sidewall height requirement, would help to address the suffocation hazard and likely prevent an infant's face from conforming to a surface of the infant support cushion. We stress that while we support the firmness requirements, infant support cushions are not safe for any duration of infant sleep and should never be used in any infant sleep product or on adult beds, or on other soft surfaces."

## **Effective Date & Stockpiling**

We strongly urge the CPSC to adopt the earliest possible implementation date, and no later than the proposed 180 days. In addition, we urge the agency to take action to prevent manufacturers from increasing production of, or "stockpiling," noncompliant infant support cushions and to prevent sellers from putting on the market large quantities of products that would not comply with this rule. We urge the CPSC to monitor the marketplace diligently, and enforce the rule robustly, to ensure non-compliant products are not for sale and prevent them from putting babies at risk of serious injury and death.

<sup>11</sup> 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. (<a href="https://www.cpsc.gov/content/Pillows-Product-Characterization-and-Testing">www.cpsc.gov/content/Pillows-Product-Characterization-and-Testing</a>).

# **Conclusion**

We thank the CPSC for the opportunity to provide comments regarding infant support cushions and urge the agency to finalize the proposed rule expeditiously. We also note that it is critically important for the CPSC to continue its diligent surveillance of data, with the goal of confirming that injuries and deaths associated with infant support cushions decline significantly.

Thank you for your consideration of our comments.

Respectfully submitted,

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