



IMPROVING
CHILDREN'S
PRODUCT
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POLICY & ACTION FROM
CONSUMER REPORTS

U.S. PIRG
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State PIRGs



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Consumer Product Safety Commission
Room 820
4330 East-West Highway
Bethesda, Maryland 20814

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**Comments of Kids In Danger, Consumer Federation of America, Consumers Union, and
Public Citizen to the U.S. Consumer Product Safety Commission on the Notice of Proposed
Rulemaking
“Safety Standard for Infant Inclined Sleep Products”
Docket No. CPSC-2017-0020**

I. Introduction

Kids In Danger (KID), Consumer Federation of America (CFA), Consumers Union (CU), and Public Citizen (PC) submit the following comments to the U.S. Consumer Product Safety Commission (“CPSC” or “Commission”) in the above-referenced matter.¹

Section 104(b) 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. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standards if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product.

In the Notice of Proposed Rulemaking, the Commission proposes a mandatory safety standard for infant inclined sleep products that is based on the voluntary standard developed by ASTM International (ASTM F3118-17), but with one definition change.² As we express in the following comments, we have significant concerns with the hazards posed by the entire product class of infant inclined sleepers. While we support the implementation of a strong mandatory

¹ Safety Standard for Infant Inclined Sleep Products, Notice of Proposed Rulemaking. Federal Register, Vol. 82, No. 66, 16963 (Apr. 7, 2017).

² Specifically, the Commission proposes to modify the definition of “infant and newborn inclined sleep product accessories” to remove the phrase “rigidly framed” so that the standard will include recently-identified soft-sided products that attach to cribs and play yards. *Id.*

safety standard – with a goal of making these products as safe as a compliant full-size crib – we propose several recommendations to improve the standard in a manner that will ensure it protects our most vulnerable family members.

II. Background

Infant inclined sleep products were not specifically addressed in section 104 of the CPSIA. Similar products had been included in the past in the ASTM International bassinets and cradles standard (ASTM F2194-13) – but that standard now requires a flat surface. Like bassinets, infant inclined sleep products are used for the youngest of consumers: newborn infants. These small, usually portable products can be used to keep babies near their parents, as they take up less room than a full-size crib. However, unlike bassinets, infant inclined sleep products do not place the baby in the recommended flat sleep position. The policy of the American Academy of Pediatrics is that all babies should be placed to sleep wholly on their back in a crib, play yard, or bassinet that meets CPSC standards.³ Some parents might believe their baby sleeps better at an incline, which may explain the rise in these types of products. However, there have been no studies that show this to be true, and most safe sleep professionals support a flat sleep surface. In addition, many of these products require a restraint for infant retention. There has been little, if any, academic study on the impact of continuous restraining on infants and development or the risks that restraints could pose in a sleep environment.

Infant inclined sleep products are designed for infants who are not likely to distinguish between daytime and nighttime sleeping, but rather nap throughout the entire 24-hour period. The parents or primary caregivers of these infants are likely to be operating on less sleep, and if the infant is a first child, be less familiar with baby gear and care. In addition, many other caregivers may use the product. Visitors, grandparents, helpers and others may be as likely to lay the baby down to sleep as the parent. Since new parents often sleep or nap when their baby is sleeping or have other children or activities requiring their attention throughout the house, it should be expected that babies will sleep unattended in inclined sleep products, both at night and during the day. Therefore, it is vital that these sleep environments offer infants the same measure of safety as a full-size crib.

III. Discussion & Recommendations

Our organizations have concerns about the entire product class of infant inclined sleep products, especially hammocks that have no discernable bottom support and may lead to posture or positioning that compromises infant safety. If the proposed standard is approved, we recommend enhancements to ASTM F3118-17 to address additional hazards, and we urge the Commission to address these hazards in the final rule. It then would be incumbent on the CPSC to keep noncompliant products off the market.

³ American Academy of Pediatrics, “How to Keep Your Sleeping Baby Safe: AAP Policy Explained” (Jan. 12, 2017) (online at www.healthychildren.org/English/ages-stages/baby/sleep/Pages/A-Parents-Guide-to-Safe-Sleep.aspx).

A. Concerns with the product class of infant inclined sleep products

As addressed in the background, our groups have significant concerns with the class of infant inclined sleepers. It was with CPSC support that the ASTM standard for bassinets was changed to require a flat surface and not include restraints. Products that cannot meet the bassinet standard simply may now fall under the scope of another category of product which allows the potentially hazardous conditions of an incline and a restraint.

In the Notice of Proposed Rulemaking, the CPSC notes 151 reports of physical deformations such as plagiocephaly (or “flat head syndrome”) and torticollis (or “twisted neck syndrome”) from extended product use. The notice does not make clear how many hospitalizations or emergency department visits were due to these conditions, which – while not unique to the use of inclined sleep products – have not been the subject of enough study, particularly to determine the impact of holding a child in place either with restraints or design of the product in a relatively small space. While CPSC staff has not recommended any changes to the standard to address these conditions, more work should be done to determine if inclined products increase the incidence of these conditions as compared to flat sleep environments such as cribs, play yards, and bassinets.

Another issue of concern is the use of restraints in a sleep environment. This is potentially hazardous for two reasons: (1) if the restraints are used, they may hold the child in an unsafe position; or (2) if the restraints are not used, they may create a strangulation hazard or fail to keep the child in the product. Similar to our concerns over head and neck conditions, we are also concerned that holding a baby in one position while sleeping may not be developmentally desirable.

Indeed, the CPSC cites fatalities as having occurred in these products that involved both the use and nonuse of restraints and babies moving into unsafe positions in the products. Section VI of the notice highlights ten fatalities and four injuries that the Commission has deemed “non-product-related.” In six of the fatalities, the restraint was not used, which led to asphyxiation. In this context, we consider “non-product-related” to be an inappropriate label for the incidents, given the understandable reasons that consumers may decide not to use restraints and the possibility that manufacturers could design the product better to address real-world use. It is foreseeable that a parent who turns to these specialized products in large part to help a fussy baby sleep might not want to disturb the child by wrangling them into a restraint when they are laid down. If an infant sleep product requires the use of restraints to make the product safe for sleep, then the product has a significant design problem that could pose risks to infants.

Another concern is the possibility that baby hammocks – which are responsible for a number of deaths – would fall into this standard, and the standard might not adequately address the risks posed by these products. No performance requirements have been included in the proposed standard to prevent potentially lethal misassembly or improper leveling of these products.

B. Additional issues to address

The CPSC's incident data illustrates that additional safety issues are not being addressed adequately by the current standard or by the CPSC's proposed modifications. We encourage the CPSC to add language to address the hazards we outline below:

1. More research on the 30-degree angle: We understand that the maximum 30-degree angle included in the definition of "infant inclined sleep product" was chosen in the voluntary standards-setting process because there were products up to that angle already on the market. Instead, the CPSC should consider if a lower maximum angle closer to the recommended flat sleep position would be safer. For instance, Canada only allows up to a 7-degree angle in their sleep products, which would fall under the 10-degrees allowed in the bassinet standard.
2. Judging from extensive discussions at ASTM International on the bassinets and cradles standard, the side height requirement proposed in the voluntary standard for infant inclined sleep products – and not amended by the CPSC – may be inadequate to contain an infant in all circumstances. This provision should match the bassinet requirement for side height of 7.5 inches.⁴
3. Restraint use in longer sleep periods: As mentioned above, restraints may be less likely to be used in a sleeping product if parents are unwilling to disturb a sleeping baby to fit them in the restraints. While some fatalities involved engaged restraints, they also may pose a strangulation hazard if not used. In addition, not enough research has been done on the impact of holding a baby in a restrained position in a confined space for prolonged sleep.
4. Likelihood of compact, freestanding inclined sleep products being used on raised surfaces (which could present a fall hazard) or in a crib or on a couch (which could present an entrapment hazard): While these products include warnings against this use, performance or design changes may be needed to reduce the likelihood of harm. For instance, with regard to rigid surfaces such as countertops and tabletops, a resistance to motion (or slip resistance) test could be developed, similar to the one that exists as part of the hand-held infant carriers standard (ASTM F2050-16). We also note that some non-compact inclined infant sleep products are held up on legs, which may make it less likely they will be placed on a raised or soft surface.
5. The CPSC notes that the voluntary standard for infant inclined sleep products sets a performance standard for the usable seat back to prevent older babies from being placed in smaller units that might not be able to safely contain an older, more mobile baby (ASTM F3118-17, subsection 6.10). However, that provision only addresses the newborn versions of these products – those meant to hold newborns up to three months of age. The voluntary standard, as it pertains to products for older babies, has no such requirement to

⁴ See ASTM F2194-13, which the CPSC incorporated by reference at 16 C.F.R. Part 1218.

keep babies older than five months from being placed in the product. As babies become more mobile, the dangers from getting themselves into a hazardous position become more likely to occur.

6. We have particular concerns about hammocks, since the placement of the infant and the leveling adjustment of the product can take a potentially safe product and turn it into a very likely unsafe product. Additional requirements to increase stability and a flat sleeping surface that doesn't allow the baby to move into a curved head-to-chest position should be included.
7. Most reported deaths in sleep environments involve the hazardous addition of soft bedding materials and/or prone sleeping by the baby. ASTM F2194-13, the voluntary bassinets and cradles standard incorporated by reference by the CPSC, includes clear, conspicuous, and strongly worded warnings about these hazards. While the voluntary standard for infant inclined sleep products also includes required warning labels about these hazards, our organizations encourage the CPSC to add pictograms to the warnings to more effectively convey the hazards and avoid language barriers that minimize comprehension of the warning labels. For instance, using the internationally recognized symbol of a red circle with a line through it, the CPSC could draft pictograms showing a prone baby with his or her face on or near a pillow or other padding. Examples of existing warnings that incorporate pictograms can be found in ASTM F2050-16, Standard Consumer Safety Specification for Hand-held Infant Carriers, and ASTM F2907-15, Standard Consumer Safety Specification for Sling Carriers.
8. If the proposed standard is finalized, we recommend that the CPSC require a marking on products that meet the new mandatory standard so that consumers can clearly identify them.

C. Enforcement of class to avoid similar hazardous products

If the CPSC moves down this path to establish new product categories under its regulations other than cribs, play yards, and bassinets for unattended sleep, care must be given to avoid having products that do not meet these standards taking themselves out of the scope of the standard through minor product changes. Especially as products are not required to disclose the standards they meet on the product, consumers are likely to assume that all similar products are tested for safety to a mandatory standard. If finalized, the proposed standard will require market surveillance to avoid the creep of similar but out-of-scope products that pose hazards.

D. Effective date

The CPSC proposed an effective date of 12 months after publishing the rule in the Federal Register. The more common six-month period would be more appropriate and bring safer products to market sooner.

IV. Conclusion

Our organizations are concerned with the hazards infant inclined sleep products may pose that have not been fully addressed by the voluntary standard ASTM F3118-17. Fatalities involving relatively newer products also are concerning. While we support the implementation of a strong mandatory safety standard for infant inclined sleep products, we hope the CPSC again reviews some of the gaps in safety, and considers adding additional requirements in line with what we have recommended. Like bassinets, infant inclined sleep products can be used for the most vulnerable infants by the most inexperienced and sleep-deprived caregivers. These products are used in a variety of settings by a variety of individuals. Infants using these products sleep intermittently throughout the day and night. Safety should be paramount – particularly because these products do not align with the trusted safe sleep recommendations advised by both medical practitioners and other safety experts.

Respectfully submitted,

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