



Consumer Federation of America

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Office of the Secretary
U.S. Consumer Product Safety Commission
Room 502
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Bethesda, Maryland 20814
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Comments of Rachel Weintraub, Legislative Director and General Counsel with Consumer Federation of America to the U.S. Consumer Product Safety Commission regarding the Notice of Proposed Rulemaking of Ban of Inclined Sleepers for Infants, CPSC Docket No. 2022-0025

Consumer Federation of America (CFA) is an association of non-profit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy, and education. CFA submits these comments in response to the U.S. Consumer Product Safety Commission's (CPSC) Notice of Proposed Rulemaking (NPR) regarding the Ban of Inclined Sleepers for Infants.

CFA strongly supports the Safe Sleep for Babies Act (SSBA), which became law on May 16, 2022 and the CPSC's Safety Standard for Infant Sleep Products (ISP), which became effective on June 23, 2022.

This law and this rule are needed because of the dire consequences posed by inclined sleeping environments for babies. The American Academy of Pediatrics' (AAP) Safe Sleep Guidelines state, "Recommendations for a safe sleep environment include supine positioning, the use of a firm sleep surface, room-sharing without bed-sharing, and the avoidance of soft bedding and overheating."¹ Since babies should only sleep on a flat surface, the category of infant products that contradicted that message by their existence in the marketplace proved problematic and unsafe. Thus, the passage of the Safe Sleep for Babies Act and the CPSC's Safety Standard for Infant Sleep Products is incredibly important to protect babies as they sleep.

Of vast importance also, is that the CPSC prioritizes enforcing this law and this rule to ensure that no loopholes are inadvertently created that would allow inclined infant sleep products that

¹ American Academy of Pediatrics, Task Force On Sudden Infant Death Syndrome. (November, 2016). SIDS and Other Sleep-Related Infant Deaths: Updated 2016 Recommendations for a Safe Infant Sleeping Environment. Retrieved from: <https://pediatrics.aappublications.org/content/138/5/e20162938>

are intended for sleep to be rebranded in some way to not fall under the law or the rule, and claim they are not intended for sleep.

Hazard

CPSC has reports of 73 deaths from infant inclined sleep products: 14 deaths were reported to the CPSC before the 2017 Notice of Proposed Rulemaking (NPR) and 59 deaths were reported since the 2017 NPR through June 30, 2019. In addition, there were 392 non-fatal incidents reported. These deaths and injuries were caused in large part by the design of the sleeping products. Babies rolled over partially or fully from their backs. Some of these babies died as a result of suffocation and asphyxiation.²

These suffocation, asphyxiation, and positional asphyxia deaths are explained in a report authored by Dr. Mannen who was commissioned by the CPSC to conduct research on the design of infant inclined sleep products. One of Dr. Mannen's findings was that "inclined surfaces and inclined sleep products resulted in significantly higher muscle activity of the turn core muscle, which may lead to quicker fatigue and suffocation if an infant finds themselves prone in an incline sleep product."³ Dr. Mannen also found that "none of the inclined sleep products that were tested and evaluated as a part of this study are safe for infant sleep."⁴ Dr. Mannen found that a 20 degree incline "puts babies at risk for muscle fatigue and suffocation,"⁵ while a "10 degree incline does not significantly impact infant motion or muscle activity."⁶ Sleeping in an inclined position also poses a positional asphyxia risk for infants which occurs when the position of the head and neck can lean downward, obstructing the airway.

Responses to Questions Posed in the NPR

1. Effective Date

The NPR includes that the CPSC proposes to implement the inclined sleeper ban in the SSBA with an effective date of November 12, 2022 and asks whether a date later than November 12, 2022 should be adopted. CFA does not believe that a date later than November 12, 2022 should be adopted. The SSBA is clear that the effective date should be 180 days after enactment and there is no reason to extend this any further.

2. Interpretation

a. How should the Commission Interpret the phrase "sleeping accommodations" for purposes of the SSBA Ban?

We previously expressed our support for the definition of infant sleep products as included in the Supplemental NPR for the Infant Sleep Products Rule, defined as "products that provide sleeping accommodations for infants and are not currently covered by bassinets/crib, cribs (full-size and non-full size), play yards, and bedside sleepers, as a durable infant or toddler product under

² U.S. Consumer Product Safety Commission, Safety Standards for Infant Sleep Products, Federal Register, Vol. 84, No. 218, Tuesday, November 12, 2019, at 60953.

³ Ibid. at 60954.

⁴ Ibid.

⁵ Ibid.

⁶ Ibid.

section 104(f) of the CPSIA.”⁷ We continue to support this definition. In addition, we urge that the CPSC interpret “sleeping accommodation” in a way that reflects the reality of how babies routinely sleep- covering both naps and overnight sleeping. Babies sleep frequently, especially younger infants, and sleeping accommodations must include inclined sleep products marketed, intended, and designed for sleep, that parents use for their routine sleeping needs.

b. What, if any, effect should inclusion of the term “designed” in the SSBA have on the Commission’s interpretation and implementation of the SSBA?

The SSBA bans inclined sleepers through considering them as a banned hazardous product under Section 8 of the Consumer Product Safety Act. The SSBA defines inclined sleepers as a “product with an inclined sleep surface greater than ten degrees that is intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old.” The ISP Rule defines an infant sleep product as a “product marketed or intended to provide a sleeping accommodation for an infant up to 5 months of age,” and that is not already subject to one of CPSC's mandatory standards for infant sleep...”

According to Merriam Webster online, the definition of design is, “to create, fashion, execute, or construct according to plan; to have as a purpose; to devise for a specific function or end.”⁸ Marketed is defined at “exposed for sale in a market.”⁹ And intended is defined as, “expected to be such in the future; intentional.”¹⁰

CFA believes that the inclusion of the term “designed” in the language of the SSBA indicates that Congress wanted to clearly establish a ban of all inclined sleep products and wanted to include those products that in addition to being intended and marketed as sleep products were also created, specifying an earlier state in the development of the product, as compared to intended and sold, with the purpose to provide a sleep environment for an infant. The inclusion of designed signals that Congress wanted to ban all inclined sleep products and wanted to prevent a rebranding of inclined sleep products to get out of the scope of the law. We urge the CPSC to similarly include language to ensure regulatory compliance and prevent the use of marketing changes to fall outside of this regulatory framework.

c. In the SSBA, what product characteristics, if any, demonstrate that a product is “designed” for sleep?

Product characteristics that demonstrate that a product is “designed” for sleep can include that the product was created and executed with the purpose of providing a sleeping accommodation for infants, including: providing a physical space for an infant to be placed unattended during sleep; including characteristics that would signal a sleeping environment such as elements that would induce sleep- such as calming, or soothing, vibrations, lights or sounds that could be turned on and off, padded elements similar to that of a basinet or crib, the absence of elements

⁷ U.S. Consumer Product Safety Commission, Safety Standards for Infant Sleep Products, Federal Register, Vol. 84, No. 218, Tuesday, November 12, 2019, at 60950.

⁸ <https://www.merriam-webster.com/dictionary/designed>

⁹ <https://www.merriam-webster.com/dictionary/marked>

¹⁰ <https://www.merriam-webster.com/dictionary/intended>

that imply or encourage engagement by an infant, and the absence of a non-sleep purpose such as use in a motor vehicle or other transportation, or feeding.

d. How should the Commission interpret and implement the terms “marketed” and “intended” as a sleeping accommodation in the SSBA? Should the terms be interpreted and implemented the same as the ISP rule? Why or why not?

The CPSC should interpret and implement the terms, “marketed” and “intended” in the same way for both the ISP Rule and the SSBA. These terms are included to specify what an inclined sleep or sleep product is for an infant. The terminology should provide the CPSC with effective authority to ban inclined sleep products for babies and having the same interpretation would create a clearer regulatory framework for the CPSC, consumers and users of these products, and the regulated community.

e. What is the significance of the age distinction between the ISP Rule and the SSBA’s ban? How might this difference bear on the implementation of the SSBA as compared to the ISP Rule, versus a newborn to a 1-year-old as identified in the SSBA?

Babies older than five months should not be sleeping in some of the products covered by the ISP Rule. All infant products should be covered by a standard. Younger and older infants have different developmental needs and behaviors such as rolling over, that must be considered for all infant sleep environments. However, the bassinet standard is appropriate to cover products for children under five months old. The fact that the SSBA law includes infants up to 1 year is helpful to the CPSC because it broadens the agency’s authority to include inclined sleep products for infants over five months. In addition, the age range keeps current infant sleep products from being marketed and designed for an older age child, while the product is intended for a younger infant.

f. How, if at all, should the SSBA’s ban of inclined for infants affect the ISP Rule or the Commission’s application of it?

CFA strongly supports both the CPSC’s Infant Sleep Rule and the Safe Sleep for Babies Act. The ISP Rule provides much needed strong protective standards for sleep products that were not previously covered by a standard and is consistent with safe sleep principals articulated for decades by doctors and other public health experts.

Similarly, the SSBA, is significant because it explicitly bans two types of products associated with unsafe sleep environments. We urge the CPSC to use both the rule and the law as the basis for its authority to ensure that babies have safe sleep environments.

3. Testing and Certification

We hope that the consequence of the clear language of the ISP Rule and the SSBA is to effectively ban infant sleep products that pose risks to babies. While we hope that such products will not remain in the marketplace, but if for some reason, they do, we urge the CPSC to use all of its authority, including enforcement, testing and certification to protect infant sleep environments.

Conclusion

CFA has consistently and strongly supported both the CPSC's ISP Rule and the SSBA. We appreciate that the CPSC is seeking to reconcile both of these provisions while prioritizing the safety of infants. We urge the CPSC to finalize this rule as quickly as possible to ensure that the impacts of these important sources of law impact the marketplace as soon as the laws allow.