September 26, 2019

The Honorable Ann Marie Buerkle, Acting Chairman
The Honorable Robert Adler, Commissioner
The Honorable Elliot Kaye, Commissioner
The Honorable Dana Baiocco, Commissioner
The Honorable Peter Feldman, Commissioner
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, Maryland 20814

Dear Acting Chairman Buerkle, Commissioners Adler, Kaye, Baiocco, and Feldman:

We, the undersigned five national medical, public health, and consumer organizations, write to convey our concern for the widespread prevalence of unsafe sleep products for infants, and to provide a set of principles to inform standard setting and regulatory decisions for any sleep-related infant products.

The substantial progress on reducing sleep-related deaths that began in the 1990s has plateaued, leaving significant need for public health interventions to reduce Sudden Unexpected Infant Death (SUID). The U.S. Centers for Disease Control and Prevention (CDC) estimates that there are about 3,500 cases of SUID in the U.S. annually, which includes sudden infant death syndrome (SIDS), accidental suffocation in a sleeping environment including positional asphyxia, and other deaths from unknown causes.[1] The Consumer Product Safety Commission (CPSC) and, due to the statutory reliance on voluntary standards, ASTM International have a critical role to reduce the risk of injuries and deaths from consumer products, and consistent regulatory action is needed to protect infants from sleep-related products that are not safe for sleep and pose a fatality risk.

Infants are uniquely vulnerable in their early stages of development, when immature cardiorespiratory or arousal systems can lead to a failure of the protective responses that older children exhibit.[2] Because of these developmental differences, a sleeping position or environment that is perfectly safe for an older child can pose potentially fatal risks for infants. Additionally, certain risk factors, including maternal smoking during pregnancy and unsafe sleep environments, contribute to the likelihood of SUID. Considering the inherent vulnerabilities of infants, the following principles for safe sleep should inform the work of the CPSC and ASTM International, including for emerging products and those not currently included in a product category or standard.

1. **Supine Position**

Infants are safest when placed for sleep in a supine position, wholly on the back, for every sleep until the child reaches one year of age. The best evidence suggests that prone and side sleeping positions are risk factors for SIDS for infants. Based on this research, the "Back-to-Sleep" campaign was initiated in 1994 to encourage parents to place their babies for sleep in the supine position, resulting in much higher rates of infants sleeping in the supine position.[3] Importantly, sleeping wholly on the back does not increase the risk of choking and aspiration in infants, even

those with gastroesophageal reflux.[4,5] Sleep positioning products that keep an infant on his or her side are not safe for infants, because they may cause the infant to roll over and suffocate against the mattress or the positioner.

2. Firm, Flat Sleep Surface

To reduce the risk of SIDS, infants should be placed on a firm mattress that retains its shape. Soft mattresses, including those made from memory foam, could create an indentation and increase the chance of rebreathing or suffocation if the infant rolls over to the prone position. The safest sleep environments for infants are cribs, bassinets, portable cribs, or play yards that conform to CPSC mandatory safety standards. Sitting devices, such as car seats, strollers, swings, infant carriers, and infant slings, are not recommended for routine sleep, particularly for young infants.[6,7,8,9,10,11] Research has identified infant sleep-related deaths in inclined sitting devices that are used for sleep in nontraveling contexts.[12,13]

Products that position infants at an incline pose a risk of asphyxia when the infant assumes a position where the airway is obstructed by fabric, bedding, or other materials. Infants are also at risk for positional asphyxia, which is when a non-neutral position of the head and neck obstructs the airway. When sleeping at an incline, an infant's head can slump downwards and potentially constrict or obstruct the airway. Depending on the infant's developmental trajectory, any age up to 1 year may be at risk.

Due to these hazards, infant inclined sleep products are inherently unsafe. The CPSC should terminate the process to make the ASTM standard for infant inclined sleep products mandatory, because these products inherently are incompatible with safe sleep, and thus any standard will not keep infants safe. Instead, all devices intended for infant sleep that do not fit into the CPSC crib or play yard standards should be subject to the bassinet safety standard, which does not allow an incline above 10 degrees. Including infant inclined sleep products in the safety standard for bassinets and cradles would protect infants from the suffocation hazards of products that are not suitable for long-term sleep by holding them to a rigorous existing safety standard and no longer allowing these products to remain on the market without meeting any current standard. In addition, we urge ASTM International to eliminate this product category altogether, as it provides a misleading sense of safety to parents and caregivers.

3. Bare is Best

An increasing number of unregulated sleep products that provide no added safety benefit to infants, and in fact can pose a risk for suffocation, can be found on the market. Soft objects such as pillows and pillow-like toys, quilts, comforters, sheepskins, sleep positioning products, and loose bedding such as blankets and nonfitted sheets can obstruct an infant's nose and mouth, posing a risk of suffocation, entrapment, or SIDS. Given current safety standards for crib slat distance, padded crib bumper products are not necessary to prevent head entrapment, and they can lead to suffocation when an infant's face is pressed against the side of the crib.[14,15] More research is need to verify the safety of supposedly "breathable" crib liners, as the risks of suffocation may outweigh the minimal safety benefit. The safest sleep environment for an infant is a crib, bassinet, portable crib, or play yard that conforms to CPSC standards and is free of soft

objects and loose bedding. We support the banning of crib bumpers federally, as several state and local jurisdictions have already successfully done.

4. **Same Room, Different Bed**

Evidence suggests that that sleeping in the parents' room but on a separate surface decreases the risk of SIDS by as much as 50%.[16] Infants sleeping in an adult bed are at higher risk of suffocation, strangulation, and entrapment.[17] However, products that purport to safely position infants in adult beds are growing in popularity. There is insufficient evidence to assure the safety of in-bed sleep products, and many of these products have soft sleep surfaces, and non-rigid sides that pose a suffocation risk. Products that are on the market should either fit within a safety standard that provides a formal mechanism to determine their safety based on the evidence, or be removed from the market. We are concerned that absent proactive action to affirmatively assure the safety of these products, parents and caregivers will assume they are safe, which could lead to dangerous outcomes.

Protecting Children and Reducing Risks of SUID

As you consider future regulatory activity, including developing product standards and potential new product categories, we urge you to consider these principles for safe sleep. Products that are incompatible with safe sleep should be removed from the market to protect children. Parents often assume that products they see on the shelves or online have been rigorously tested and proven to pose no harm to their child. Allowing dangerous products to remain on the market, or creating safety standards that make a product seem safe without addressing inherent hazards, sends a dangerous, confusing message to parents.

To avoid preventable fatalities, the burden of proof for safety should be on the products. Infant sleep products should be rigorously tested and proven to meet safety standards that meet these principles. As new products are developed, the CPSC and ASTM International must take a proactive approach to identifying potential hazards, testing, and applying safety standards, rather than a reactive approach once a hazard is shown to be fatal. Once hazards are identified, the CPSC and ASTM International should address them promptly through voluntary recalls and additional safety standards.

We hope these principles and recommendations for safe sleep can inform your crucial work to protect consumers from dangerous products. Our organizations appreciate our past collaboration with you to promote safe sleep and look forward to continuing this important partnership. If you have further questions, you may reach out to Zach Laris with the American Academy of Pediatrics at zlaris@aap.org. Thank you for your consideration.

Sincerely,

American Academy of Pediatrics
Consumer Federation of America
Consumer Reports
Kids in Danger
Public Citizen

CC: Rick Rosati, Chairman, Committee F15 on Consumer Products, ASTM International

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