

June 13, 2018

The Honorable Ann Marie Buerkle, Chairman
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

Dear Chairman Buerkle:

The undersigned organizations write to express our strong concern about the U.S. Consumer Product Safety Commission's (CPSC) May 31, 2018, announcement, "Caregivers Urged To Use Restraints With Inclined Sleep Products."ⁱ We are concerned that this announcement puts the onus on parents and caregivers to protect against the hazard posed by inherently unsafe inclined sleep products, the use of which does not align with American Academy of Pediatrics (AAP) safe sleep recommendations.ⁱⁱ In addition, the CPSC announcement mentions that the agency "is aware of infant deaths associated with inclined sleep products," but does not provide clear information about which products have been associated with deaths. We are concerned that this announcement could be taking the place of stronger and more appropriate compliance and enforcement actions by the Commission to get dangerous products off the market. Finally, we are concerned that one of the main suggestions for consumers in this statement—to secure restraints while using the product—may not prevent deaths linked to use of this type of product.

Parents and caregivers may seek out inclined sleep products out of concern about gastroesophageal reflux in their infants. However, the AAP's safe sleep experts have reviewed extensive research and concluded that elevating the head of the infant's crib or using an inclined sleep product while the infant is supine (placed on his or her back), is not recommended.ⁱⁱⁱ It is ineffective in reducing gastroesophageal reflux; in addition, it might result in the infant sliding to the foot of the crib into a position that might compromise respiration.

Some parents are concerned that infants that spit up or gag might choke, but again, research shows that the supine sleep position does not increase the risk of choking and aspiration in infants, even those with gastroesophageal reflux, because they have protective airway mechanisms.^{iv,v} The AAP continues to recommend that infants with gastroesophageal reflux should be placed for sleep in the supine and flat position for every sleep, with rare exceptions under the direction of a physician.

Sitting devices, such as car safety seats, strollers, swings, infant carriers, and infant slings, are also not recommended for routine sleep in the hospital or at home.^{5,6,7,8,9} Infants who are younger than 4 months are particularly at risk, because they might assume positions that can create a risk of suffocation or airway obstruction. If an infant falls asleep in a sitting device, he or she should be removed from the product and moved to a crib or other appropriate flat surface as soon as is practical.

For these reasons, we are deeply concerned that the CPSC's May 31 announcement makes it seem, incorrectly, that inclined sleep products are safe if used with restraints. The CPSC

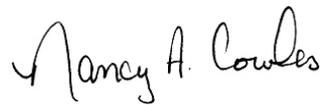
fails to provide any data upon which it bases this implicit claim, and we are concerned that this improper portrayal of infant inclined sleep products could result in additional infant deaths and injuries. We ask that the CPSC further clarify the consumer announcement of May 31 by listing the products involved in deaths and using its compliance and enforcement authorities to recall inclined sleep products posing a hazard to infants. The Commission also should follow the recommendation of several of our groups in comments dated June 21, 2017, by implementing a strong mandatory safety standard to ensure these products are as safe as a compliant full-size crib.^{vi,vii} If such a standard is not feasible, the Commission should take steps to ensure infant inclined sleep products and infant sleep positioners can no longer be sold.

The CPSC's safe sleep message should be a clear one: a bare crib is best, babies should be placed on their backs for every sleep time, and parents and caregivers should use a sleep product that meets current mandatory standards such as cribs, play yards, and bassinets for very young infants. Using restraints in a sleep product, allowing inclines in sleep products that might allow rolling into unsafe positions, and other hazards present in current inclined sleep products should not be promoted by the CPSC. As the CPSC considers issuing a final rule for infant inclined sleep products, the incident data that presumably led to the May 31 warning should inform the agency's action on the rule. If the current products that are involved in deaths would meet the rule, then it is far too weak, and CPSC and ASTM International should revisit the standard and implement revisions to make it more protective of infant safety.

Sincerely,



Colleen A. Kraft, MD, FAAP
President
American Academy of Pediatrics



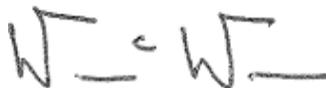
Nancy Cowles
Executive Director
Kids In Danger



Rachel Weintraub
Legislative Director and
General Counsel
Consumer Federation of America



Don Huber
Director, Product Safety
Consumer Reports



William Wallace
Senior Policy Analyst
Consumers Union

ⁱ <https://www.cpsc.gov/Newsroom/News-Releases/2018/CPSC-Consumer-Alert-Caregivers-Urged-To-Use-Restraints-With-Inclined-Sleep-Products>.

ⁱⁱ <http://pediatrics.aappublications.org/content/early/2016/10/20/peds.2016-2938>.

ⁱⁱⁱ Tobin JM, McCloud P, Cameron DJ. Posture and gastro-oesophageal reflux: a case for left lateral positioning. *Arch Dis Child*. 1997; 76(3):254–258.

^{iv} Malloy MH. Trends in postneonatal aspiration deaths and reclassification of sudden infant death syndrome: impact of the “Back to Sleep” program. *Pediatrics*. 2002;109(4): 661– 665.

^v Tablizo MA, Jacinto P, Parsley D, Chen ML, Ramanathan R, Keens TG. Supine sleeping position does not cause clinical aspiration in neonates in hospital newborn nurseries. *Arch Pediatr Adolesc Med*. 2007;161(5): 507–510.

^{vi} <https://www.regulations.gov/document?D=CPSC-2017-0020-0006>.

^{vii} <https://www.regulations.gov/document?D=CPSC-2017-0020-0008>.