



UNITED STATES  
CONSUMER PRODUCT SAFETY COMMISSION  
4330 EAST WEST HIGHWAY  
BETHESDA, MARYLAND 20814

This document has been electronically  
approved and signed.

## Memorandum

DATE: May 26, 2021

TO: The Commission  
Alberta E. Mills, Secretary

THROUGH: Jennifer Sultan, Acting General Counsel  
Mary T. Boyle, Executive Director  
DeWane Ray, Deputy Executive Director for Safety Operations

FROM: Duane E. Boniface, Assistant Executive Director  
Office of Hazard Identification and Reduction

Celestine T. Kish, Project Manager  
Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Draft Final Rule for Infant Sleep Products: Staff's Response to  
Commissioner's Hearing Questions

Staff's responses to Commissioners' questions, raised during the staff briefing on the Draft Final Rule for Infant Sleep Products held on May 19, 2021, are below.

### Questions from Commissioner Baiocco and Commissioner Feldman

1. *Was the Mannen Study peer-reviewed? If so, and if the information is available, by whom?*

Dr. Mannen has one full-length manuscript published in the *Journal of Biomechanics*, and one manuscript currently under review in the same journal, both based on her research. She has also published the work at two American Society of Biomechanics conferences. The citations for these publications are listed below. All of these publications are peer-reviewed, but the review process is blind, so staff does not know the names of specific reviewers. However, staff understands that reviewers are Dr. Mannen's peers in the biomechanics field.

#### Full-length manuscript published:

- Wang J, Siddicky SF, Carroll JL, Rabenhorst BM, Bumpass DB, Whitaker BN, Mannen EM. "Do inclined sleep surfaces impact infants' muscle activity and movement? A safe sleep product design perspective," *Journal of Biomechanics*. Oct 9;111:109999. Epub 2020 Aug 17. doi: 10.1016/j.jbiomech.2020.109999. PMID: 32862027.

Conference proceedings published:

- Mannen EM, Wang J, Siddicky SF, Carroll JL, Rabenhorst BM, Bumpass DB, Whitaker BN. "Is This Safe for Baby? Using Biomechanics to Explore Safety of Inclined Sleepers." American Society of Biomechanics Annual Meeting, 2021, (virtual due to COVID-19).
- Wang J, Siddicky SF, Carroll JL, Rabenhorst BM, Bumpass DB, Whitaker BN, Mannen EM, "Do inclined sleeping surfaces impact infants' upper body muscle activity and movement?" American Society of Biomechanics Annual Conference, 2020; Atlanta, GA (virtual due to COVID-19).

2. *Did staff consider how people who are in a lower socio-economic status may be disadvantaged by this rule?*

In the process of developing the Regulatory Flexibility Analysis, staff considered the impact on consumers, characterizing price ranges for products impacted by this rule (largely \$50 to \$150 or more), finding that compliant products such as bassinets are available throughout this price range. As such, consumers who were able to purchase products in this price range prior to adoption of the rule will still be able to do so if the draft rule goes into effect.

Staff also considered a CDC study that consists of data from a large national survey on different bed-sharing practices based on race, state of residence, education, and age. Among other aspects, the study noted higher prevalence of bed-sharing among American Indians/Alaska Natives, non-Hispanic blacks, or Asians/Pacific Islanders compared with non-Hispanic whites or Hispanics, and similar differences for use of soft bedding. These have been identified as higher risk behaviors. The study is referenced in footnote 11 in Tab E of the staff briefing package and provided here:

[https://www.cdc.gov/mmwr/volumes/67/wr/mm6701e1.htm?s\\_cid=mm6701e1\\_w](https://www.cdc.gov/mmwr/volumes/67/wr/mm6701e1.htm?s_cid=mm6701e1_w)

The conclusions of the study indicate that “[i]mproved implementation of the safe sleep practices recommended by the American Academy of Pediatrics could help reduce sleep-related infant mortality. Evidence-based interventions could increase use of safe sleep practices, particularly within populations whose infants might be at higher risk for sleep-related deaths.” The report went on to note that “[o]ther strategies include removing known barriers to safe sleep practices (e.g., providing free or reduced cost cribs for families), identifying and addressing cultural and social practices that are unsafe (e.g., by holding safe-sleep baby showers), and implementing legislative and regulatory supports (e.g., requiring SIDS risk reduction training for licensed child care providers)” Therefore, socio-demographic populations whose infants may be at higher-risk for sleep-related deaths are likely to benefit from the rule.

3. *Why didn't staff hold a forum as part of the consultation process to discuss including flat products in the final rule?*

As part of section 104 of the CPSIA, CPSC is required to consult with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and

experts to examine and assess voluntary safety standards for durable infant or toddler products. Staff's participation in the ASTM process fulfilled this obligation because ASTM subcommittees are comprised of the variety of these representatives. Staff's participation in the ASTM subcommittee and task group meetings for inclined sleep products, bassinets (compact and regular), and in-bed sleepers, involved multiple and extensive discussions of proposed revisions to performance requirements, test methods, and labeling for flat and inclined products. In addition, the SNPR specifically asked for comments related to flat infant sleep products that would be impacted by the rule. Comments received demonstrated that stakeholders understood flat sleep products were included in the proposed rule.