



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

This document has been electronically
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DATE: October 16, 2019

BALLOT VOTE SHEET

TO: The Commission
Alberta E. Mills, Secretary

THROUGH: Melissa V. Hampshire, Acting General Counsel
Mary T. Boyle, Executive Director

FROM: Patricia M. Pollitzer, Assistant General Counsel
Mary A. House, Attorney, OGC

SUBJECT: Supplemental Notice of Proposed Rulemaking for Infant Sleep Products

BALLOT VOTE DUE Tuesday, October 22, 2019

The U.S. Consumer Product Safety Commission (CPSC) published a notice of proposed rulemaking in April 2017 (2017 NPR) pursuant to the Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) to promulgate a consumer product safety standard for infant inclined sleep products. Based on subsequent information and events, CPSC staff is recommending that the Commission issue a supplemental notice of proposed rulemaking (Supplemental NPR), proposing to adopt the current ASTM standard for infant inclined sleep products, with modifications that would make the mandatory standard more stringent than the voluntary standard. The draft Supplemental NPR proposes to limit the seat back angle for sleep to 10 degrees or less, and to change the scope of the standard to cover products intended for infant sleep that are not already addressed by another standard. Accordingly, the draft Supplemental NPR proposes to use the term “infant sleep products” for the CPSC standard. The draft Supplemental NPR also proposes to amend the consumer registration rule (16 CFR part 1130) to identify explicitly infant sleep products as a durable infant or toddler product subject to part 1130, and the regulation regarding third party conformity assessment bodies (16 CFR part 1112) to add infant sleep products to the Commission’s list of notices of requirements.

The Office of the General Counsel (OGC) is forwarding a draft Supplemental NPR for Commission consideration.

Consumer Hotline and General Information: 1-800-638-2772 ★ CPSC's Web Site: <http://www.cpsc.gov>

Please indicate your vote on the following options:

I. Approve publication of the attached document in the *Federal Register*, as drafted.

(Signature)

(Date)

II. Approve publication of the attached document in the *Federal Register*, with the specified changes:

(Signature)

(Date)

III. Do not approve publication of the attached document in the *Federal Register*.

(Signature)

(Date)

IV. Take other action specified below:

(Signature)

(Date)

Attachment: Draft *Federal Register* Notice: Supplemental Notice of Proposed Rulemaking to Establish a Safety Standard for Infant Sleep Products

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112, 1130, and 1236

[CPSC Docket No. 2017-0020]

Safety Standard for Infant Sleep Products

AGENCY: Consumer Product Safety Commission.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: In the **Federal Register** of April 7, 2017, the Consumer Product Safety Commission (CPSC) published a notice of proposed rulemaking (2017 NPR) pursuant to the Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), to promulgate a consumer product safety standard for infant inclined sleep products (inclined sleep products). The 2017 NPR allowed an incline between 10 and 30 degrees for the seat back angle of an inclined sleep product. The 2017 NPR proposed to adopt a voluntary standard for inclined sleep products developed by ASTM International, with a modification to the standard's definition of "accessory." Based on subsequent information and events, the Commission is now issuing a supplemental proposed rule (Supplemental NPR), proposing to adopt the current ASTM standard for inclined sleep products, with modifications that would make the mandatory standard more stringent than the voluntary standard. The proposed changes include limiting the seat back angle for sleep to 10 degrees or less. CPSC's proposed standard would cover products intended for infant sleep that are not already addressed by another standard. Additionally, the Commission proposes to include the mandatory standard for infant sleep products in the Commission's list of notices of requirements (NORs). The Commission also proposes to amend the consumer registration rule to identify

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explicitly infant sleep products as a durable infant or toddler product subject to CPSC's consumer registration requirements.

DATES: Submit comments by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature requirements of the proposed mandatory standard for infant sleep products should be directed to the Office of Information and Regulatory Affairs, the Office of Management and Budget, Attn: CPSC Desk Officer, FAX: 202-395-6974, or e-mailed to oir_submission@omb.eop.gov.

Other comments, identified by Docket No. CPSC-2017-0020, may be submitted electronically or in writing:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments. CPSC does not accept comments submitted by electronic mail (e-mail), except through www.regulations.gov. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions in the following way: Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions) to: Division of the Secretariat, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this proposed rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided,

to: <http://www.regulations.gov>. Do not submit electronically any confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to provide such information, please submit it in writing.

Docket: For access to the docket to read background documents or comments received, go to: <http://www.regulations.gov>, and insert the docket number, CPSC-2017-0020, into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Celestine T. Kish, Project Manager, Directorate for Engineering, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 987-2547; email: ckish@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

A. Statutory Authority

Section 104(b) of the CPSIA, 15 U.S.C. 2056a(b), requires the Commission to: (1) examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts; and (2) promulgate consumer product safety standards for durable infant or toddler products. Standards issued under section 104 are to be “substantially the same as” the applicable voluntary standards, or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. 15 U.S.C. 2056a(b)(1)(B).

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Section 104 of the CPSIA requires the Commission to consult with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts to examine and assess the effectiveness of the relevant voluntary standards. CPSC staff regularly participates in the juvenile products subcommittee meetings of ASTM International (ASTM). ASTM subcommittees consist of members who represent producers, users, consumers, government, and academia.¹ The consultation process for the inclined sleep products rulemaking commenced in 2011, and CPSC staff has been actively participating in the development of the new standard since that time.

A “durable infant or toddler product” is a “durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years.” *Id.* 2056a(f)(1). The CPSIA includes a non-exhaustive list of categories of products that are durable infant or toddler products, such as cribs, toddler beds, and bassinets and cradles. *Id.* 2056a(f)(2). As discussed in section I.B of this preamble, in the 2017 NPR CPSC proposed to categorize infant inclined sleep products as a “durable infant or toddler product” under section 104 of the CPSIA, as a subset of the bassinet and cradle category. In this Supplemental NPR, CPSC proposes to identify “infant sleep products” as a category of durable infant or toddler products under section 104(f) of the CPSIA. CPSC proposes to define “infant sleep products” as products that provide sleeping accommodations for infants and are not currently covered by bassinets/cradles, cribs (full-size and non-full size), play yards, and bedside sleepers, as a durable infant or toddler product under section 104(f) of the CPSIA. Section 104(d) of the CPSIA requires durable infant or toddler products to establish product registration programs and comply with CPSC’s implementing rule, 16 CFR part 1130. Under section 14 of the CPSA, children’s products (such as durable infant or

¹ ASTM International website: www.astm.org, About ASTM International.

toddler products) must comply with testing and certification requirements that are implemented through 16 CFR parts 1107 and 1109.

B. 2017 NPR

When staff began work on the bassinet and cradle standard, staff considered infant inclined sleep products to fall within the scope of the bassinet/cradle standard. However, because the bassinet/cradle standard did not address products on the market that had a sleep incline greater than 10 degrees, the Commission directed staff to initiate a separate rulemaking effort for infant inclined sleep products. Accordingly, the infant inclined sleep products safety standard was an outgrowth of the bassinet/cradle safety standard, intended to address products with an incline greater than 10 degrees from horizontal.

In 2011, at the time CPSC separated infant inclined sleep products from the bassinet/cradle standard, ASTM simultaneously began work on developing a voluntary standard for infant inclined sleep products. ASTM published the resulting infant inclined sleep products standard in May 2015, and updated the standard twice in 2016 and twice in 2017. ASTM's latest standard for this product category is designated, ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products* (ASTM F3118-17a).

Pursuant to the procedure described in section 104 of the CPSIA, the 2017 NPR proposed a mandatory standard for infant inclined sleep products, incorporating by reference the then-current voluntary standard, ASTM F3118-17, with a modification to the standard's definition of "accessory." 82 FR 16964 (April 7, 2017). At the time of the 2017 NPR for infant inclined sleep products, which included hammocks, the Commission was aware of 14 fatal incidents related to infant inclined sleep products, which were reported to have occurred between January 1, 2005 and September 30, 2016. Staff determined that 8 of the 14 infant deaths involved

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freestanding, framed inclined sleep products, and that 3 infant deaths involved an unrestrained infant who was found to have rolled over into a facedown position. Staff found that in two additional deaths, the infant reportedly rolled over into a facedown position, but the reports did not include any information about use of a restraint. CPSC staff had little information about the cause or manner of the three remaining infant deaths. *Id.* at 16965-66. Staff's incident data analysis in the 2017 NPR considered that these 14 fatalities and other reported incidents could be addressed by the requirements in the voluntary standard, ASTM F3118-17. *Id.* at 16967-68.

The 2017 NPR indicated that ASTM F3118-17 addressed the primary hazard patterns CPSC identified in the 657 incidents (including 14 deaths), except for the definition of "accessory." Specifically, the 2017 NPR proposed that CPSC's standard would not include the term "rigid frame" in the definition of "accessory inclined sleep product" in section 3.1.1 of ASTM F3118-17, broadening the definition to encompass a new product that did not have a rigid frame. *Id.* at 16968-69, and 16975. The Commission concluded that these more stringent requirements were necessary to further reduce the risk of injury associated with infant inclined sleep products relating to the use of an inclined sleep product accessory. *Id.* at 16967.

As the 2017 NPR explained, durable infant or toddler products are children's products that must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a); 82 FR at 16969. Certification must be based on testing conducted by a CPSC-accepted third party conformity assessment body (test laboratory). 15 U.S.C. 20163(a)(2). CPSC must publish a NOR for the accreditation of test laboratories to assess a product's conformity with a children's product safety rule, such as the proposed rule on infant inclined sleep products. Accordingly, the 2017 NPR proposed that if issued as a final rule, the new *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, to be codified at 16 CFR part 1236,

would be added to the list of NORs for children’s product safety rules in 16 CFR part 1112, so that test laboratories applying for CPSC-acceptance could seek accreditation to test inclined infant sleep products. 82 FR at 16969.

Finally, the 2017 NPR proposed to amend 16 CFR part 1130, the Commission’s requirements for consumer registration for durable infant or toddler products. *Id.* at 16969-70. The Commission proposed to amend the definition of “durable infant or toddler product” to clarify that infant inclined sleep products fall within the term, and are subject to the product registration card requirements in part 1130. *Id.*

On June 12, 2019, CPSC staff submitted a briefing package and a draft **Federal Register** notice to the Commission recommending that the Commission terminate the 2017 NPR. Staff recommended terminating the 2017 NPR because, by that time, CPSC had received reports of 42 additional fatalities since issuing the 2017 NPR, which were associated with rocker-like inclined sleep products, and because the Commission had issued additional safety alerts and recalls involving infant inclined sleep products. On October 16, 2019, staff provided the Commission with a briefing package recommending that the Commission instead issue this Supplemental NPR.²

C. 2019 Supplemental NPR - Overview

In this Supplemental NPR, the Commission proposes to issue a standard for infant sleep products, *i.e.*, products that (1) provide sleeping accommodations for infants and (2) are not currently covered by bassinets/cradles, cribs (full-size and non-full size), play yards, and bedside sleepers. The Supplemental NPR proposes to incorporate by reference ASTM F 3118-17a with

² The October 16, 2019, Staff Briefing Package: Draft Supplemental Notice of Proposed Rulemaking for Infant Sleep Products under the Danny Keysar Child Product Safety Notification Act (Staff Supplemental Briefing Package) is available at: [\[INSERT LINK TO STAFF BRIEFING PACKAGE\]](#)

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modifications to require that: (1) the seat back angle intended for sleep must be equal to or less than 10° and (2) the infant sleep product must meet the requirements for a bassinet/cradle in the standard at 16 CFR part 1218. The Commission also proposes to amend the consumer registration rule to identify “infant sleep products” as a category of durable infant or toddler products under section 104(f) of the CPSIA. Additionally, the Commission proposes to amend its regulation at 16 CFR part 1112 to add infant sleep products to the list of products that require third party testing.

II. Product Description

A. Scope of Products Within the Supplemental NPR

The scope of products covered by the 2017 NPR tracked the scope of ASTM F3118-17, covering “a free standing product with an inclined sleep surface primarily intended and marketed to provide sleeping accommodations for an infant up to 5 months old or when the infant begins to roll over or pull up on sides, whichever comes first.” The Supplemental NPR proposes to incorporate ASTM F3118-17a with substantial modifications, including revisions in the scope of the standard, section 1.3, to remove the term “inclined,” and to include any infant sleep product not currently covered by another mandatory rule for infant sleep products: bassinets/cradles, cribs (full-size and non-full-size), play yards, and bedside sleepers. Accordingly, the scope of the Supplemental NPR includes all of the products in the 2017 NPR, plus additional infant sleep products not covered by any other infant sleep product standard. The following types of infant sleep products fall within the scope of the Supplemental NPR:

- *Frame-Type Inclined Sleep Products* – Frame-type inclined sleep products are elevated, intended to be placed on the floor, and are self-supporting. Typically, this design uses a metal frame covered by a fabric insert that contains the occupant. Some

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frame-type products have a rigid plastic insert under the sleeping surface, and/or extra padding with head positioning cushions. The base may be stationary or allow side-to-side/head-to-toe rocking. This type of product could have a fixed incline or be adjustable. Frame-type products can be intended for use by newborns or infants, or both, depending on the size of the product.

- *Hammocks* – Hammocks are typically constructed of fabric and suspended from one or two points, either above or on either side. Hammock products are constructed of various materials and generally conform to the shape of the child when placed in the product. However, some hammock designs use a mat, mattress, or other type of pad to provide a semi-rigid sleeping surface that maintains the product's form.

Hammocks are intended to be suspended and can be supported by a frame or other structure, such as a ceiling.

- *Compact Inclined Sleep Products* – Compact inclined sleep products are freestanding, with the bottom of the seat a maximum of 6 inches (152 mm) above the floor. These products tend to be constructed of foam and are intended to be used on the floor.
- *Accessory Inclined Sleep Products* – An accessory inclined sleep product is intended to provide sleeping accommodations for infants or newborns and are attached to, or supported in some way, by another product. These products can be fixed or adjustable. An inclined sleep accessory is typically a rigid-frame product that has a stationary or fixed base and, in some cases, inclined sleep product accessories may be removed and used independently.

B. Market Description

The Supplemental NPR proposes to cover any infant product “primarily intended and marketed³ to provide sleeping accommodations” that is designed for infants five months old or younger and that is not covered by another standard.⁴ In general, the Supplemental NPR does not propose to cover products with adjustable seat back positions that are covered by other mandatory or voluntary standards in inclined position(s), such as bouncers, rockers, hand-held carriers, or infant swings, unless they have a seat back angle that is specifically marketed for sleep for children 5 months or younger. To date, CPSC staff has found one bouncer on the market with an inclined position marketed for sleep for children in this age range.

Inclined infant sleep products sell on the U.S. market for approximately \$65 for a frame-style inclined sleeper, \$110 for a compact sleeper, \$165 for an infant hammock,⁵ and \$236 for a play yard with an inclined sleeper accessory.⁶ A hammock-style crib accessory that would be covered by the Supplemental NPR (but does not currently fall under the voluntary inclined sleeper standard or another sleep standard) sells for approximately \$50.

Several product categories would not fall under the scope of the Supplemental NPR: (1) sleep positioners; (2) sleep wedges, many of which are marketed as medical devices, putting them under the jurisdiction of the Food and Drug Administration; and (3) miniature infant hammocks marketed exclusively for use as photographic props (*i.e.*, photos of newborn babies).

³ This would include marketing information (such as on websites or in ad campaigns), product and retail package labeling, as well as supplier statements about the product.

⁴ These include: Safety Standard for Full-Size Baby Cribs (16 CFR 1219); Safety Standard for Non-Full-Size Baby Cribs and Ply Yards (16 CFR 1220 and 1221); Safety Standard for Bedside Sleepers (16 CFR 1222); and Safety Standard for Bassinets and Cradles (16 CFR 1218).

⁵ The average price for an infant hammock supplied by a home-based manufacturer is approximately \$200.

⁶ Staff averaged prices across all models found for a particular type. Staff ignored as unknown shipping costs for a few hammock models delivered from overseas suppliers, which means that the average cost for an infant hammock may be a low estimate, depending upon how many hammocks are entering the U.S. via these overseas suppliers.

III. Incident Data and Hazard Patterns

At the time of the 2017 NPR, the Commission was aware of 14 fatal incidents related to infant inclined sleep products, which were reported to have occurred between January 1, 2005 and September 30, 2016. Eight of the 14 deaths involved rocker-like inclined sleep products; in three cases, the unstrapped decedent was found to have rolled over into a facedown position. Two additional cases also reported a rollover into a facedown position, but the reports did not include any information about use of a restraint. CPSC had little information about the cause or manner of the three remaining deaths. The NPR recognized that reporting was ongoing and the number of reported fatalities could change. This Supplemental NPR updates fatal and nonfatal incident reports associated with the use of an infant inclined sleep product.

CPSC is aware of 451 incidents (59 fatal and 392 nonfatal) related to infant inclined sleep products that occurred from January 1, 2005 through June 30, 2019 and reported between October 1, 2016 and June 30, 2019. This count includes incidents reported after the reporting end date stated in the 2017 NPR. Forty-three percent of the incident reports (196 out of 451) are based solely on information from manufacturers/retailers. Various sources, such as hotlines, Internet reports, newspaper clippings, medical examiners, and other state/local authorities provided the remaining incident reports to CPSC. Reporting is ongoing, and therefore, the number of reported fatalities, nonfatal injuries, and non-injury incidents may change in the future. Tab A of the Staff Supplemental Briefing Package describes the incident data and the hazard patterns associated infant inclined sleep products.

A. *Fatalities*

Since the 2017 NPR, through June 30, 2019, CPSC received reports of 59 deaths. One fatality involved a foam-based infant reclined sleeper; two fatalities occurred in napper attachments of play yards; and the remaining fatalities occurred in freestanding framed inclined sleep products. CPSC staff reviewed and categorized incident reports associated with the fatalities:

- Twenty-eight of the 59 reports contain unclear, conflicting, and/or inconsistent information. For example, in this category medical examiners often conclude the cause of death to be Sudden Infant Death Syndrome (SIDS) or Sudden Unexpected Infant Death (SUID) along with a co-contributing condition such as unsafe sleep environment (*e.g.*, soft bedding, inclined sleep surface) or other pre-existing medical condition. Considering all factors in each report confounds staff's ability to determine the pre-dominant factor causing a fatality. Occasionally, wording on the documents cite "several possibilities" and the cause of death is coded as Undetermined. Lack of clarity in these reports make it difficult for CPSC staff to consistently classify the 28 deaths.
- Eighteen reports describe infants placed in the product supine but who ended up in a compromised position in the product, resulting in suffocations or positional asphyxiations. In 11 of the 18 cases, no restraints were used; another six infants were placed in a supine position, but the use of restraints is unknown; and in one case, the infant was left restrained and supine, but found supine, slumped in a chin-to-chest position. One additional unrestrained infant fell out of the product and became wedged in a confined space.

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- Eight reports provide very little information on the incidents. Lack of any information on the circumstances leading up to the death does not allow staff to classify these deaths.
- Four reports describe infant placement issues; three of the four decedents were reportedly placed prone on soft bedding in the product; and another decedent suffocated when a young sibling climbed into the sleep product on top of her.

CPSC does not know the age for 10 deceased infants. Staff concludes that for the remaining deaths, 39 infants were 5 months or less in age, while six infants were between 6- and 8-months of age. One decedent was 9-months old.

B. Nonfatal Incidents

Reports indicate that 96 of the 451 inclined sleep product-related nonfatal incidents involved an injury to the infant during product use. The severity of the injury types among the 96 reported injuries are as follows:

- Seven infants required hospital admission. Six of the seven infants suffered episodes of respiratory distress due to rolling over in the product; mold in the product; or undetermined reasons. One of the seven infants had to be hospitalized for *scoliosis* (curvature) of the back attributed to product use.
- Sixteen infants were treated and released from emergency departments (EDs). Eleven of these infants were treated for head injuries and contusions/bruises resulting from falls; three infants were treated for unexplained respiratory distress. Mold growth on the product was associated with respiratory distress in one additional infant and seizure symptoms in another.

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- Seventy-three infants received some professional medical care, first-aid treatment, or the level of care received was not reported. Among them, 32 infants suffered from plagiocephaly (flat head syndrome), torticollis (twisted neck syndrome), or both conditions, associated with the use of the inclined sleep product; 27 infants suffered mostly respiratory and some skin problems associated with mold on the product; infants sustained the remaining injuries due to a fall from the product or a minor electric shock, or their injuries are unspecified.

The remaining 296 incident reports indicate that no injury occurred to the infant or provided no information about an injury. However, many of the descriptions indicate the potential for a serious injury, or even death, similar to those reported in the incident data.

C. Hazard Pattern Identification

The 2017 NPR identified nine hazard patterns among the 657 reported incidents. These hazard patterns included: design issues, lack of structural integrity, inadequate restraints, electrical issues, non-product-related or unknown issues, difficulty with correct positioning, miscellaneous product-related issues, unspecified falls, and consumer comments. Although the distribution of the data in this Supplemental NPR update varied somewhat, CPSC finds that the broader hazard categories are very similar. Within the broader hazard category of design, the Supplemental NPR identifies one new hazard pattern, as described below.

CPSC staff considered all 451 reported incidents (59 fatal and 392 nonfatal) to identify hazard patterns associated with infant inclined sleep products. The infant inclined sleep products category includes a variety of products. Some products, like hammocks, are suspended in air, while other seat-like products are meant to be placed on a floor level (yet incident reports indicate these products often were not placed on floor level). Other products sit on top of larger

nursery products as attachments. CPSC staff identified hazard patterns that are quite different depending on which product is involved and how the product is being used. In order of frequency of incident reports, CPSC staff grouped the hazard patterns into the following categories:

1. **Design** of the infant inclined sleep product: One hundred and thirty-eight of the 451 reported incidents (31 percent) are in this category. Staff identified three major issues:
 - a. Fifty-nine reported incidents (43 percent) involved infants who developed respiratory and/or skin ailments due to the growth of mold on the product;
 - b. Forty-six reported incidents (33 percent) involved infants that rolled over—fully or partially—from their original supine position. Reports describe infants as young as 1- or 2-months of age as having rolled over; parents/caregivers, who witnessed and reported some of the nonfatal incidents, were able to rescue distressed infants quickly. Eighteen infants died due to suffocation or asphyxiation. Although a few of the infants were strapped into the product, a majority of the infants were either not restrained or the use of restraint is unreported.
 - c. Thirty-three reported incidents (24 percent) involved infants that developed physical deformations from extended product use, such as *plagiocephaly* (flat head syndrome), *scoliosis* (curvature) of the back, and/or *torticollis* (twisted neck syndrome).

The design category includes 19 deaths, 5 hospitalizations, and 4 emergency department (ED) visits. All but two of the deaths resulted from infants rolling over into a prone or semi-prone position, one decedent was found still supine and restrained, but slumped in a chin-to-chest position. The other infant rolled out of the product and wedged into a confined space. Infants

unrestrained in the product caused two ED-treated falls. An additional 62 non-hospitalized, non-ED injuries are reported in this category.

2. **Electrical** issues: One hundred and twenty-seven of the 451 incident reports (28 percent) report battery leakage, electric shock, and/or overheating/melting of components, such as the vibrating unit, battery cover, switch, plug, or motor. Reports include two injuries in this category due to electric shock.

3. **Consumer comments**: Ninety of the 451 reports (20 percent) fall into this category. The reports consist of consumer comments/observations of perceived safety hazards, complaints about unauthorized sale of infant inclined sleep products, or inquiries regarding safety recall on inclined sleep products. One complaint describes misinformation in the instruction material. None of these reports indicate that an incident actually occurred.

4. **Undetermined** due to confounding information: Thirty-four of the 451 reports (8 percent) provide unclear, conflicting, and/or inconsistent information. Among the 28 deaths reported in this category, for example, medical examiners often concluded the cause of death to be SIDS or SUID, along with a co-contributing condition such as an unsafe sleep environment (e.g., soft bedding, inclined sleep surface) or pre-existing medical condition. Staff is unable to determine the role of the product when documents describe multiple potentially contributing factors. Occasionally, the wording on the documents cite “several possibilities,” and the cause of death is coded as Undetermined. For the 6 nonfatal injuries, including the 2 hospitalized and 2 ED-treated injuries, the report described respiratory distress due to temporary cessation of breathing; however, these reports contain no official diagnosis for these episodes.

5. Lack of **structural integrity**: Twenty-eight of the 451 incidents (6 percent) report some sort of breakage of the product or its components. These reports include complaints of

buckle/straps breaking, components such as hub, rail, or leg detaching/disengaging, hardware coming loose, and other unspecified components breaking. This category includes two ED-treated injuries, both due to falls.

6. ***Other product-related*** issues: Thirteen of the 451 incidents (3 percent) report other product-related issues, such as instability (product tipping over), inadequacy of restraint (infants falling out in spite of being restrained), or product assembly/installation difficulties. This category contains seven fall-related injuries, including two injuries that were treated and released from a hospital ED.

7. ***Infant placement*** issues: Four of the 451 incidents reports (1 percent) indicate that infant placement contributed to the incident. Of the four fatalities, reports describe three infants placed in a prone position on soft bedding; and another infant being crushed by a young sibling who climbed on top of her.

8. ***Insufficient information***: For 17 of the 451 incidents (4 percent), reports contain insufficient information for staff to categorize them accurately. Staff has no information available on the circumstances of 8 deaths in this category. Reports for six injuries in this category describe unspecified falls treated in hospital EDs, with no information was on restraint usage.

D. Product Recalls and Safety Alerts

From May 10, 2000 to August 20, 2019, CPSC conducted 13 consumer-level recalls involving infant inclined sleep products. The recalls were conducted in response to hazards involving strangulation, suffocation, fall, structural stability, entrapment, exposure to mold, and death. Six recalls involved infant hammocks, six recalls involved infant inclined sleep products, and one recall involved an infant inclined sleep accessory included with a play yard. Tab G in

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the Staff Supplemental Briefing Package contains a detailed chart outlining recalls involving infant inclined sleep products.

The six infant hammocks were recalled for hazards including: strangulation, suffocation, fall, structural stability, and entrapment. Recalls affected approximately 25,400 units of infant hammocks.

The six infant inclined sleep products and one infant inclined sleep accessory included with a play yard were recalled due to hazards including: entrapment, suffocation, fall, exposure to mold, and death after infants rolled from their back to their stomach or side while unrestrained in the products. Recalls affected approximately 6.4 million units of infant inclined sleep products. One recall for exposure to mold affected 800,000 units, and two recalls for entrapment and suffocation affected 195,000 units.

In 2019, two recalls occurred due to reports of infant deaths while using infant inclined sleep products, after the infants rolled from their back to their stomach or side while unrestrained, or under other circumstances. In response to the reported deaths in those products, CPSC conducted two additional recalls due to safety concerns with infant inclined sleep products, one with an infant inclined sleep product, and one with an infant inclined sleep accessory included with a play yard. Recalls involving infant inclined sleep products affected approximately 5.4 million units and the recall involving the infant inclined sleep accessory affected approximately 71,000 units.

The Commission also has issued two safety alerts involving infant inclined sleep products. A May 31, 2018 safety alert⁷ advised of infant rollover deaths in inclined sleep products, and reminded caregivers to always use restraints and to stop using the product as soon

⁷ <https://www.cpsc.gov/content/cpsc-consumer-alert-caregivers-urged-to-use-restraints-with-inclined-sleep-products>

as an infant can roll over. An April 5, 2019 safety alert⁸ advised consumers to stop use of the inclined sleep product when an infant reaches three months of age, or as soon as an infant exhibits rollover capabilities.

IV. Mannen Study

During the development of this Supplemental NPR briefing package, staff received reports of 451 new incidents, 59 of which were deaths that occurred while in infant inclined sleep products. Accordingly, Commission staff contracted with Dr. Erin Mannen, Ph.D., a mechanical engineer with a biomechanics specialization, to conduct infant testing to evaluate the design of inclined sleep products. Tab B of the Staff Supplemental Briefing Package contains Dr. Mannen's study, *Biomechanical Analysis of Inclined Sleep* (Mannen Study).

The Mannen Study examined how 10 infants move and use their muscles on flat, inclined surfaces, and in selected inclined sleep products, and whether such product designs directly impact safety or present a risk factor that could contribute to the suffocation of an infant. Testing compared infants' muscle movement and oxygen saturation on a flat crib mattress at 0°, 10°, and 20° versus seven different inclined sleep products. Researchers recorded infant muscle activity using surface electromyography (EMG), and recorded oxygen saturation using a medical grade pulse oximeter. Researchers placed infants in a random order in each of the 10 testing conditions, in both the supine and prone positions, for at least 60 seconds (unless the oximeter data fell below 95%, in which case they were removed early to ensure safety).

Following are key findings of the Mannen Study:

⁸ <https://www.cpsc.gov/Newsroom/News-Releases/2019/CPSC-ALERT-CPSC-and-Fisher-Price-Warn-Consumers-About-Fisher-Price-Rock-N-Play-Due-to-Reports-of-Death-When-Infants-Roll-Over-in-the-Product>

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- Inclined surfaces and incline sleep products resulted in significantly higher muscle activity of the turn core muscle (abdominals), which may lead to quicker fatigue and suffocation if an infant finds themselves prone in an incline sleep product.
- Muscle synergies (*i.e.*, how muscles work together) are significantly different in inclined sleep products. If an infant rolls from supine to prone in an inclined sleep product, it is likely the first time the baby has experienced the position and the demands the position requires of the muscles.
- Some inclined sleep products require greater neck and trunk adjustments during prone positioning, indicating that infants may struggle to adjust their posture to enable breathing and attempt to self-correct if a roll from supine to prone occurs.
- Prone lying in the incline sleep products puts infant at higher risk of suffocation as evidenced by oxygen saturation results.
- Some evidence was found that supports the idea that the inclined sleep products make the babies roll more easily from supine to prone. The flexed trunk and ease of head lifting during supine lying in an inclined sleep product may indicate that supine to prone rolling is achieved more easily.
- If babies roll from supine to prone in an inclined sleep product, then, due to the high musculoskeletal demands necessary to maintain safe posture to prevent suffocation, babies would fatigue faster than they would on a stable, flat surface.
- None of the inclined sleep products that were tested and evaluated as a part of this study are safe for infant sleep.

Additionally, the Mannen Study concludes:

- ***20-Degree Incline Puts Infants at Risk for Muscle Fatigue and Suffocation***

Based on the results of the biomechanical study, the 20-degree incline resulted in significantly different muscle activity for the infants compared to the zero-degree incline surface. The increased demand on the abdominal muscles could lead to increased fatigue and suffocation if an infant is unable to reposition themselves after an accidental roll from supine to prone occurs.

- ***10-Degree Incline Does Not Significantly Impact Infant Motion or Muscle Activity***

Based on the results of the biomechanical study, fewer differences in muscle activity or lying posture were revealed at a 10-degree mattress incline compared to the zero-degree incline surface. Ten degrees is a safe incline for sleep on a crib mattress surface.

- ***Inclines Between 10 and 20 Degrees Should Be More Thoroughly Studied***

The experimental design of this study did not examine the angles between 10 and 20 degrees, so future work should focus on understanding which, if any, angles between 10 and 20 degrees may be safe for infant sleep.

The Mannen Study further states: “It is likely that in incidents where babies were found deceased in the prone position, that an accidental roll occurred, and after some amount of struggling, the baby was fatigued and could no longer move into a position to prevent suffocation.” Dr. Mannen concludes that an incline of 20 degrees or more puts an infant at risk compared to a 0-10 degree incline. Although her study did not test infants on inclines between 10-20 degrees, and thus did not offer conclusions for these angles, CPSC staff advises that additional testing on inclines between 10-20 degrees is unnecessary, because staff concludes that a flat surface that does not

exceed 10 degrees offers the safest sleep environment for infants. This conclusion comports with staff's recommendations to remove the term "inclined" from the proposed mandatory standard, and to require that all sleep products not otherwise specified as cribs (full-size or non-full-size), play yards, or bedside sleepers meet the requirements in 16 CFR 1218 Safety Standard for Bassinets and Cradles, which, among other requirements, mandates that the seat back surface angle intended for sleep be 10 degrees or less.

V. International Standards for Inclined Sleep Products

The 2017 NPR described international standards that include infant inclined sleep products within their scope, noting that these standards are intended primarily to address hazards associated with products having flat sleeping surfaces, such as bassinets and cradles. These standards include:

- *The Cribs, Cradles, and Bassinets regulation included in the Canada Consumer Product Safety Act:* The Canadian regulation has similar requirements to ASTM F3118, such as warnings, labels, and general performance requirements (*e.g.* lead content, small parts, openings). The Canadian regulation has additional requirements for slat strength, mesh material, structural integrity, and mattress supports. CPSC staff determined that the Canadian regulation provides similar performance requirements as ASTM F3118, but contains a more stringent requirement limiting the sleep seat back angle to 7° or less. However, the Canadian regulation allows a product to be marketed as a "napper," which the Supplemental NPR proposes not to allow.
- *The European standard (SS-EN 1130: Furniture, Cribs, and Cradles Safety Requirements):* EN 1130 covers only inclined sleep products with a body and frame.

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The European standard would not include hammocks or similar products that are suspended from ceilings or other structures. EN 1130 includes requirements for construction and materials similar to the general ASTM F3118 requirements.

Additional requirements include labeling, use instructions, packaging, and stability.

EN 1130 is intended primarily to address hazards associated with bassinets and cradles and not the unique hazards associated with inclined sleep products. CPSC staff believes the ASTM standard is more inclusive because it includes all hammock styles. Additionally, EN 1130 does not address the hazards identified in the Mannen Study.

- *The Australian standard (AS/NZS 4385 Infants' rocking cradles --Safety requirements):* AS/NZS 4385 is intended for rocking cradles that swing, rock, or tilt, but specifically excludes hammocks that do not have this feature. Staff is unclear whether tilt means incline, thereby including in the Australian standard inclined sleep products as defined in ASTM F3118. AS/NZS 4385 contains requirements for construction, toxicology, and flammability, as well as general provisions, such as those for included toys. AS/NZS 4385 has some similar performance requirements as ASTM F3118, but is not as comprehensive. Additionally, the AS/NZS 4385 does not address the hazards identified in the Mannen Study.

VI. Voluntary Standard—ASTM F3118

A. History of ASTM F3118

Section 104(b)(1)(A) of the CPSIA requires the Commission to consult representatives of “consumer groups, juvenile product manufacturers, and independent child product engineers and experts” to “examine and assess the effectiveness of any voluntary consumer product safety

standards for durable infant or toddler products.” As a result of incidents arising from inclined sleep products, the Commission directed CPSC staff to work with ASTM to develop voluntary requirements to address the hazard patterns related to the use of inclined sleep products. ASTM first approved ASTM F3118 on April 1, 2015, and published it in May 2015. Through the ASTM process, CPSC staff consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public. The current standard, ASTM F3118-17a, was approved on September 1, 2017, and published in October of 2017. This is the fourth revision to the standard since it was first published in May 2015. ASTM F3118-17a is intended to address the following hazards: (1) falls, (2) positional asphyxiation, and (3) obstruction of nose and mouth by bedding.

B. Description of the Current Voluntary Standard—ASTM F3118-17a

The 2017 NPR described the key provisions of ASTM F3118-17, including: scope, terminology, general requirements, performance requirements, test methods, marking and labeling, and instructional literature. 82 FR at 16967. The Supplemental NPR proposes to incorporate by reference the most recent version of the voluntary standard, ASTM F3118-17a, which is substantially the same as ASTM F3118-17, except that the accessory definition was updated to match the modification recommended in the 2017 NPR. Like the previous version, ASTM F3118-17a describes the scope of the voluntary standard, defines terms for various types of inclined sleep products, and sets out requirements for performance (such as for structural integrity and stability) and for warnings and instructions. As discussed elsewhere in this

preamble, CPSC’s proposed standard would make substantial modifications to ASTM F3118-17a.

VII. Assessment of the Voluntary Standard ASTM F3118-17a

In the 2017 NPR, CPSC proposed that incorporating by reference ASTM F3118-17, with a modification to the definition of “accessory,” would address the primary hazard patterns identified in the incident data. 82 FR at 16967-68. However, since the 2017 NPR, CPSC has become aware of additional fatalities and contracted the Mannen Study. The Mannen Study and more recent incident data indicate that ASTM F3118-17a is not adequate to address the risk of injury associated with infant inclined sleep products because the standard allows for products with a seat back angle greater than 10 degrees. The Commission finds that more stringent requirements than those found in ASTM F3118-17a are necessary in a mandatory rule to further reduce the risk of injury associated with infant inclined sleep products.

Following is an explanation of how the Supplemental NPR would address the product-related hazard patterns identified in section III.C of this preamble, discussing the proposed more stringent requirements where appropriate.

A Design Problems

1. Suffocation Hazard

The Mannen Study results reveal that a 20° incline results in significantly different muscle activity for the infants compared to a 0° incline surface. The increased demand on infant abdominal muscles could lead to increased fatigue and suffocation if an infant is unable to reposition themselves after a roll from supine to prone occurs. At a 10° incline, fewer differences in muscle activity or lying posture were revealed compared to the 0° incline surface. According to Dr. Mannen’s report, “ten degrees is likely a safe incline for sleep on a crib

mattress surface.” Accordingly, the Commission proposes modifications to the introduction, scope, definitions, and performance requirements in ASTM F3118-17a, as described in section VIII of this preamble, to address the potential hazards of an infant sleeping on an inclined surface. Although her study did not test infants on inclines between 10°-20°, and thus did not offer conclusions for these angles, CPSC staff advises that additional testing on inclines between 10°-20° is unnecessary, concluding that a flat surface that does not exceed 10° offers the safest sleep environment for infants and would further reduce the risk of injury associated with inclined sleep products.

2. Additional Design Issues

CPSC staff identified two additional design issues: (1) Infant respiratory and/or skin ailments due to mold growth on the product, and (2) infant physical deformations such as *plagiocephaly* (flat head syndrome) and/or *torticollis* (twisted neck syndrome) from extended product use. In the reported cases of mold that resulted in respiratory problems for infants using the product, all cases were related to one particular manufacturer’s inclined sleep product. CPSC conducted a recall of that product in 2013. Infants who use an inclined sleep product that is known to develop visible mold can be at risk of developing health effects such as allergies, asthma, mycosis, and effects of mycotoxins. However, because the mold growth was restricted to one manufacturer’s product and that product was recalled, the Commission is not proposing any modifications to address potential hazards associated with mold.

Plagiocephaly, cranial deformity or asymmetry (commonly known as flat head) is a condition that may exist at birth due to mechanical constraint of fetal head movement in the womb, birth-related injuries during assisted delivery, or as a result of increased likelihood of skull deformity as a consequence of premature birth. Muscular torticollis (twisted neck) is a

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known risk factor associated with plagiocephaly caused by constraint of head and neck movement. Although incident data indicate that consumers believe use of an inclined sleep product is the cause for their child's plagiocephaly/torticollis, no evidence supports this belief. Increase in the number of children with plagiocephaly may actually be attributed to the American Academy of Pediatrics' (AAP) recommendation to place infants to sleep on their backs to decrease the risk of sudden infant death syndrome (SIDS). Because the development of plagiocephaly and torticollis is not exclusively attributable to the use of infant inclined sleep products, the conditions are not addressable with performance standards. The Commission is not proposing any modifications to the voluntary standard to address these issues. Tab E of the Staff Supplemental Briefing Package provides the Directorate for Health Science's analysis of plagiocephaly and torticollis related to infant sleep products.

B. Electrical issues

Staff determined that 127 of the 451 new incidents are related to electrical issues. The electrical-related issues included battery leakage, electric shock, and overheating of components. Some inclined sleep products have accessories that provide music, rocking motion, or vibration, which are either battery- or a/c-powered; however, F3118-17a does not include any performance requirements for electrical components. Other juvenile products that have similar features include performance requirements that could apply for infant sleep products. CPSC staff has raised this issue and is working with the ASTM Ad Hoc task group to develop performance requirements to address electrical hazards across juvenile products. Performance requirements would apply to other children's product standards, such as bouncers, swings, and bassinets. Because these requirements are currently under development, the Commission is not proposing electrical requirements in this Supplemental NPR, and instead expects staff to continue working

with applicable ASTM subcommittees to develop electrical requirements for all applicable durable infant or toddler products with electrical components.

C. Structural Integrity and Other Product Related Issues

Structural integrity and other product related issues identified in this Supplemental NPR are similar to issues previously found in bassinet/cradle incidents. Accordingly, performance and testing requirements in the bassinet/cradle standard will likely address these incidents for infant sleep products.

D. Infant Placement Issues

Infants placed prone on soft bedding in inclined sleep products are at great risk for suffocation because of the incline and the soft bedding. Although requiring infant sleep products to comply with the bassinet/cradle standard will reduce the incline angle, and will provide warnings about not using soft bedding, parents may still place infants prone in the product. Staff will continue to work with ASTM and other organizations with information and education campaigns to prevent infants' deaths due to unsafe sleep practices.

VIII. Proposed Standard for Infant Sleep Products

This Supplemental NPR proposes to establish a children's product safety standard for infant sleep products as a type of durable infant or toddler product under section 104 of the CPSIA. The Mannen Study findings and incident reports indicate that neither ASTM F3118-17, nor ASTM F3118-17a, are adequate to address the risk of injury associated with infant inclined sleep products, because these voluntary standards allow for infant inclined sleep products with a seat back angle greater than 10 degrees. More stringent requirements are necessary in the mandatory standard to further reduce the risk of injury associated with infant inclined sleep

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products. Accordingly, the Supplemental NPR proposes to incorporate by reference ASTM F3118-17a as the mandatory standard for infant sleep products, with the following modifications:

- a. Modify the introduction and scope of the standard to state the purpose of the standard is to address all infant sleep products not already covered by traditional sleep product standards.
- b. Modify the definitions of accessory, compact, infant inclined sleep products, and newborn inclined sleep products to remove the term “inclined.”
- c. Modify seat back angle so the maximum allowable seat back angle must be equal to or less than 10° in all positions recommended for sleep.
- d. Add new requirement - infant sleep products must meet 16 CFR 1218 Safety Standard for Bassinets and Cradles.
- e. Remove all the performance requirements except for the above new or modified requirements.
- f. Remove all test methods except for maximum seat back angle.

The Supplemental NPR proposes that infant sleep products meet 16 CFR 1218 Safety Standard for Bassinets and Cradles because this standard is an established standard for products that provide sleep accommodations for infants, and the standard addresses the hazard associated with inclined sleep by limiting the seat back angle to 10 degrees or less. Additionally, the name of CPSC’s standard would not include the term “inclined,” and would be codified as 16 CFR part 1236, Safety Standard for Infant Sleep Products. A redline of these proposed changes is included at Tab C of the Staff Supplemental Briefing Package.

The Supplemental NPR proposes that infant sleep products meet the warning requirements in the bassinet and cradle standard, instead of those stated in ASTM F3118-17a.

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For this proposed modification, the Supplemental NPR relies on focus groups with parents and grandparents of infants less than 1 year of age. Participants provided information on caregivers' perceptions and reactions to safety messaging, indicating that participants were aware of warning labels on infant sleep products. Additionally, participants reported that the label shown during the focus group looked similar and contained comparable information to labels that they find on products they own. Some participants reported that they tend to gloss over warning labels, as they believe the language to be the same on every label. Some participants reported that they thought the main message on a warning label was to be careful and keep an eye on their infant. In contrast, a few participants believed that manufacturers use warning labels to protect themselves from liability or litigation. Participants' recommendations to improve warning labels included making the labels more concise and making the labels "stand out." CPSC staff is working with a contractor to develop new safe sleep warnings and messaging, potentially across all sleep products. In the future, staff could recommend changes in warnings based on this work.

IX. Proposed Amendment to 16 CFR part 1112 to Include NOR for Infant Sleep Products

The CPSA establishes certain requirements for product certification and testing. Products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Certification of children's products subject to a children's product safety rule must be based on testing conducted by a CPSC-accepted third party conformity assessment body. *Id.* 2063(a)(2). The Commission must publish an NOR for the accreditation of third party conformity assessment bodies to assess

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conformity with a children's product safety rule to which a children's product is subject. *Id.* 2063(a)(3). Thus, the proposed rule for 16 CFR part 1236, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, if issued as a final rule, would be a children's product safety rule that requires the issuance of an NOR.

The Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 78 FR 15836 (March 12, 2013), codified at 16 CFR part 1112 ("part 1112") and effective on June 10, 2013, which establishes requirements for accreditation of third party conformity assessment bodies to test for conformity with a children's product safety rule in accordance with section 14(a)(2) of the CPSA. Part 1112 also codifies all of the NORs issued previously by the Commission.

All new NORs for new children's product safety rules, such as the inclined sleep products standard, require an amendment to part 1112. To meet the requirement that the Commission issue an NOR for the inclined sleep products standard, as part of this NPR, the Commission proposes to amend the existing rule that codifies the list of all NORs issued by the Commission to add inclined sleep products to the list of children's product safety rules for which the CPSC has issued an NOR.

Test laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard for inclined sleep products would be required to meet the third party conformity assessment body accreditation requirements in part 1112. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, the laboratory can apply to the CPSC to have 16 CFR part 1236, *Standard Consumer Safety Specification for Infant Sleep Products*, included in the laboratory's scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at: www.cpsc.gov/labsearch.

X. Proposed Amendment to Definitions in Consumer Registration Rule

The statutory definition of “durable infant or toddler product” in section 104(f) applies to all of section 104 of the CPSIA. In addition to requiring the Commission to issue safety standards for durable infant or toddler products, section 104 of the CPSIA also directed the Commission to issue a rule requiring that manufacturers of durable infant or toddler products establish a program for consumer registration of those products. Pub. L. 110-314, section 104(d).

Section 104(f) of the CPSIA defines the term “durable infant or toddler product” and lists examples of such products:

(f) DEFINITION OF DURABLE INFANT OR TODDLER PRODUCT. As used in this section, the term “durable infant or toddler product” –

(1) means a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years; and

(2) includes –

(A) full-size cribs and non-full-size cribs;

(B) toddler beds;

(C) high chairs; booster chairs, and hook-on-chairs;

(D) bath seats;

(E) gates and other enclosures for confining a child;

(F) play yards;

(G) stationary activity centers;

(H) infant carriers;

(I) strollers;

(J) walkers;

(K) swings; and

(L) bassinets and cradles.

Pub. L. 110-314, section 104(f).

As discussed previously, the infant sleep products safety standard is an outgrowth of the bassinet safety standard. The Supplemental NPR proposes that any infant sleep product that is not already subject to a mandatory consumer product safety rule for infant sleep, be subject to proposed part 1236, which would limit the seat back incline angle to 10 degrees or less. Like bassinets, such sleep products are durable products within the meaning of section 104 of the CPSIA.

Because this infant sleep product standard is an outgrowth of the bassinet standard, infant sleep products may be considered a sub-category of bassinets. To provide greater clarity that inclined sleep products are durable infant or toddler products, the Commission proposes to amend the Commission's consumer registration rule to explicitly include infant sleep products.

In 2009, the Commission issued a rule implementing the consumer registration requirement. 16 CFR part 1130. As the CPSIA directs, the consumer registration rule requires each manufacturer of a durable infant or toddler product to: provide a postage-paid consumer registration form with each product; keep records of consumers who register their products with the manufacturer; and permanently place the manufacturer's name and certain other identifying information on the product. When the Commission issued the consumer registration rule, the Commission identified six additional products as "durable infant or toddler products":

- children's folding chairs
- changing tables;

- infant bouncers;
- infant bathtubs;
- bed rails; and
- infant slings.

16 CFR 1130.2. The Commission stated that the specified statutory categories were not exclusive, but that the Commission should explicitly identify the product categories that are covered. The preamble to the 2009 final consumer registration rule states: “Because the statute has a broad definition of a durable infant or toddler product but also includes 12 specific product categories, additional items can and should be included in the definition, but should also be specifically listed in the rule.” 74 FR 68668, 68669 (Dec. 29, 2009).

In this Supplemental NPR, the Commission proposes to amend the definition of “durable infant or toddler product” in the consumer registration rule to clarify that infant sleep products fall within the term “durable infant or toddler product” as a subset of bassinets and cradles, and must comply with the product registration card rule and section 104 of the CPSIA.

XI. Incorporation by Reference

The Commission proposes to incorporate by reference ASTM F3118-17a, with substantial modifications to further reduce the risk of injury. The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. For a proposed rule, agencies must discuss in the preamble of the NPR ways that the materials the agency proposes to incorporate by reference are reasonably available to interested persons or how the

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agency worked to make the materials reasonably available. In addition, the preamble of the proposed rule must summarize the material. 1 CFR 51.5(a).

In accordance with the OFR's requirements, section VIII of this preamble summarizes the provisions of ASTM F3118-17a that the Commission proposes to incorporate by reference. ASTM F3118-17a is copyrighted. By permission of ASTM, the standard can be viewed as a read-only document during the comment period on this NPR, at: <http://www.astm.org/cpsc.htm>. Interested persons may also purchase a copy of ASTM F3118-17 from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; <http://www.astm.org/cpsc.htm>. One may also inspect a copy at CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923.

XII. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). ASTM F3118-17a is a relatively new voluntary standard that covers a variety of products whose manufacturers may not be aware that their product must comply. The Commission is proposing to incorporate by reference ASTM F3118-17a, with substantial modifications to further reduce the risk of injury associated with infant inclined sleep products. To allow time for infant sleep product manufacturers to bring their products into compliance after a final rule is issued, the Commission proposes a 12-month effective date after publication of a final rule, for products manufactured or imported on or after that date. Because of the number of proposed modifications to ASTM F3118-17a, compliance with the mandatory standard may require time beyond the typical 6-month effective date for a section 104 rule. The Commission expects that most firms should be

able to comply within the 12-month timeframe. Alternatively, given the hazards involved with infant inclined sleep products, the Commission could issue a final rule with a shorter effective date so that safer products would be available sooner. The Commission requests comments on whether either a longer or shorter effective date would be appropriate.

XIII. Regulatory Flexibility Act

A. Introduction

The Regulatory Flexibility Act (RFA) requires that agencies review a proposed rule for the rule's potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that agencies prepare an initial regulatory flexibility analysis (IRFA) and make the analysis available to the public for comment when the agency publishes an NPR. 5 U.S.C. 603. Section 605 of the RFA provides that an IRFA is not required if the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. The IRFA must describe the impact of the proposed rule on small entities and identify significant alternatives that accomplish the statutory objectives and minimize any significant economic impact of the proposed rule on small entities. Specifically, the IRFA must contain:

- a description of the reasons why action by the agency is being considered;
- a succinct statement of the objectives of, and legal basis for, the proposed rule;
- a description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of

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small entities subject to the requirements and the type of professional skills necessary for the preparation of reports or records; and

- identification, to the extent possible, of all relevant federal rules that may duplicate, overlap, or conflict with the proposed rule; and

Additionally, the IRFA must describe any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and minimize any significant economic impact of the proposed rule on small entities.

CPSC staff prepared an IRFA for this rulemaking which appears at Tab F of the Staff Supplemental Briefing Package. We provide a summary of the IRFA below.

B. Reasons for Agency Action and Legal Basis for Supplemental NPR

As explained elsewhere in this preamble, section 104 of the CPSIA authorizes the Commission to issue standards for durable infant or toddler products and requires that such products comply with product registration requirements. The Commission is issuing this Supplemental NPR in response to reports of deaths involving inclined sleep products.

C. Supplemental NPR Requirements

The Supplemental NPR would incorporate by reference the voluntary standard for inclined sleep products (ASTM F3118-17a) with substantial modifications described in section VIII of this preamble. Products subject to the proposed standard would need to have a sleep surface angle no greater than 10° and would need to meet the requirements of the CPSC standard for bassinets and cradles. If the Commission issues a final rule, the proposed rule would become a mandatory standard, and firms with a sleep product that is subject to the rule would need to evaluate their product, determine what changes would be required to meet the standard, and modify the product so that it complies with the standard or cease supplying the product to the

U.S. market. The manufacture or importation of noncompliant products would be prohibited after the effective date of the standard. Additionally, manufacturers and importers must certify that their products comply with applicable children’s products safety standards, and this certification must be based on testing by a third party. 16 CFR part 1107.

D. Small Entities Supplying Infant Sleep Products and the Supplemental NPR’s Impact on Small Businesses

Since the Commission issued the 2017 NPR, the U.S. inclined sleep product market has changed substantially. Manufacturers and importers have largely stopped producing for sale most frame-style inclined sleep products from the market, including some that were not subject to recalls, although one or two types of products remain.⁹ Additionally, a significant decline in the infant hammock market has occurred, both among larger-scale suppliers and home-based manufacturers.

As part of the current market evaluation, staff identified 18 firms still supplying sleep products to the U.S. market with sleep surface angles greater than 10 degrees, but less than or equal to 30 degrees. Staff identified an additional firm supplying a sleep product with an incline of 10 degrees or less that is not being tested for compliance with either the bassinet standard or another sleep product standard (and thus, likely would be subject to the Supplemental NPR). Of these 19 total firms, six appear to be very small, home-based manufacturers of infant hammocks (two operating domestically and four overseas).¹⁰ The RFA covers only domestic suppliers. Seven of the 19 firms are not as small as the home-based infant hammock manufacturers, but would meet the definition of “small” domestic entities based on U.S. Small Business

⁹ Some units may still be available for sale even for products that are no longer being produced (this does *not* include recalled models).

¹⁰ These suppliers were identified online, and staff believes that there may be additional home-based manufacturers supplying infant hammocks on a very small scale (possibly including some without an on-line presence).

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Administration (SBA) guidelines for their North American Industry Classification System (NAICS) codes. These seven firms typically have only one inclined sleep model in their product lines.

In summary, CPSC staff is aware of nine small domestic firms currently marketing products that would be impacted by the Supplemental NPR in the United States (two home-based domestic hammock manufacturers, four small domestic manufacturers of inclined sleep products, and three small importers of inclined sleep products). Staff cannot definitively determine the impact of the Supplemental NPR because the impact would depend on several unknown factors including:

- How firms respond to the rule (*e.g.*, they would redesign, remarket, or drop products subject to the Supplemental NPR);
- The costs associated with redesigning, remarketing, or replacing an inclined sleep product;
- The change, if any, on demand for that product.

Staff estimates that third party testing costs could be \$30 to \$100 per sample for the maximum incline test alone, and testing to the bassinet standard could add costs up to another \$1000. Reliance on third party tests obtained by suppliers as allowed by the component part testing rule (16 CFR part 1109) could reduce testing costs to some extent. Staff found that third party costs are likely to be significant for the two very small home-based manufacturers of infant hammocks *if they choose to redesign*; and costs could be significant for an additional two small manufacturers, if they chose to redesign their products and testing as few as four units per model were required to provide a “high degree of assurance.”

E. Alternatives

At least two alternatives are available that could minimize the economic impact on small entities while also meeting the statutory objectives:¹¹ (1) eliminate the requirement that products must meet the bassinet standard if they do not already fall into another sleep product standard; or (2) allow a later effective date. However, under the first alternative, the cost of redesign would still likely be significant. Moreover, the Supplemental NPR is intended to ensure that all products providing sleep accommodations for infants meet a base set of safety requirements. This alternative would not accomplish this goal.

Second, the Commission could also reduce the Supplemental NPR's impact on small businesses by setting a later effective date than the proposed 12 months. A later effective date would reduce the economic impact on firms redesigning their existing products in two ways. Firms would be less likely to experience a lapse in production/importation, which could result if they are unable to bring their products into compliance and certify compliance based on third party tests within the required timeframe. Also, firms could spread the costs of developing compliant products over a longer time period, thereby reducing their annual costs, as well as the present value of their total costs (*i.e.*, they could time their spending to better accommodate their individual circumstances). The Commission requests comments on the 12-months effective date, which was set to help reduce the impact on affected firms, as well as feedback on how firms would likely respond to the Supplemental NPR.

¹¹ Staff considered whether adopting the voluntary inclined sleeper standard with no modifications might also be an alternative, but ruled it out because it would not address the injuries and deaths that led to the recent inclined sleeper recalls.

F. Small Business Impacts of the Accreditation Requirements for Testing Laboratories

In accordance with section 14 of the CPSA, all children's products that are subject to a children's product safety rule must be tested by a CPSC-accepted third party conformity assessment body (i.e., testing laboratory) for compliance with applicable children's product safety rules. Testing laboratories that want to conduct this testing must meet the NOR pertaining to third party conformity testing. NORs have been codified for existing rules at 16 CFR part 1112. Consequently, the Commission proposes to amend 16 CFR part 1112 to establish the NOR for those testing laboratories that want to test for compliance with the infant sleep products final rule (in essence, test for maximum seat back angle). This section assesses the impact of the amendment on small laboratories.

A final regulatory flexibility analysis (FRFA) was conducted as part of the promulgation of the original 1112 rule (78 FR 15836, 15855-58), as required by the RFA. Briefly, the FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements were imposed on laboratories that did not intend to provide third party testing services. The only laboratories that were expected to provide such services were those that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

Based on similar reasoning, amending the rule to include the NOR for the infant sleep product standard will not have a significant adverse impact on small laboratories. Moreover, based upon the number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for

conformance with the infant sleep product standard. Most of these laboratories will have already been accredited to test for conformance to other juvenile product standards, and the only costs to them would be the cost of adding the infant sleep product standard to their scope of accreditation, a cost that test laboratories have indicated is extremely low when they are already accredited for other section 104 rules. Consequently, the Commission certifies that the NOR for the infant sleep product standard will not have a significant impact on a substantial number of small entities.

XIV. Environmental Considerations

The Commission's regulations address whether the agency is required to prepare an environmental assessment or an environmental impact statement. Under these regulations, certain categories of CPSC actions normally have "little or no potential for affecting the human environment," and therefore do not require an environmental assessment or an environmental impact statement. Safety standards providing requirements for products come under this categorical exclusion. 16 CFR 1021.5(c)(1). The Supplemental NPR falls within the categorical exclusion.

XV. Paperwork Reduction Act

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). In this document, pursuant to 44 U.S.C. 3507(a)(1)(D), we set forth:

- a title for the collection of information;
- a summary of the collection of information;

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- a brief description of the need for the information and the proposed use of the information;
- a description of the likely respondents and proposed frequency of response to the collection of information;
- an estimate of the burden that shall result from the collection of information; and
- notice that comments may be submitted to the OMB.

Title: Safety Standard for Infant Sleep Products

Description: The Supplemental NPR would incorporate by reference ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, but with modifications, including to sections 8 and 9 which contain requirements for marking, labeling, and instructional literature. The Supplemental NPR would exclude from the rule infant sleep products covered by another mandatory standard for sleep products (Section 1.3). However, the Supplemental NPR would modify section 5.2 of ASTM F3118-17a to require that accessory, compact, infant sleep products, and newborn sleep products meet the requirements of the Safety Standard for Bassinets and Cradles (16 CFR 1218), including the marking, labeling, and instructional requirements. These marking, labeling, and instructional requirements fall within the definition of “collection of information,” as defined in 44 U.S.C. 3502(3).

Description of Respondents: Persons who manufacture or import infant sleep products.

Estimated Burden: We estimate the burden of this collection of information as follows:

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Table 1 – Estimated Annual Reporting Burden

Burden Type	Type of Supplier	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours
Labeling	Home-based manufacturers	6	1	6	7	42
	Other Suppliers	13	1	13	1	13
Labeling Total						55
Instructional literature	Home-based manufacturers	6	1	50	300	300
TOTAL BURDEN						355

Our estimate is based on the following:

Two groups of quantifiable entities supply infant sleep products to the U.S. market that will likely need to make some modifications to their existing warning labels to meet the requirements for bassinet and cradle warnings. The first group consists of very small home-based manufacturers, which may not currently have warning labels on their infant sleep products. Similar rulemakings (such as that for sling carriers) assumed that it would take home-based manufacturers approximately 15 hours to develop a new label. Given that some home-based manufacturers supply infant sleep products with warning labels already, we have estimated approximately 7 hours per response for this group of suppliers. Therefore, the total burden hours for very small home-based manufacturers is 7 hours per model x 6 entities x 1 models per entity = 42 hours.

The second group of quantifiable entities supplying infant sleep products to the U.S. market that will need to make some modifications to their existing warning labels are non-home-based manufacturers and importers. These firms do not operate at the low production volume of the home-based firms. All of the firms in this second group have existing warning labels on their

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products, but not for bassinets and cradles and would therefore, have to make label modifications. Given that these firms are used to working with warning labels, we estimate that the time required to make any modifications now or in the future would be about 1 hour per model. Based on an evaluation of supplier product lines, each entity supplies an average of 1 model of infant sleeper; therefore, the estimated burden associated with labels for this second group is 1 hours per model x 13 entities x 1 models per entity = 13 hours.

The total burden hours attributable to warning labels is the sum of the burden hours for both entity groups: very small home-based manufacturers (42 burden hours) + non-home-based manufacturers and importers (13 burden hours) = 55 burden hours. We estimate the hourly compensation for the time required to create and update labels is \$34.61 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” March 2019, total compensation for all sales and office workers in goods-producing private industries, series id CMU201G000200000D: <http://www.bls.gov/ncs/>). Therefore, the estimated annual cost to industry associated with the labeling requirements is \$1,904 (\$34.61 per hour x 55 hours = \$1,904). No operating, maintenance, or capital costs are associated with the collection.

The Standard for Bassinets and Cradles (section 9) requires instructions to be supplied with the product. As already noted, the proposed Safety Standard for Infant Sleep Products requires accessory, compact, infant sleep products, and newborn sleep products to meet these requirements. Under the OMB’s regulations (5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the “normal course of their activities” are excluded from a burden estimate, where an agency demonstrates that the disclosure activities required to comply are “usual and customary.”

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We are unaware of infant sleep products that generally require use instructions but lack such instructions. However, it is possible that the six home-based manufacturers of infant hammocks may not supply instruction manuals as part of their “normal course of activities.” Based on information collected for the infant slings rulemaking, staff tentatively estimates that each small entity supplying homemade infant hammocks might require 50 hours to develop an instruction manual to accompany their products. These firms typically supply only one infant hammock model. Therefore, the costs of designing an instruction manual for these firms could be as high as \$10,383 (50 hours per model x 6 entities x 1 models per entity = 300 hours x \$34.61 per hour = \$10,383). Not all firms would incur these costs every year, but new firms that enter the market would incur these costs, and this is a highly fluctuating market. Other firms are estimated to have no burden hours associated with section 9 of the Standard for Bassinets and Cradles because any burden associated with supplying instructions with infant sleep products would be “usual and customary” and not within the definition of “burden” under the OMB’s regulations.

Based on this analysis, CPSC staff estimates that the Supplemental NPR for infant sleep products would impose a burden to industry of 355 hours at a cost of \$12,287 annually.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this rule to the OMB for review. Interested persons are requested to submit comments regarding information collection by **INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**], to the Office of Information and Regulatory Affairs, OMB (see the ADDRESSES section at the beginning of this notice).

Pursuant to 44 U.S.C. 3506(c)(2)(A), we invite comments on:

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- whether the collection of information is necessary for the proper performance of the CPSC's functions, including whether the information will have practical utility;
- the accuracy of the CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- ways to enhance the quality, utility, and clarity of the information to be collected;
- ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology;
- the estimated burden hours required for home-based manufacturers to modify warning labels;
- the estimated burden hours associated with label modification for non-home-based suppliers, including any alternative estimates;
- the estimated burden hours required for home-based manufacturers to modify (or, in some cases, create) instruction manuals.

XVI. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that when a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a standard or regulation that prescribes requirements for the performance, composition, contents, design, finish, construction, packaging, or labeling of such product dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as

“consumer product safety rules.” Therefore, the preemption provision of section 26(a) of the CPSA would apply to a rule issued under section 104.

XVII. Request for Comments

This Supplemental NPR proposes a rule under section 104(b) of the CPSIA to issue a consumer product safety standard for infant sleep products, to amend part 1112 to add infant sleep products to the list of children’s product safety rules for which the CPSC has issued an NOR, and to amend part 1130 to identify infant sleep products as a durable infant or toddler product subject to CPSC consumer registration requirements. The Commission requests comments on the standard’s scope language; the proposed effective date; the costs of compliance with, and testing to, the proposed Safety Standard for Infant Sleep Products; and any aspect of this proposal. During the comment period, the ASTM F3118-17a Standard Consumer Safety Specification for Infant Inclined Sleep Products, is available as a read-only document at: <http://www.astm.org/cpsc.htm>.

The Commission requests comments on the following specific issues:

- Products likely to be impacted by the Supplemental NPR, including the product categories discussed in the preamble and any additional types of products that commenters believe may be impacted by the Supplemental NPR.
- How firms with inclined sleep surfaces will likely respond to the Supplemental NPR, including suppliers of products with inclines above 10 degrees and products with inclines less than or equal to 10 degrees that do not already comply with the bassinet standard. We would also appreciate any information on the possible responses of consumers to changes in marketing. Additionally, any information on the approximate percentage of revenue attributable to these types of products

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would be valuable. The Commission also requests any information regarding the safety of sleep angles in excess of 10 degrees but less than 20 degrees

- The impact that promulgating the Supplemental NPR would have on the cost of testing and certifying products, particularly on small manufacturers and importers. Any information on the number of samples that must be tested would be especially helpful. The Commission also requests comments on the third party testing costs of the maximum incline test in the Supplemental NPR.
- The cost of redesign, the time required for redesign, the likely response of manufacturers to the Supplemental NPR's requirements (*i.e.*, redesign, remarket, or drop), the possible change in demand due to remarketing or changing the sleep surface's degree of incline, the cost of (and time required for) remarketing, and (for firms supplying comments) the relative significance of inclined sleepers to their total revenue. The Commission also requests comments on testing costs, including the number of inclined sleeper units that typically need to be tested to provide a "high degree of assurance" of compliance.
- The age and developmental milestones referenced in the scope and definitions of the various infant inclined sleep products covered by ASTM F3118-17a. Because this Supplemental NPR proposes to address "infant sleep products" not already covered by traditional sleep products, the Commission is considering removing the upper age limit from the scope of the mandatory standard, to accommodate a broad scope of infant sleep products within the standard. The Commission's consideration is based on the fact that when staff knew the age of an infant, twenty percent of the fatalities and injuries involved infants 6 months and older.

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- The APA generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). Section XII of this preamble proposes a 12-month effective date after publication of a final rule, for products manufactured or imported on or after that date, stating that a longer effective date than the typical 6 months for a section 104 rule may be necessary because of the number of proposed modifications to ASTM F3118-17a. Given the hazards involved with infant inclined sleep products, the Commission could issue a final rule with a shorter effective date so that safer products would be available sooner. The Commission requests comments on whether either a longer or shorter effective date would be appropriate.

Comments should be submitted in accordance with the instructions in the **ADDRESSES** section at the beginning of this notice.

List of Subjects

16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third party conformity assessment body.

16 CFR Part 1130

Administrative practice and procedure, Business and industry, Consumer protection, Reporting and recordkeeping requirements.

16 CFR Part 1236

Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, and Toys.

For the reasons discussed in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulations as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

1. The authority citation for part 1112 continues to read as follows:

Authority: 15 U.S.C. 2063; Pub. L. 110-314, section 3, 122 Stat. 3016, 3017 (2008).

2. Amend § 1112.15 by adding paragraph (b)(46) to read as follows:

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule and/or test method?

* * * * *

(b) * * *

(46) 16 CFR part 1236, Safety Standard for Infant Sleep Products.

* * * * *

3. The authority citation for part 1130 continues to read as follows:

Authority: 15 U.S.C. 2056a, 2056(b).

4. Amend § 1130.2 by revising paragraph (a)(12) to read as follows:

PART 1130—REQUIREMENTS FOR CONSUMER REGISTRATION OF DURABLE INFANT OR TODDLER PRODUCTS

§ 1130.2 Definitions.

* * * * *

(a) * * *

(12) Bassinets and cradles, including bedside sleepers and infant sleep products;

* * * * *

5. Add part 1236 to read as follows:

PART 1236-SAFETY STANDARD FOR INFANT SLEEP PRODUCTS

Sec.

1236.1 Scope.

1236.2 Requirements for infant sleep products.

Authority: Sec. 104, Pub. L. 110-314, 122 Stat. 3016 (15 U.S.C. 2056a); Sec. 3, Pub. L. 112-28, 125 Stat. 273.

§ 1236.1 Scope.

This part establishes a consumer product safety standard for infant sleep products, including: frame-type, hammock, compact, and accessory. This consumer product safety standard covers all infant sleep products that are not covered by another consumer product safety standard, including:

- 16 CFR 1218 Safety Standard for Bassinets and Cradles
- 16 CFR 1219 Safety Standard for Full-Size Baby Cribs
- 16 CFR 1220 Safety Standard for Non-Full-Size Baby Cribs
- 16 CFR 1221 Safety Standard for Play Yards
- 16 CFR 1222 Safety Standard for Bedside Sleepers

§ 1236.2 Requirements for infant sleep products.

(a) Except as provided in paragraph (b) of this section, each infant sleep product must comply with all applicable provisions of ASTM F3118-17a, Standard Consumer Safety Specification for Infant Inclined Sleep Products (approved on September 1, 2017). The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Bar Harbor

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Drive, P.O. Box 0700, West Conshohocken, PA 19428; <http://www.astm.org/cpsc.htm>. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) Comply with ASTM F3118-17a with the following additions or exclusions:

(1) Instead of complying with Introduction of ASTM F3118-17a, comply with the following:

(i) INTRODUCTION

This consumer safety specification addresses incidents associated with infant inclined sleep products identified by the U.S. Consumer Product Safety Commission (CPSC).

In response to incident data compiled by the CPSC, this consumer safety specification attempts to minimize the following: (1) fall hazards, (2) positional asphyxiation, and (3) obstruction of nose and mouth by bedding. The purpose of the standard is to address infant sleep products not already covered by traditional sleep product standards and to prevent deaths due to the use of Infant Sleep Products with a seat back angle greater than 10° from the horizontal.

This consumer safety specification is written within the current state-of-the-art of infant sleep product technology and will be updated whenever substantive information becomes available that necessitates additional requirements or justifies the revision of existing requirements.

(ii) [Reserved]

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(2) In section 1.1 of ASTM F3118-17a, replace the term “infant inclined sleep products” with “infant sleep products.”

(3) In section 1.2 of ASTM F3118-17a, replace the term “infant inclined sleep products” with “infant sleep products.”

(4) Instead of complying with section 1.3 of ASTM F3118-17a, comply with the following:

(i) 1.3 This consumer safety performance specification covers products that are not covered by other ASTM standards such as:

- ASTM F1169 Standard Consumer Safety Specification for Full-Size Baby Cribs
- ASTM F406 Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards
- ASTM F2194 Standard Consumer Safety Specification for Bassinets and Cradles
- ASTM F2906 Standard Consumer Safety Specification for Bedside Sleepers

This consumer safety performance specification covers free standing products with an infant sleep surface primarily intended and marketed to provide sleeping accommodations for an infant up to 5 months old or when the infant begins to roll over or pull up on sides, whichever comes first. It also covers a smaller products intended for newborns up to 3 months old or when a newborn begins to wiggle out of position or turn over in the product or weighs more than 15 lb (6.8 kg), whichever comes first. It also covers infant and newborn sleep product accessories, which are attached to or supported by, another product with the same age or abilities, or both, as the free standing products. If the infant sleep product can be converted into a product for which another ASTM standard consumer safety specification exists, the product shall meet the applicable requirements of that standard.

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(ii) [Reserved]

(5) In section 1.4 of ASTM F3118-17a, replace the term “infant inclined sleep product” with “infant sleep product.”

(6) Instead of complying with section 2 of ASTM F3118-17a, comply with the following:

(i) 2. Referenced Documents

(ii) 2.1 ASTM Standards.¹²

- F406 Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards
- F1169 Standard Consumer Safety Specification for Full-Size Baby Cribs
- F2194 Consumer Safety Specification for Bassinets and Cradles
- F2906 Standard Consumer Safety Specification for Bedside Sleepers

(iii) 2.2 Federal Standards.¹³

- 16 CFR 1218 - Safety Standard for Bassinets and Cradles
- 16 CFR 1219 - Safety Standard for Full-Size Baby Cribs
- 16 CFR 1220 - Safety Standard for Non-Full-Size Baby Cribs
- 16 CFR 1221 - Safety Standard for Play Yards
- 16 CFR 1222 - Safety Standard for Bedside Sleepers

(8) Do not comply with sections 2.3 and 2.4 of ASTM F3118-17a, including Figures 1 and 2.

(9) In section 3.1.1 of ASTM F3118-17a, replace the following terms:

¹² For referenced ASTM standard, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For Annual Book of ASTM Standards volume information, refer to the standard’s Document Summary page on the ASTM website.

¹³ Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, <http://www.access.gpo.gov>.

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(i) Replace the term “accessory inclined sleep product” with “accessory infant sleep product.”

(ii) Replace the term “inclined sleep product” with “infant sleep product.”

(10) In section 3.1.2 of ASTM F3118-17a, replace the following terms:

(i) Replace the term “compact inclined sleep product” with “compact infant sleep product.”

(ii) Replace the term “newborn inclined sleep product” with “newborn infant sleep product.”

(11) Do not comply with sections 3.1.3 through 3.1.6 of ASTM F3118-17a.

(12) Instead of complying with section 3.1.7 of ASTM F3118-17a, comply with the following:

(i) 3.1.7 *infant sleep product, n*—a freestanding product, intended to provide a sleeping accommodation for an infant up to approximately 5 months of age, that is generally supported by a stationary or rocker base and that is not subject to any of the following standards:

- 16 CFR 1218 – Safety Standard for Bassinets and Cradles
- 16 CFR 1219 – Safety Standard for Full-Size Baby Cribs
- 16 CFR 1220 and 1221 – Safety Standard for Non-Full-Size Baby Cribs and Play Yards
- 16 CFR 1222 – Safety Standard for Bedside Sleepers

(ii) [Reserved]

(13) Do not comply with sections 3.1.7.1 through 3.1.9 of ASTM F3118-17a.

(14) Instead of complying with section 3.1.10 of ASTM F3118-17a, comply with the following:

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(i) 3.1.10 *newborn sleep product, n*—a free standing product, intended to provide sleeping accommodations for a newborn up to approximately 3 months of age, that is supported by a stationary or rocker base and whose seat back length, measured from the bight, is not greater than 17 in. (432 mm) and that is not subject to any of the following standards:

- 16 CFR 1218 – Safety Standard for Bassinets and Cradles
- 16 CFR 1219 – Safety Standard for Full-Size Baby Cribs
- 16 CFR 1220 and 1221 – Safety Standard for Non-Full-Size Baby Cribs and Play Yards
- 16 CFR 1222 – Safety Standard for Bedside Sleepers

(ii) [Reserved]

(15) Do not comply with sections 3.1.11 through 3.1.13 of ASTM F3118-17a.

(16) Do not comply with section 5 of ASTM F3118-17a.

(17) Do not comply with sections 6.1 through 6.8 of ASTM F3118-17a.

(18) Instead of complying with section 6.9 of ASTM F3118-17a, comply with the following:

(i) 6.9 *Maximum Seat Back Angle:*

(ii) 6.9.1 *Accessory, Compact, and Infant Sleep Product*—The angle of the seat back surface intended for sleep along the occupants head to toe axis relative to the horizontal shall not exceed 10° when tested in accordance with 7.11.2.

(iii) 6.9.2 *Accessory, Compact, and Newborn Sleep Product*—The angle of the seat back surface intended for sleep along the occupants head to toe axis relative to the horizontal shall not exceed 10° when tested in accordance with 7.11.3.

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(iv) 6.9.3 *Accessory, Compact, Infant Sleep Products, and Newborn Sleep Products*— shall meet requirements of 16 CFR 1218 Safety Standard for Bassinets and Cradles.

(19) Do not comply with sections 6.10 through 7.10 of ASTM F3118-17a.

(20) In section 7.11.2.1 of ASTM F3118-17a, replace “*Infant Inclined Sleep Product and Infant Inclined Sleep Product Accessory*” with “*Accessory, Compact, Infant Sleep Products, and Newborn Sleep Products.*”

(21) In section 7.11.2.1 of ASTM F3118-17a, replace “If applicable, place the product in the manufacturer’s recommended highest incline angle position.” with “If applicable, place the product in the manufacturer’s recommended highest seat back angle position intended for sleep.”

(22) In section 7.11.3 of ASTM F3118-17a, replace “*Newborn Inclined Sleep Product and Newborn Inclined Sleep Product Accessory*” with “*Accessory, Compact, Infant Sleep Products, and Newborn Sleep Products.*”

(23) Do not comply with sections 7.12 through 9, or the Appendix, of ASTM F3118-17a.

Dated: _____

Alberta E. Mills,
Secretary, Consumer Product Safety Commission



Staff Briefing Package

**Draft Supplemental Notice of Proposed Rulemaking
for Infant Sleep Products under the Danny Keysar
Child Product Safety Notification Act**

October 16, 2019

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Briefing Memorandum



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

Memorandum

DATE: October 16, 2019

TO: The Commission
Alberta E. Mills, Secretary

THROUGH: Melissa V. Hampshire, 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 Supplemental Notice of Proposed Rulemaking for Infant Sleep Products

I. INTRODUCTION

On April 7, 2017, the Consumer Product Safety Commission (CPSC) published a proposed rule for Infant Inclined Sleep Products (82 *Fed. Reg.* 16963 (April 7, 2017)) (2017 NPR)¹ under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), Danny Keysar Child Product Safety Notification Act. This briefing package pertains to a draft supplemental notice of proposed rulemaking (Supplemental NPR) for infant sleep products that is based on the current voluntary standard, ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, with modifications. Under the ASTM standard, the infant inclined sleep products category covers sleep products with an inclined angle between 10° and 30° for use by infants up to about 5 months of age. The briefing package reviews the relevant incident data, assesses the ASTM standard's effectiveness, and recommends that the Commission issue a Supplemental NPR with a modified name and more limited scope than the ASTM standard. In addition, the briefing package discusses the potential impact the draft Supplemental NPR would have on small businesses, reviews recent recalls associated with infant inclined sleep products, and provides

¹ On June 12, 2019, CPSC staff submitted a briefing package to the Commission, recommending that the Commission terminate the 2017 NPR, stating that CPSC staff received reports of 42 additional fatalities that involved rocker-like inclined sleep products and detailing Commission safety alerts and recalls. As of this date, the Commission has not voted on the package.

staff's recommendations to the Commission. Finally, the draft Supplemental NPR includes a notice of requirements (NOR), which explains how test laboratories could become CPSC-accepted third party conformity assessment bodies to test infant sleep products to the new safety standard.

Throughout this package, the term "Infant Inclined Sleep Products" is used to describe the current voluntary standard and current products on the market that are associated with the voluntary standard. The term "Infant Sleep Products" is used to describe products within the scope of the draft Supplemental NPR, because the proposed rule will limit sleep product seat back angles to 10° or less, thus eliminating the need for the word "inclined" to describe the products.

II. BACKGROUND

A. Requirements for CPSIA Section 104 Rules

Section 104 of the CPSIA requires CPSC to: (1) examine and assess voluntary safety standards for durable infant or toddler products, and (2) promulgate mandatory consumer product safety standards that are substantially the same as the voluntary standards or more stringent than the voluntary standards, if the Commission determines that more stringent standards would further reduce the risk of injury associated with these products. Section 104(f) of the CPSIA defines "durable infant or toddler products" as "durable products intended for use, or that may be reasonably expected to be used, by children under the age of 5 years."

The list of products in section 104(f) of the CPSIA does not specifically include infant inclined sleep products. However, when considering a standard for bassinets and cradles, the Commission determined that hammocks and other inclined sleep products² should be addressed separately from bassinets and cradles, which are specifically identified as "durable infant or toddler products."³ Staff recommends that, in addition to proposing a standard establishing requirements for infant sleep products, the Commission propose to amend 16 CFR part 1130, Requirements for Consumer Registration of Durable Infant or Toddler Products, to clarify that the category of infant sleep products covers all other infant sleep products not currently covered by bassinets/cradles, cribs (full-size and non-full size), play yards, and bedside sleepers.

Section 104 of the CPSIA also requires the Commission to consult with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts to examine and assess the effectiveness of the relevant voluntary standards. CPSC staff regularly participates in the juvenile products subcommittee meetings of ASTM International

² 77 *Fed. Reg.* 64055, 64059 (October 18, 2012) (16 CFR part 1218).

³ 74 *Fed. Reg.* 68668 (December 29, 2009) (16 CFR part 1130.2(a)(16)).

(ASTM). ASTM subcommittees consist of members who represent producers, users, consumers, government, and academia.⁴ The consultation process for this rulemaking commenced in 2011, when ASTM began developing a new voluntary standard to address hammocks and inclined sleep products. Staff has been actively participating in the development of the new standard since 2011.

B. ASTM Voluntary Standard Overview

ASTM F3118, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, is the voluntary standard developed to address the identified hazard patterns associated with the use of infant inclined sleep products. The current standard, ASTM F3118-17a, was approved on September 1, 2017, and published in October 2017. This is the fourth revision since the standard was first published in May 2015.

ASTM F3118-17a contains both general and product-specific performance requirements, and references CPSC requirements for lead in paint, sharp edges or points, and small parts. ASTM F3118-17a contains mechanical requirements for scissoring, shearing, and pinching. Performance requirements in ASTM F3118-17a relate to stability, unintentional folding, restraints, side height, containment, incline, structural integrity, dynamic load, static load, and newborn products' seat back length. The scope of the standard encompasses a wide variety of products that offer not only an inclined sleep position, but also other uses while the child is awake. Due to the variety of products that are covered by ASTM F3118-17a, manufacturers must choose from multiple warning labels in the standard to address appropriately hazards associated with different combinations of product features.

C. Products

Staff began to consider hammocks and inclined sleep products as a part of its work toward a section 104 mandatory standard for bassinets and cradles. "Bassinets/cradles" are defined as providing sleep accommodations with an inclined surface 10° to flat. As work progressed, it became evident to staff that one rule could not effectively address all products without possibly banning hammocks as a class. The Commission directed staff to begin a separate rulemaking for the subset of hammock/inclined sleep products.⁵ At the same time, ASTM began work on developing a voluntary standard for inclined sleep products (including hammocks).

⁴ ASTM International website: www.astm.org, About ASTM International.

⁵ <https://www.regulations.gov/docket?D=CPSC-2010-0028>.

Developed in response to incident data supplied by CPSC staff, ASTM F3118-17a addresses: (1) fall hazards, (2) positional asphyxiation, and (3) obstruction of nose and mouth by bedding.

The scope section of ASTM F3118-17a states:

“1.3 This consumer safety performance specification covers a free standing product with an inclined sleep surface *primarily intended and marketed* to provide sleeping accommodations for an infant up to 5 months old or when the infant begins to roll over or pull up on sides, whichever comes first. It also covers a smaller product intended for newborns up to 3 months old or when newborn begins to wiggle out of position or turn over in the product or weighs more than 15 lb (6.8 kg), whichever comes first. It also covers infant and newborn inclined sleep product accessories, which are attached to, or supported by, another product with the same age or abilities, or both, as the free standing products. If the inclined sleep product can be converted into a product for which another ASTM standard consumer safety specification exists, the product shall meet the applicable requirements of that standard. For example, an inclined sleep product that can have the recline angle adjusted below 10° shall also comply with the applicable requirements of Consumer Safety Specification F2194.” (Emphasis added).

ASTM F3118-17a provides definitions for several types of products covered by the standard:

- an “infant inclined sleep product” is “a freestanding product, intended to provide a sleeping accommodations (sic) for an infant up to approximately 5 months of age, that is generally supported by a stationary or rocker base with one or more inclined sleep surface positions for the seat back that are greater than 10° and do not exceed 30° from the horizontal.”
- a “newborn inclined sleep product” is “a free standing product, intended to provide sleeping accommodations for a newborn up to approximately 3 months of age, that is supported by a stationary or rocker base with one or more inclined sleep surface positions for the seat back that are greater than 10° and do not exceed 30° from the horizontal and whose seat back length, measured from the bight, is not greater than 17 in. (432 mm).”
- “compact infant inclined sleep products” is “a free standing infant or newborn inclined sleep product having a distance of 6.0 in. (152 mm) or less between the underside of the lowest point on the seat bottom and the support surface (floor).”
- “accessory inclined sleep products” is “an inclined sleep product that is intended to provide sleeping accommodations for infants or newborns and attaches to or is supported by another product.”

The voluntary standard does not provide a “hammock” definition. However, hammocks fall under the “infant inclined sleep product” definition in ASTM F3118-17a because hammocks have a sleep incline angle between 10° and 30°.

D. Juvenile Products Manufacturers Association Certification⁶

The Juvenile Products Manufacturers Association (JPMA) has a certification program for a variety of juvenile products, including infant inclined sleep products. To obtain JPMA certification, manufacturers submit their products to an independent test laboratory for conformance testing to the most current ASTM voluntary standard. Currently, four manufacturers supply JPMA-certified infant inclined sleep products. CPSC staff notes that a lack of participation in the JPMA certification program does not mean that the products are not compliant with, or tested to, the ASTM standard. ASTM F3118-17a is currently in effect for testing purposes under the JPMA certification program. Typically, a 6-month period exists between the time an ASTM standard is published and the time JPMA adopts the standard for use in manufacturer testing to receive JPMA certification.

E. Incident Data

The memorandum from the Directorate for Epidemiology staff (Tab A) discusses 451 incidents (59 fatal and 392 nonfatal) related to infant inclined sleep products that occurred from January 1, 2005 through June 30, 2019, and reported between October 1, 2016 and June 30, 2019. The memorandum updates information provided in the 2017 NPR. Thus, the memorandum includes incidents reported after the end date specified in the 2017 NPR. Forty-three percent of the incident reports (196 out of 451) are based solely on information from manufacturers/retailer. Various sources, such as hotlines, Internet reports, newspaper clippings, medical examiners, and other state/local authorities provided the remaining incident reports to CPSC. Reporting is ongoing, and therefore, the number of reported fatalities, nonfatal injuries, and non-injury incidents may change in the future.

1. Fatalities

CPSC received reports of 59 fatalities associated with the use of an infant inclined sleep product. When age was known, reports indicate that 39 infants were 5 months or less in age, while six infants were between 6 and 8 months of age. One decedent was 9 months old.

Reports indicate that 56 of the 59 infant deaths involved freestanding, framed inclined sleep products; two deaths involved napper attachments of play yards; and one death involved a foam-based infant reclined sleeper. Twenty-eight of the 59 reports contain unclear,

⁶ Certification JPMA. Juvenile Product Manufacturers Association. (n.d.). Retrieved on April 29, 2016, from: <http://jpma.org/content/certification/overview>.

conflicting, and/or inconsistent information. Eight reports provide very little information on the incident, preventing staff from classifying these deaths. Eighteen reports describe infants placed in the product supine, but note that these infants ended up in a compromised position in the product, resulting in suffocations or positional asphyxiation. One unrestrained infant fell out of the product and became wedged in a confined space. Three decedents were placed prone in the product on soft bedding, and one infant suffocated when a sibling climbed on top of her in the product.

2. Nonfatal Incidents

Reports indicate that 96 of the 451 inclined sleep product-related, nonfatal incidents involved an injury to the infant during product use.

The severity of the injury types among the 96 reported injuries are described below:

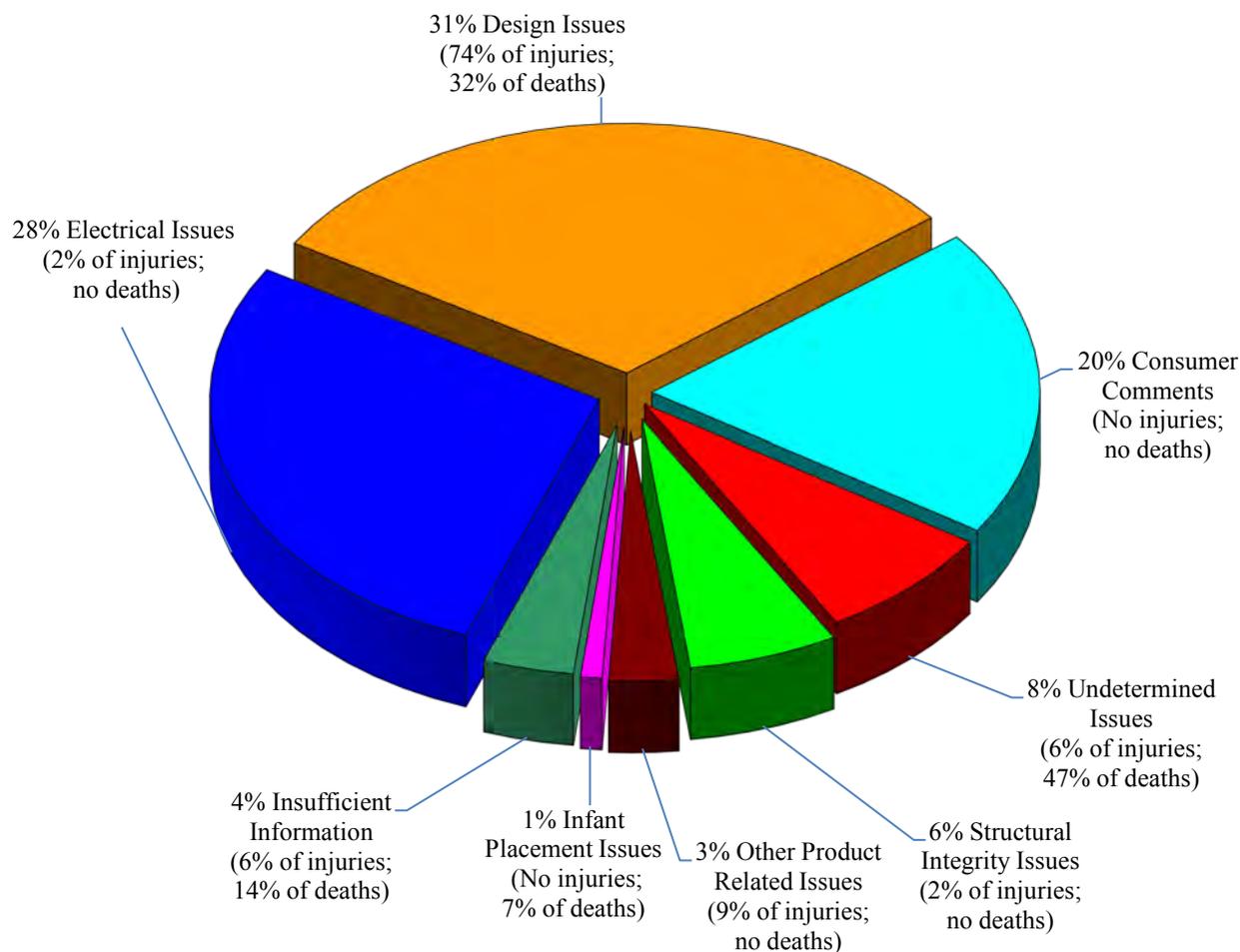
- Seven infants required hospital admission. Six of the seven infants suffered episodes of respiratory distress due to rolling over in the product; mold in the product; or undetermined reasons. One of the seven infants was hospitalized for *scoliosis* (curvature) of the back attributed to product use.
- Sixteen infants were treated and released from emergency departments (EDs). Eleven of these infants were treated for head injuries and contusions/bruises resulting from falls; three infants were treated for unexplained respiratory distress. Mold growth on the product was associated with respiratory distress for one additional infant and seizure symptoms in another.
- Seventy-three infants received some professional medical care, first-aid treatment, or the level of care received was not reported. Among them, 32 infants suffered from plagiocephaly (flat head syndrome), torticollis (twisted neck syndrome), or both conditions, associated with the use of the inclined sleep product; 27 infants suffered mostly respiratory and some skin problems associated with mold on the product; infants sustained the remaining injuries due to a fall from the product, or a minor electric shock, or unspecified.

The remaining 296 incident reports indicate that no injury occurred to the infant or provided no information about an injury. However, many of the descriptions indicate the potential for a serious injury, or even death, similar to the descriptions reported in the incident data.

F. Hazard Pattern Characterization Based on Incident Data

This section summarizes the hazard pattern characterizations based on the incident data. Figure 1 shows the distribution of hazard patterns by frequency.

Figure 1: Distribution of Incident Reports Associated with Infant Inclined Sleep Products by Hazard Pattern Characterizations Reported Between October 1, 2016 - June 30, 2019



Source: CPSC epidemiological databases CPSRMS and NEISS. Note: Percentages do not always add to 100 due to rounding.

1. **Design** of the infant inclined sleep product: 138 of the 451 reported incidents (30 percent) are in this category. Staff identified three major issues:
 - a. According to 59 of the 138 reported incidents (43 percent), infants developed respiratory and/or skin ailments due to the growth of mold on the product;

- b.* According to 46 of the 138 reported incidents (33 percent), infants rolled over—fully or partially—from their original supine position. Although some of the infants were rescued, 18 died due to suffocation or asphyxiation. A few of the infants were strapped into the product, but a majority of the infants was either not restrained or the use of restraint is unreported.
- c.* According to 33 of the 138 reported incidents (24 percent), infants developed physical deformations from extended use of the product, such as *plagiocephaly* (flat head syndrome), *scoliosis* (curvature) of the back, and/or *torticollis* (twisted neck syndrome).

The *Design* category includes 19 deaths, 5 hospitalizations, and 4 ED visits. All but 2 of the deaths resulted from infants rolling over into a prone or semi-prone position; 1 decedent was found still supine and restrained, but slumped in a chin-to-chest position. The other infant rolled out of the product and ended up wedged into a confined space. Infants unrestrained in the product led to two ED-treated falls.

- 2. **Electrical** issues: CPSC staff determined that 127 of the 451 incident reports (28 percent) reported battery leakage, electric shock, and/or overheating/melting of components, such as the vibrating unit, battery cover, switch, plug, or motor. Reports include two injuries in this category due to electric shock.
- 3. **Consumer comments**: CPSC staff determined that 90 of the 451 reports (20 percent) involved consumer comments, however, none of these reports indicates that an incident occurred. The reports consist of consumer comments/observations of perceived safety hazards, complaints about unauthorized sale of infant inclined sleep products, or inquiries regarding safety recalls on inclined sleep products. One complaint describes misinformation in the product instruction materials.
- 4. **Undetermined** due to confounding information: CPSC staff determined that 34 of the 451 reports (8 percent) provided unclear, conflicting, and/or inconsistent information. Among the 28 deaths reported in this category, for example, medical examiners often concluded the cause of death to be Sudden Infant Death Syndrome (SIDS) or Sudden Unexpected Infant Death (SUID), along with a co-contributing condition, such as unsafe sleep environment (*e.g.*, soft bedding, inclined sleep surface) or pre-existing medical condition. Staff is unable to determine the product’s role when documents describe multiple potentially contributing factors. Occasionally, the wording on the documents cites “several possibilities,” and the cause of death is coded as “Undetermined.” For the 6 nonfatal injuries, including the 2 hospitalized and 2 ED-treated injuries, the documents describe respiratory distress due to temporary cessation of breathing; however, the documents contain no official diagnosis for these episodes.

5. Lack of *structural integrity*: CPSC staff found that 28 of the 451 incidents (6 percent) report some sort of breakage of the product or its components. These reports include complaints of buckle/straps breaking, components such as hub, rail, or leg detaching/disengaging, hardware coming loose, and other unspecified components breaking. This category includes 2 ED-treated injuries, both due to falls.
6. *Other product-related* issues: Thirteen of the 451 incidents (3 percent) report other product-related issues, such as instability (product tipping over), inadequacy of restraints (infants falling out in spite of being restrained), or product assembly/installation difficulties. This category contains 7 fall-related injuries, including 2 that were treated and released from a hospital ED.
7. *Infant placement* issues: Four of the 451 incident reports (1 percent) indicate that infant placement contributed to the incident. Of the four fatalities, reports describe three infants placed in a prone position on soft bedding, and another infant being crushed by a young sibling who climbed on top of her.
8. *Insufficient information*: Seventeen of the 451 incident reports (4 percent) contain insufficient information to categorize the reports accurately. Staff has no information available on the circumstances of the remaining 8 deaths in this category. Reports for 6 injuries in this category describe unspecified falls treated in hospital EDs, with no information on restraint usage.

III. DISCUSSION

A. Reason for Draft Supplemental NPR

The Commission issued a June 2010 NPR for bassinets and cradles acknowledging that, by their nature, most infant hammocks would likely be unable to meet the proposed performance criteria of a 5° rest angle, 5° flatness angle, and a 20° maximum rock/swing angle, and thus, would be effectively banned. However, the Commission stated that until a new standard for hammocks was established, hammocks should be included in the bassinet standard. In October 2012, the Commission issued a Supplemental NPR for bassinets and cradles that did not include hammocks and other inclined sleep products, both in response to comments to the NPR and because ASTM was making progress developing a new voluntary standard for hammocks and other inclined sleep products.⁷ Comments on the 2012 bassinet Supplemental NPR universally opposed including hammocks and other inclined sleep products in the bassinet and cradle standard, asserting that inclusion in the standard would effectively ban hammocks and other

⁷ 77 Fed. Reg. 64055 (Oct. 18, 2012).

inclined sleeping products because of the restriction on the level of incline. In addition, commenters argued that hammocks and other inclined sleeping products have utility and should be subject to a standard specific to those products. Comments on the 2012 bassinet Supplemental NPR also opined that banning hammocks and other inclined sleeping products might increase hazardous sleeping arrangements, causing consumers to resort to a substitute product, such as a car seat or makeshift soft bedding, to prop up an infant at an incline. At the time, the Commission agreed with the commenters that alternative products or makeshift products would present additional hazards if consumers chose to use them instead of cribs, bassinets, or other common juvenile products intended for sleep.

At the time of the 2017 NPR for Infant Inclined Sleep Products, which included hammocks, the Commission was aware of 14 fatal incidents related to infant inclined sleep products, which were reported to have occurred between January 1, 2005 and September 30, 2016. Eight of the 14 deaths involved freestanding, framed inclined sleep products; in three cases, the unrestrained decedent was found to have rolled over into a facedown position. Two additional cases also reported a rollover into a facedown position, but they did not include any information about use of a restraint. CPSC staff had little information about the cause or manner of the three remaining deaths. The analysis in the 2017 NPR considered that these fatalities and other incidents were addressable by the design and performance requirements in the voluntary standard.

However, as staff continued to work with ASTM to strengthen the voluntary standard, which a final rule for infant inclined sleep products would reference, CPSC staff received reports of 59 additional fatalities that involved freestanding, framed inclined sleep products, two accessories, and one compact product. The dates of death among the new reports span from 2005 to 2019.

As staff became aware of more deaths in the products, staff worked with manufacturers to alert and remind consumers to use the restraints and to stop using the products when the infant begins to roll over. Because the units involved in the incidents met the ASTM F3118-17a voluntary standard referenced in the 2017 NPR, staff recommended that the Commission terminate rulemaking and withdraw the 2017 NPR⁸. Staff is now recommending instead that the Commission issue a Supplemental NPR, as described in this memorandum.

B. Biomechanical Study (See Tab B)

Commission staff contracted with Dr. Erin Mannen, Ph.D., a mechanical engineer with a biomechanics specialization, to conduct infant testing to evaluate the design of inclined sleep products. The study examined how 10 infants moved and used their muscles on flat and inclined surfaces and in selected inclined sleep products, and studied whether those designs directly impact safety or present a risk factor that could contribute to the suffocation of an

⁸ See footnote 1 for status of 2017 NPR.

infant. Testing compared infants' muscle movement and oxygen saturation on a flat crib mattress at 0°, 10°, and 20° versus seven different inclined sleep products. Infant muscle activity was recorded using surface electromyography (EMG), and oxygen saturation was recorded using a medical grade pulse oximeter. Researchers placed the infants in a random order in each of the 10 testing conditions in both the supine and prone positions for at least 60 seconds (unless the oximeter data fell below 95 percent, in which case they were removed early to ensure safety).

Key findings from Dr. Mannen's study include:

- “Inclined surfaces and incline sleep products resulted in significantly higher muscle activity of the turn core muscle (abdominals), which may lead to quicker fatigue and suffocation if an infant finds themselves prone in an incline sleep product.
- Muscle synergies (*i.e.*, how muscles work together) are significantly different in inclined sleep products. If an infant rolls from supine to prone in an inclined sleep product, it is likely the first time the baby has experienced the position and the demands the position requires of the muscles.
- Some inclined sleep products require greater neck and trunk adjustments during prone positioning, indicating that infants may struggle to adjust their posture to enable breathing and attempt to self-correct if a roll from supine to prone occurs.
- Prone lying in the incline sleep products puts infant at higher risk of suffocation as evidenced by oxygen saturation results.
- Some evidence was found that support the idea that the inclined sleep products make the babies roll more easily from supine to prone. The flexed trunk and ease of head lifting during supine lying in an inclined sleep product may indicate that supine to prone rolling is achieved more easily.
- If babies roll from supine to prone in an inclined sleep product, then, due to the high musculoskeletal demands necessary to maintain safe posture to prevent suffocation, babies would fatigue faster than they would on a stable, flat surface.
- None of the inclined sleep products that were tested and evaluated as a part of this study are safe for infant sleep.”

C. Adequacy of F3118 Requirements (See Tabs C, D, and E)

Based on the incident data discussed above and the biomechanical study, staff finds ASTM F3118-17a inadequate to address the hazards of an infant lying in an inclined sleep product with an angle greater than 10°. Staff concludes that more stringent requirements are needed to further reduce the risk of injury associated with infant inclined sleep products.

Introduction, and Scope

The introduction of ASTM F3118 *Standard Consumer Safety Specification for Infant Inclined Sleep Products* presents the category of “*Infant Inclined Sleep Products*” and the scope identifies the products. According to the scope, this standard covers:

“a free standing product with an inclined sleep surface primarily intended and marketed to provide sleeping accommodations for an infant up to 5 months old or when the infant begins to roll over or pull up on side, whichever comes first. It also covers smaller product intended for newborns up to 3 months old or when newborn begins to wiggle out of position or turn over in the product or weighs more than 15 lb (6.8 kg), whichever comes first. It also covers infant and newborn inclined sleep product accessories, which are attached to, or supported by another product with the same age or abilities, or both as the free standing product.”

Staff considers the use of the word “inclined” within the introduction and scope of this standard inappropriate because an “inclined” position is not a safe sleep position. Therefore, staff recommends not including the word “inclined” in the CPSC standard and identifying the products covered in CPSC’s safety standard as “infant sleep products.” This standard would cover any infant sleeping products not currently covered by standards and regulations for traditional sleeping products, such as, bassinets/crib, cribs (full-size and non-full-size), play yards, and bedside sleepers. In addition, CPSC staff believes that any mention of sleep, including “napping,” should be considered “primarily intended and marketed to provide sleeping accommodations” and, therefore, be covered by this standard.

Staff is interested in receiving comments regarding the age and developmental milestones referenced in the scope and definitions of the various infant inclined sleep products covered by the current standard. Since this Supplemental NPR is attempting to address “infant sleep products” not already covered by traditional sleep products, staff believes removing the upper age limit from the scope will allow for broader coverage of the standard. When age was known, twenty percent of the fatalities and injuries involved infants 6 months and older.

Product design

The results of the biomechanical study revealed that a 20° incline resulted in significantly different muscle activity for the infants, compared to a 0° incline surface. The increased demand on the abdominal muscles could lead to increased fatigue and suffocation if an infant is unable to reposition itself after rolling from a supine to prone position. At a 10° incline, fewer differences in muscle activity or lying posture were revealed, compared to the 0° incline surface. According to Dr. Mannen’s report, “ten degrees is likely a safe incline for sleep on a crib mattress surface.” Dr. Mannen concludes that an incline of 20° or more puts an infant at risk compared to a 0°-10° incline. Although her study did not test infants on inclines between 10°-20°, and thus did not offer conclusions for these angles, CPSC staff does

not believe additional testing on inclines between 10°-20° is necessary because we conclude that a flat surface that does not exceed 10° offers the safest sleep environment for infants. Staff recommends requiring 16 CFR 1218 Safety Standard for Bassinets and Cradles because it is an established standard, which, among other requirements, mandates that the seat back surface angle intended for sleep be 10 degrees or less.

Based on the incident reports and the results of the biomechanical study, CPSC staff recommends that the Commission propose to incorporate by reference ASTM F3118-17a with the following modifications to address the hazards of an infant lying on an inclined surface:

1. Modify the introduction and scope of the standard to state that the purpose of the standard is to address infant sleep products not already covered by traditional sleep product standards.
2. Modify the definitions of “accessory,” “compact,” “infant inclined sleep products,” and “newborn inclined sleep products” to remove the term “inclined.”
3. Modify seat back angle so that the maximum allowable seat back angle intended for sleep must be equal to or less than 10° in all positions recommended for sleep.
4. Add new requirement – accessory, compact, infant and newborn sleep products must meet 16 CFR part 1218 – Safety Standard for Bassinets and Cradles.
5. Remove all of the performance requirements, except for the new or modified requirements mentioned above.
6. Remove all test methods, except for maximum seat back angle.

Electrical

Staff determined that 127 of the 451 new incidents are related to electrical issues. The electrical-related issues included battery leakage, electric shock, and overheating of components. Some inclined sleep products have accessories that provide music, rocking motion, or vibration, which are either battery- or a/c-powered; however, F3118-17a does not include any performance requirements for electrical components. Other juvenile products that have similar features include performance requirements that could apply for infant sleep products. CPSC staff has raised this issue and is working with the ASTM Ad Hoc task group to develop performance requirements to address electrical hazards across juvenile products. Performance requirements would apply to other children’s product standards, such as bouncers, swings, and bassinets. Because these requirements are currently under development, CPSC staff recommends not proposing electrical requirements in this Supplemental NPR, and instead suggests continuing to work with applicable ASTM subcommittees to develop electrical requirements for all applicable durable infant or toddler products with electrical components.

Warnings

Focus groups with parents and grandparents of infants less than 1 year of age provided information on caregivers' perceptions and reactions to safety messaging¹, indicating that participants were aware of warning labels on infant sleep products. Additionally, participants reported that the label shown during the focus group looked similar and contained comparable information to labels that they find on products they own. Some participants reported that they tend to gloss over warning labels, as they believe the language to be the same on every label. Regarding the purpose of warning labels, some participants reported that they thought the main message was to be careful and keep an eye on their infant, while a few participants believed that manufacturers use warning labels to protect themselves from liability or litigation. Participants' recommendations to improve warning labels included making the labels more concise and making the labels "stand out." CPSC staff is working with a contractor to develop new safe sleep warnings and messaging, potentially across all sleep products. In the future, staff could recommend changes in warnings based on this work.

Plagiocephaly/torticollis

Although the incident data indicate that consumers believe using an inclined sleep product caused their child's plagiocephaly/torticollis, staff found no evidence to support this belief. The increase in the number of children with plagiocephaly may result from the American Academy of Pediatrics' (AAP) recommendation to place infants to sleep on their backs to decrease the risk of SIDS. In the first few months of life, infants spend most of their awake and sleep time on their back. The weight and pressure of their head facing up, causes the back of the head to flatten, regardless of the product the child is using. To help prevent the development of flat head, and to promote the upper shoulder muscle strength necessary for healthy growth, AAP currently recommends a certain amount of prone positioning, or "tummy time," while the infant is awake and under parental supervision. Because the development of plagiocephaly and torticollis is not exclusively attributable to the use of infant inclined sleep products, and the conditions are not addressable with performance standards, staff is not recommending any modifications to the voluntary standard to address these issues.

D. Product Registration Rule Amendment

In addition to requiring the Commission to issue safety standards for durable infant or toddler products, section 104 of the CPSIA also directed the Commission to issue a rule requiring that manufacturers of durable infant or toddler products establish a program for consumer registration of those products. The statutory definition of "durable infant or toddler product" in section 104(f) applies to all of section 104 of the CPSIA.

Section 104(f) of the CPSIA defines the term "durable infant or toddler product" and lists examples of such products:

(f) DEFINITION OF DURABLE INFANT OR TODDLER PRODUCT. As used in this section, the term "durable infant or toddler product" –

(1) means a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years; and

(2) includes –

- (A) full-size cribs and non-full-size cribs;
- (B) toddler beds;
- (C) high chairs; booster chairs, and hook-on-chairs;
- (D) bath seats;
- (E) gates and other enclosures for confining a child;
- (F) play yards;
- (G) stationary activity centers;
- (H) infant carriers;
- (I) strollers;
- (J) walkers;
- (K) swings; and
- (L) bassinets and cradles.

The infant inclined sleep products safety standard developed out of the bassinet safety standard. Inclined sleep products, like bassinets, are durable products intended for use by children under the age of 5 years. While considering the bassinet standard, the Commission stated that a separate standard targeted specifically to inclined sleep products would address more effectively the hazards associated with those products. *77 Fed. Reg.* 64055, 64059 (Oct. 18, 2012). Therefore, CPSC staff began working with ASTM to develop a voluntary standard that would cover the wide array of products on the market that provide infants and toddlers with inclined sleeping environments.

In 2009, the Commission issued a rule implementing the consumer registration requirement, 16 CFR part 1130. As the CPSIA directs, the consumer registration rule requires each manufacturer of a durable infant or toddler product to provide a postage-paid consumer registration form with each product; keep records of consumers who register their products with the manufacturer; and permanently place the manufacturer's name and certain other identifying information on the product. When the Commission issued the consumer registration rule, the Commission identified six additional products as “durable infant or toddler products”:

- children's folding chairs;
- changing tables;
- infant bouncers;
- infant bathtubs;
- bed rails; and
- infant slings.

The Commission stated that the specified statutory categories were not exclusive, but that the Commission should explicitly identify the product categories that are covered. The preamble to the 2009 final consumer registration rule states: “Because the statute has a broad definition of a durable infant or toddler product but also includes 12 specific product categories, additional items can and should be included in the definition, but should also be specifically listed in the rule.” 74 *Fed. Reg.* 68668, 68669 (Dec. 29, 2009).

Staff recommends that the Commission propose to amend the definition of “durable infant or toddler product” in the consumer registration rule to reduce any uncertainty about whether infant sleep products fall within the term “durable infant or toddler product,” as used in the product registration card rule and section 104 of the CPSIA. Staff’s recommendation to require infant sleep products to meet the bassinets standard, but also keep infant sleep products as a separate standard provides a clear connection between the two sleep categories for infants under the age of 5 months. Specifically, staff recommends amending 16 CFR part 1130.2(a)(12) to read:

- Bassinets and cradles, including bedside sleepers and infant sleep products.

E. Potential Small Business Impact

Staff identified 18 firms still supplying sleep products to the U.S. market with sleep surface angles greater than 10 degrees, but less than or equal to 30 degrees, which under the current voluntary standard are considered infant inclined sleep products. One additional firm supplies a sleep product with an angle of 10 degrees or less that is not tested for compliance with either the bassinet standard or another sleep product standard. The majority of suppliers to the U.S. market are domestic (13 firms). Of these, two appear to be very small, home-based domestic manufacturers of infant hammocks.⁹ None has more than one infant hammock model in their product line, and they supply few, if any, other products. They generally have low sales volumes. Staff identified another seven firms (four manufacturers and three importers) that, although not as small as the home-based suppliers, still meet the definition of “small” domestic entities, based on U.S. Small Business Administration (SBA) guidelines in their North American Industry Classification System (NAICS) codes. These firms also typically have only one inclined sleep product model in their product lines, but have much larger sales volumes than the home-based suppliers.

The remaining two firms are foreign manufacturers (along with four home-based foreign manufacturers). Additionally, staff identified a few inclined sleep products entering the U.S. market via online retailers that operate marketplaces for smaller sellers and foreign retailers

⁹ These suppliers were identified online and staff believes that there may be additional home-based suppliers operating in the infant sleep product market on a very small scale (possibly including some without an on-line presence).

willing to supply foreign-manufactured inclined sleepers directly to U.S. consumers. Foreign suppliers are not considered in the regulatory flexibility analysis because SBA guidelines and definitions pertain only to U.S.-based entities.

As described in Tab F, the draft Supplemental NPR could have a significant impact on small firms that currently manufacture or import infant inclined sleep products, as well as small firms whose products may have difficulty meeting the bassinet standard's requirements. However, the impact depends on several unknown factors, including:

- How firms respond to the rule (*e.g.*, would they redesign, remarket, or drop);
- The costs associated with redesigning, remarketing, or replacing their inclined sleep product
- The change in demand, if any, for that product.

Staff found that third party costs are likely to be significant for the two very small, home-based manufacturers of infant hammocks (*if* they choose to redesign) and could be significant for two additional small manufacturers, if they choose to redesign their products *and* four or five units per model were required to provide a “high degree of assurance.”

Staff seeks comments from firms that manufacture or import infant inclined sleep products regarding how they are likely to meet the requirements of the draft Supplemental NPR and the impact that the draft Supplemental NPR would have on them. We also seek comments concerning any alternatives to the draft Supplemental NPR that would meet the same safety objectives but reduce the burden on small entities. This includes the 12 months effective date that staff recommended to help reduce the impact of the draft Supplemental NPR on small firms and give them additional time to familiarize themselves with the scope of the standard and develop new/modified products, if needed.

F. Compliance Recall Information

Compliance staff reviewed recalls of infant inclined sleep products from May 10, 2000 to August 20, 2019. During that period, there were 13 consumer-level recalls involving infant inclined sleep products. The recalls were conducted in response to hazards involving strangulation, suffocation, fall, structural stability, entrapment, exposure to mold, and deaths. Six recalls involved infant hammocks, six recalls involved infant inclined sleep products, and one recall involved an infant inclined sleep accessory included with a play yard. The 13 recalls involved approximately 6.5 million units.

IV. NOTICE OF REQUIREMENTS

Section 14(a) of the CPSA requires that any children's product subject to a consumer product safety rule under the CPSA must be certified as complying with all applicable CPSC-enforced requirements. The children's product certification must be based on testing conducted by a CPSC-accepted third party conformity assessment body (test laboratory). The CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party test laboratories to determine compliance with a children's product safety rule to which a children's product is subject. A Supplemental NPR for infant sleep products, if issued as a final rule, would be a children's product safety rule that requires issuing an NOR.

The Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 16 CFR part 1112 (78 Fed. Reg. 15836 (March 12, 2013)) (referred to here as part 1112). This rule took effect on June 10, 2013. Part 1112 establishes the requirements for accreditation of third party testing laboratories to test for compliance with a children's product safety rule. The final rule also codifies all of the NORs that the CPSC has published, to date, for children's product safety rules. All new children's product safety rules, such as the proposed rule for infant sleep products, would require an amendment to part 1112 to create an NOR. Therefore, staff recommends that the Commission propose to amend part 1112 to include infant sleep products in the list of children's product safety rules for which the CPSC has issued NORs.

V. RECOMMENDED EFFECTIVE DATE

To allow time for infant sleep product manufacturers to bring their products into compliance after a final rule is issued, staff recommends an effective date of 12 months after publication of a final rule for products manufactured or imported on or after that date. Staff is recommending incorporating by reference ASTM F3118-17a, with modifications. Staff believes that the proposed modifications may require time beyond the typical 6-month effective date for a section 104 rule. Staff believes that most firms should be able to comply within the 12-month timeframe, but requests comments on the appropriate effective date. Specifically, the APA generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. § 553(d). As noted above, typically section 104 rules have effective dates between 6 and 12 months after the final rule is issued, but given the hazards involved with these products, staff could recommend a shorter time period for effectiveness.

VI. STAFF RECOMMENDATIONS

CPSC staff recommends that the Commission propose to incorporate by reference the voluntary standard, ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, with modifications to introduction, scope, performance, and testing requirements so infant sleep products that are not covered by standards for bassinets, cribs (full-size and non-full size), play yards, or bedside sleepers must have seat back angles intended for sleep of 10° or less

and must meet the requirements of 16 CFR part 1218 Safety Standard for Bassinets and Cradles.

Specifically, staff recommends that the Commission publish the draft Supplemental NPR, incorporating by reference the current standard, with modifications as noted in this package. Staff also recommends requesting public comment regarding all aspects of the draft Supplemental NPR. Because infant sleep products were not specifically mentioned as a durable infant or toddler product in section 104(f)(2), staff also recommends proposing to amend 16 CFR part 1130 to identify specifically infant sleep products.

TAB A: Infant Inclined Sleep Product-Related Deaths, Injuries, and Potential Injuries Reported Between October 1, 2016 and June 30, 2019 Covering Incidents from January 1, 2005 – June 30, 2019

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

Memorandum

Date: August 26, 2019

TO : Celestine T. Kish
Infant Inclined Sleep Products Project Manager
Division of Human Factors
Directorate for Engineering Sciences

THROUGH: Stephen Hanway
Associate Executive Director
Directorate for Epidemiology

FROM : Risana Chowdhury, Division Director
Division of Hazard Analysis
Directorate for Epidemiology

SUBJECT : Infant Inclined Sleep Product-Related Deaths, Injuries, and Potential Injuries
Reported Between October 1, 2016 and June 30, 2019¹

This memorandum updates the data in the Infant Inclined Sleep Products notice of proposed rulemaking briefing package presented to the Commission in March 2017 (2017 NPR). Staff of the Consumer Product Safety Commission (CPSC staff) extracted data for the 2017 NPR on October 14, 2016. The 2017 NPR data included all incidents reported to have occurred from January 1, 2005 through September 30, 2016. This memorandum includes any newly reported infant inclined sleep product-related incidents from the January 2005 – September 2016 timeframe, as well as all new incidents reported to have occurred between October 1, 2016 and June 30, 2019. Staff found that the number of emergency department (ED)-treated injuries reported through the National Electronic Surveillance System (NEISS) associated with infant inclined sleep products, for the time frame covered, was insufficient to derive any reportable national estimates.² Hence, staff does not present injury estimates in this

¹ This analysis was prepared by CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

² According to the NEISS publication criteria, an estimate must be 1,200 or greater, the sample size must be 20 or greater, and the coefficient of variation must be 33 percent or smaller.

memorandum. However, staff includes the emergency department-treated injuries in the total count of reported incidents.

Incident Data³

Since the 2017 NPR, CPSC staff received a total of 451 new incident reports related to infant inclined sleep products. Eighty-four percent of the new incidents are reported to have occurred between October 2016 and June 2019 (*i.e.*, after the timeframe covered in the 2017 NPR); the remaining 16 percent are newly reported incidents that occurred in the earlier timeframe of 2005 – September 2016. Forty-three percent of the incident reports (196 out of 451) are based solely on information from manufacturers/retailer.

Of the 451 reported incidents, 59 are fatalities; among the remaining 392 non-fatal incidents, 96 report an injury. Two hundred and seventy-six (276) incident reports provide the victim’s age. Table 1 provides the age breakdown from the 451 incident reports.

Table 1: Age Distribution in Infant Inclined Sleep Product-Related Incidents Reported Between October 1, 2016 and June 30, 2019

<i>Age of Child</i>	<i>All Incidents</i>		<i>Injuries and Fatalities</i>	
	<i>Frequency</i>	<i>Percentage</i>	<i>Frequency</i>	<i>Percentage</i>
Unreported*	175	39	16	10
One – Five Months	218	48	108	70
Six – Eight Months	49	11	23	15
Nine – Twelve Months	7	2	6	4
Over One year	2	<0.5	2	1
Total	451	100	155	100

Source: CPSC epidemiological databases CPSRMS and NEISS. Percentages may not add to 100 due to rounding.

* Age may be “unreported” under two circumstances: age was unknown or age was not reported because the incident involved no injury.

Fatal Incidents

Since the 2017 NPR, CPSC staff received reports of 59 deaths. One product is a foam-based infant reclined sleeper; two products are napper attachments of play yards; and the remaining products are

³ CPSC staff searched two databases: the Consumer Product Safety Risk Management System (CPSRMS) and the National Electronic Injury Surveillance System (NEISS). Reported deaths and incidents do not provide a complete count of all that occurred during this period. However, they do provide a minimum number of deaths and incidents occurring during this period and illustrate the circumstances involved in the incidents related to infant inclined sleep products.

CPSC staff extracted reported incident data on 7/19/19. Staff extracted all data coded under product codes 5037 (hammocks), 1537 (bassinet/cradles), 1513 (playpens), 1529 (portable cribs), 1542 (baby mattresses or pads), 1553 (portable baby swings), and 1558 (baby bouncer seats), and staff used keyword searches to identify the potentially in-scope cases. Upon careful joint review with CPSC’s Directorates for Engineering Sciences and Economics staff, staff considered many cases out-of-scope for the purposes of this memorandum. For example, staff excluded from the analysis cases where a pre-existing medical condition was the official cause of death or cases where the infant using the product was much older than the recommended age. However, staff retained all incidents where hazardous environments in and around the infant inclined sleep product resulted in fatalities, injuries, or near-injuries. With the exception of incidents occurring on U.S. military bases, staff excluded all incidents that occurred outside of the U.S. To prevent any double counting, staff consolidated and counted as one incident when staff identified multiple reports of the same incident.

freestanding framed inclined sleep products. Staff reviewed and categorized incident reports associated with the fatalities:

- Twenty-eight of the 59 reports contain unclear, conflicting, and/or inconsistent information. For example, in this category medical examiners often conclude the cause of death to be Sudden Infant Death Syndrome (SIDS) or Sudden Unexpected Infant Death (SUID) along with a co-contributing condition such as unsafe sleep environment (*e.g.*, soft bedding, inclined sleep surface) or other pre-existing medical condition. Considering all factors in each report confounds staff's ability to determine the predominant factor causing a fatality. Occasionally, wording on the documents cite "several possibilities" and the cause of death is coded as Undetermined. Lack of clarity in these reports make it difficult for CPSC staff to consistently classify the 28 deaths.
- Eighteen reports describe infants placed in the product supine but who ended up in a compromised position in the product, resulting in suffocations or positional asphyxiations. In 11 of the 18 cases, no restraints were used; another six infants were placed in a supine position, but the use of restraints is unknown; and in one case, the infant was left restrained and supine, but found supine, slumped in a chin-to-chest position. One additional unrestrained infant fell out of the product and became wedged in a confined space.
- Eight reports provide very little information on the incidents. Lack of any information on the circumstances leading up to the death does not allow staff to classify these deaths.
- Four reports describe infant placement issues; three of the four decedents were reportedly placed prone on soft bedding in the product; and another decedent suffocated when a young sibling climbed into the sleep product on top of her.

CPSC does not know the age for 10 deceased infants. Staff concludes that, for the remaining deaths, 39 infants were 5 months or less in age, and six infants were between 6- and 8-months of age. One decedent was 9-months old.

Nonfatal Incidents

Ninety-six of the 451 infant inclined sleep product-related incident reports involve a nonfatal injury. Among these injuries staff found:

- Seven infants required hospital admission. Six of the seven infants suffered episodes of respiratory distress due to rolling over in the product; mold in the product; or undetermined reasons. One of the seven infants was hospitalized for *scoliosis* (curvature) of the back attributed to product use.
- Sixteen infants were treated and released from hospital emergency departments. Eleven of the sixteen infants were treated for head injuries and contusions/bruises resulting from falls; three infants were treated for unexplained respiratory distress. Mold growth on the product was associated with respiratory distress in one additional infant and seizure symptoms in another.
- Seventy-three infants received some professional medical care, first-aid treatment, or the level of care received was not reported. Among them, 32 infants suffered from *plagiocephaly*

(flat head syndrome), *torticollis* (twisted neck syndrome), or both conditions, associated with the use of the inclined sleep product; 27 infants suffered mostly respiratory and some skin problems associated with mold on the product; infants sustained the remaining injuries due to a fall from the product or a minor electric shock, or their injuries are unspecified.

The remaining 296 incident reports indicate that no injury occurred or provided no information about an injury. However, many of the descriptions indicate the potential for a serious injury or even death.

Hazard Patterns

In the 2017 NPR, CPSC staff identified nine hazard patterns in the 657 reported incidents. These hazard patterns include: design issues, lack of structural integrity, inadequate restraints, electrical issues, non-product-related or unknown issues, difficulty with correct positioning, miscellaneous product-related issues, unspecified falls, and consumer comments. Although the distribution of the data in this 2019 update varied somewhat, staff finds that the broader hazard categories are very similar. However, within the broader hazard category of design, staff identified one new hazard pattern, as described below.

Staff considered all 451 reported incidents (59 fatal and 392 nonfatal) to identify hazard patterns associated with infant inclined sleep products. The infant inclined sleep products category includes a variety of products. Some products, like hammocks, are suspended in air. Other seat-like products are meant to be placed on a floor, but incident reports indicate these products often were not placed on floor level. Yet other products sit on top of larger nursery products as attachments. Staff identified hazard patterns that are quite different depending on which product is involved and how the product is being used. In order of frequency of incident reports, staff grouped the hazard patterns into the following categories:

1. **Design** of the infant inclined sleep product: One hundred and thirty-eight of the 451 reported incidents (30 percent) are in this category. Staff identified three major issues:
 - a. According to 59 of the 138 reported incidents (43 percent), infants developed respiratory and/or skin ailments due to the growth of mold on the product;
 - b. According to 46 of the 138 reported incidents (33 percent), infants rolled over—fully or partially—from their original supine position. Reports describe infants as young as 1- or 2-months of age as having rolled over; parents/caregivers, who witnessed and reported some of the nonfatal incidents, were able to rescue distressed infants quickly. Eighteen infants died due to suffocation or asphyxiation. Although a few of the infants were strapped into the product, a majority of the infants were either not restrained or the restraint use is unreported.
 - c. According to 33 of the 138 reported incidents (24 percent), infants developed physical deformations from extended product use, such as *plagiocephaly* (flat head syndrome), *scoliosis* (curvature) of the back, and/or *torticollis* (twisted neck syndrome).

The design category includes 19 deaths, 5 hospitalizations, and 4 emergency department (ED) visits. All but two of the deaths resulted from infants rolling over into a prone or semi-prone position; one decedent was found still supine and restrained, but slumped in a chin-to-chest position. The other infant rolled out of the product and wedged into a confined space. An additional 62 non-hospitalized, non-ED injuries are reported in this category.

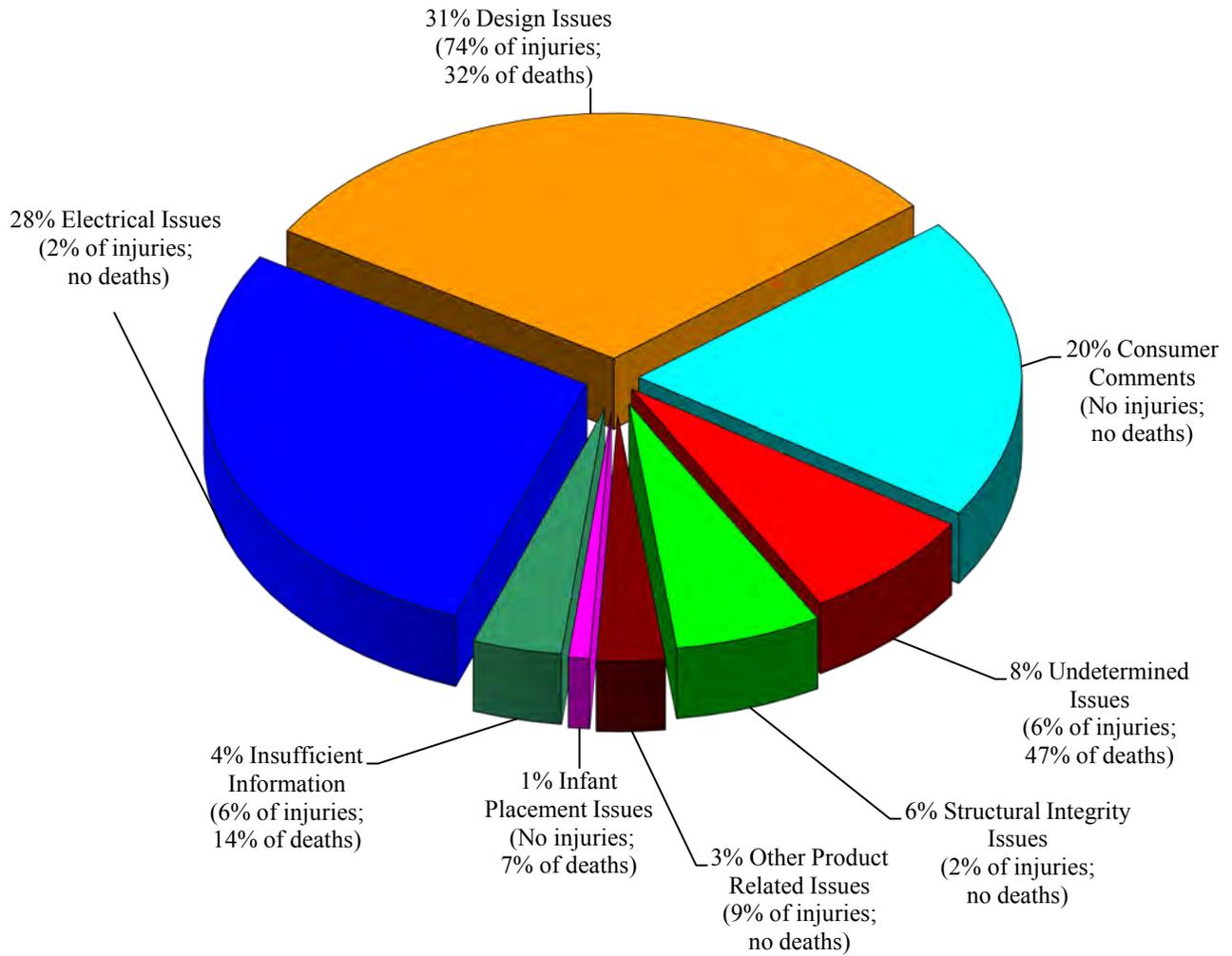
2. **Electrical** issues: One hundred and twenty-seven of the 451 incident reports (28 percent) report battery leakage, electric shock, and/or overheating/melting of components, such as the vibrating unit, battery cover, switch, plug, or motor. Reports include two injuries in this category due to electric shock.
3. **Consumer comments**: Ninety of the 451 reports (20 percent) included consumer feedback, but did not report an actual incident. The reports consist of consumer comments/observations of perceived safety hazards, complaints about unauthorized sale of infant inclined sleep products, or inquiries regarding safety recall on inclined sleep products. One complaint describes misinformation in the instruction material.
4. **Undetermined** due to confounding information: Thirty-four of the 451 reports (8 percent) provide unclear, conflicting, and/or inconsistent information. Among the 28 deaths reported in this category, for example, medical examiners often concluded the cause of death to be SIDS or SUID, along with a co-contributing condition such as an unsafe sleep environment (e.g., soft bedding, inclined sleep surface) or pre-existing medical condition. Staff is unable to determine the role of the product when documents describe multiple potentially contributing factors. Occasionally, the wording on the documents cite “several possibilities” and the cause of death is coded as Undetermined. For the 6 nonfatal injuries, including the 2 hospitalized and 2 ED-treated injuries, the report described respiratory distress due to temporary cessation of breathing; however, these reports contain no official diagnosis for these episodes.
5. Lack of **structural integrity**: Twenty-eight of the 451 incidents (6 percent) report some sort of breakage of the product or its components. These reports include complaints of buckle/straps breaking, components such as hub, rail, or leg detaching/disengaging, hardware coming loose, and other unspecified components breaking. This category includes two ED-treated injuries, both due to falls.
6. **Other product-related** issues: Thirteen of the 451 incidents (3 percent) incidents report other product-related issues, such as instability (product tipping over), inadequacy of restraint (infants falling out in spite of being restrained), or product assembly/installation difficulties. This category contains nine, mostly fall-related injuries, including two injuries that were treated and released from a hospital ED.

7. ***Infant placement*** issues: Four of the 451 incidents reports (1 percent) indicate that infant placement contributed to the incident. Of the four fatalities, reports describe three infants placed in a prone position on soft bedding and another infant being crushed by a young sibling who climbed on top of her.

8. ***Insufficient information***: For 17 of the 451 incidents (4 percent), reports contain insufficient information for staff to categorize them accurately. Staff has no information available on the circumstances of 8 deaths in this category. Reports for six injuries in this category describe unspecified falls treated in hospital EDs, with no information was on restraint usage.

Figure 1 displays the hazard pattern distribution for the 451 incident reports:

Figure 1: Distribution of Incident Reports Associated with Infant Inclined Sleep Products by Hazard Pattern Characterizations Reported Between October 1, 2016 - June 30, 2019



Source: CPSC epidemiological databases CPSRMS and NEISS.
 Note: Percentages do not always add to 100 due to rounding.

TAB B: Biomechanical Analysis of Inclined Sleep

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1. BACKGROUND

Since 1992, the American Academy of Pediatrics (AAP) has recommended that infants under the age of one should be placed for sleep on a flat and firm surface in the supine position to reduce the incidence of Sudden Infant Death Syndrome (SIDS). The rate of SIDS deaths has decreased by 70% since the National Institute of Child Health and Development (NICHD) “Safe-to-Sleep” campaign (formerly “Back-to-Sleep”) was implemented in 1992.¹ However, some infants are currently placed to sleep in Inclined Sleep Products, designed to keep an infant supine at a 10 to 30 degree incline, and do not meet safe sleep guidelines set forth by the NICHD and AAP. Parents are advised to always use restraints in the products and to discontinue use once an infant has the ability to roll over. However, several infant deaths have been reported in Inclined Sleep Products with the deceased infants often found in the prone position, with suffocation as the apparent cause of death. It is, therefore, imperative to understand if the *design* of the Inclined Sleep Products contribute directly to an increased rate of infant deaths by either making it easier to roll from the supine to the prone position or making it more difficult to self-correct from the prone to the supine position when infants are prone in the product. It is hypothesized that an infant’s body position on or within a product is related to the infant’s ability to move, to perform a head lift, or to achieve a roll. Movement demands based on a product design or body position may have a direct relationship to an infant’s risk of suffocation due to inability to maneuver into a safe breathing position.

The following studies were proposed to begin answering these questions:

1. An analysis of the **incident reports** related to Inclined Sleep Products to qualitatively assess trends, similarities, or differences in the incidents that may inform product safety,
2. A thorough **product analysis** of various Inclined Sleep Products within the product class to identify differences in design,
3. A non-invasive *in vivo* **biomechanics study** of infants 2-6 months of age to determine:
 - (a) the strength and space requirements for infants to move their heads and/or roll from the supine to the prone position in Inclined Sleep Products compared to a Flat Sleep Product,
 - (b) the strength and space requirements for infants to lift their heads and/or roll from the prone to the supine position in Inclined Sleep Products compared to a Flat Sleep Product.

The outcomes of this study will inform the Consumer Product Safety Commission (CPSC) on whether the designs of Inclined Sleep Products impact an infant’s ability to move within the products, and if those designs directly impact safety or present a risk factor contributing to suffocation of an infant. Based on the results of the studies, if necessary, the current ASTM International standard will be reviewed to make recommendations to mitigate hazards from this class of products.

Summaries of the project team can be found in Appendix A. Summaries of the facilities and equipment used in this study can be found in Appendix B.

2. INCIDENT REPORT ANALYSIS

2.1 Incident Report Methods

The CPSC provided the research team with details of incidents involving Inclined Sleep Products. At the time of this report (July 2019), there were 91 separate incidents reported to or investigated by the CPSC involving an incident (hazard, injury, or death). Varying amounts of information were provided for each incident, including police reports, coroner reports, witness statements, photos, videos, and summaries of the event written by CPSC employees. The summaries written by the CPSC were not considered in this qualitative analysis.

Each incident was reviewed by two members of the research team, separately confirming details of the events. The following data was gathered from the reports and organized in a spreadsheet: date of incident, incident (hazard, injury, or death), manufacturer and model, city and state, infant demographics at time of incident (age, sex, race/ethnicity, height, weight), incident details (initial position, found position, time since last checked, found by, restraint used, soft goods found with infant, other items found with infant, room temperature, current medical conditions, usual sleeping position, other notes), birth and pregnancy details (pregnancy concerns, gestational age, maternal age, paternal age, Apgar Score, height, weight, previous medical history), coroner report details (medical findings, cause of death, manner of death, medical notes), conflicting details noted by the team, and other notes of interest.

The incidents were sorted into the following six categories with descriptions:

- *Supine-supine*: infant was placed in a supine position and found in a supine position.
- *Supine-prone*: infant was placed in a supine position and found in a prone or side-lying position.
- *Supine-other*: infant was placed in a supine position and found in a sitting position, was hanging from the product, or had fallen out of the product.
- *Prone-prone*: infant was placed in a prone position and found in a prone position.
- *Other circumstances*: external circumstances not related to the product caused the incident.
- *Not enough information*: reports do not have enough information to determine event; there were no witness statements, detailed description of the event, police report, hospital records, or medical records included in these incidents.

Because some incident reports were incomplete or contained conflicting details regarding initial and found positions, extra attention was given to these incidents to categorize them as accurately as possible. For instance, if autopsy or police investigative evidence supported that the found position was different than initially reported by the caregivers (i.e. location of lividity in autopsy reports), the categorization was based on an evaluation of all information available for that incident.

Descriptive qualitative analysis of each of these incident categories was provided, with the biomechanists and pediatric orthopaedists focusing on the movement-based incidents (*supine-prone*, *supine-other*), and the biomechanists and pediatric pulmonologist focusing on the *supine-supine* and *prone-prone* categories. Student's t-tests ($p=0.05$) were used to compare average ages of infants who experienced *supine-supine* v. *supine-prone* events. Reference to specific product manufacturers or designs has been blinded from the main portion of this report, so companies are referred to as "Company A, Company B," etc. Similarly, the products are coded as "S01, S02," etc. The key for company and product codes can be found in Appendix C.

2.2 Incident Report Results

All 91 incidents were reviewed and sorted into the following categories described in section 2.4:

- **Supine-supine:** 38 [Company A (products S01 and S02); Company B (products S03 and S06)]. Of these, 33 were deaths, 4 were injuries, and 1 was a hazardous event.
- **Supine-prone:** 25 [Company A (products S01 and S02); Company B (products S03 and S06); Company C (product S08)]. Of these, 21 were deaths and 4 were injuries.
- **Supine-other:** 4 [Company A (product S01)]. Of these, 2 were injuries and 2 were hazardous events.
- **Prone-prone:** 3 [Company A (products S01 and S02)]. All 3 of these incidents were deaths.
- **Other circumstances:** 2 [Company A (products S01 and S02)].
- **Not enough information:** 19 [Company A (products S01 and S02)].

Detailed summaries of all incidents are provided in Appendix D.

The **Other circumstances** category included incidents where external circumstances not related to the product caused the event. Both cases were deaths. These two events are not under consideration as incidents that may have been caused by the inclined sleep products.

After eliminating the two incidents from the **Other circumstances** category, 89 events were left to analyze. Nineteen incidents were categorized as **Not enough information**. If incidents did not contain police reports or interviews, medical records, descriptive information regarding the event, or autopsy/coroner's reports, they were considered in this **Not enough information** category. Two of these incidents (1 death, 1 injury) were reported to the CPSC or found via internet research but attempts by the CPSC for follow-up communication were unsuccessful. Of the remaining 17 events, 14 were deaths and 3 were injuries. Most of these incidents were reported to or discovered by the CPSC after the April 2019 voluntary recall of two companies' inclined sleep products. Therefore, many of the CPSC investigations are ongoing. It is expected that many of these events will eventually fall into either the **supine-supine, supine-prone, supine-other, or prone-prone** categories after in-depth investigations have been completed, but there is not enough information to be certain at the time of this report.

After excluding the 19 incidents from the **Not enough information** category, 70 events remained. The **supine-supine, supine-prone, supine-other, and prone-prone** events were considered the highest priority in analyzing and understanding the circumstances surrounding the events, therefore these categories were examined in more detail.

Figure 1 shows a map of the continental United States with pins placed at the locations of each **supine-supine, supine-prone, supine-other, or prone-prone** incident, and colors indicate the event (blue-death; orange-injury; green-hazard). Events occurred in 29 states throughout the country.



Figure 1. Map of the United States showing *supine-supine*, *supine-prone*, *prone-prone*, and *supine-other* incidents related to inclined sleep products reported to and investigated by the CPSC. Blue-death; orange-injury; green-hazard.

Supine-Supine Events

There were 38 **supine-supine** events reported and investigated between 2011 to 2019. Of these, 33 resulted in death, 4 resulted in injury, and 1 was a hazard. Events occurred in products from Companies A and B, with basic (S01 and S03) and deluxe (S02 and S06) versions of their inclined sleep products. Sex distribution was 20 males and 18 females. Racial/ethnicity distribution was 23 White, 5 Black, 3 Hispanic, and 7 Not Reported. The average age of the infants at the time of the event was 3.2 ± 2.3 months (adjusted age 3.0 ± 2.3 months). Six infants were reportedly born pre-term (<37 weeks gestation).

The incidents in which a death occurred when an infant was placed supine and found supine show a few notable trends. First, 10/33 (30%) of the deaths occurred in infants who were currently sick with colds, respiratory symptoms, or fevers. Upon further review, 4/33 (12%) of infant deaths occurred in infants with significant health problems or chronic health issues. Four reports indicated smoking in the home, and all of these were of infants who were currently sick or chronically ill. A pediatric pulmonologist determined that 4/33 (12%) of the deaths are likely attributed to health issues not necessarily caused by the sleeping position. While only a few incidents specifically indicated a “chin-to-chest” position, the deaths or injuries may have been related to either a chin-to-chest position that restricted airflow, and/or carbon dioxide rebreathing from contact or near-contact of the infants’ faces to the sides of the products, a position that was commonly noted in the police reports in the in-depth investigations. However, no further analyses on these incidents nor on the chin-to-chest position were performed, so the impact of the chin-to-chest position in inclined sleep products is unknown. In addition, many of the reports indicate the parents utilized an inclined sleep product on the recommendation of a medical professional or friend to aid with either respiratory sickness or reflux, though this recommendation is not supported with evidence-based research. Of the infants who were not suffering from a chronic health condition or temporary illness at the time of the death, four were sick within the last month. 6/33 (18%) of infants who died were born premature. Two reports indicated the inclined sleep product was not the infant’s

regular sleeping surface, but most reports had missing information regarding normal sleeping position. Several infants were placed supine with their lower extremities swaddled and their upper extremities free to move. Twelve infants were reportedly not buckled into the product, while six were initially buckled, with many reports not listing the information. No significant trends were found regarding other demographic or situational data, partly due to incomplete reports across the many categories.

Positional asphyxiation is the most likely cause of death for most of the infants in the **supine-supine** group, particularly when considering most of the products were “deluxe” versions (S02 and S06) which feature very heavy padding with a pillow-like headrest. It is likely that infants’ noses and mouths were too close to the side of the product, resulting in reduced airflow and carbon dioxide rebreathing, leading to their demise. This is further supported by the number of infants who had blood and/or mucus on their noses or mouths when they were found. Nasal hemorrhaging is associated with suffocation in infant deaths (Bercroft et al., 2001), and the presence of blood noted in these reports supports suffocation as the cause of death. However, no breathability analysis was conducted as a part of this study, so it cannot conclusively be stated that the material or design of the product promoted carbon dioxide rebreathing or suffocation based on the incident analyses.

Supine-Prone Events

There were 25 **supine-prone** events reported and investigated between 2010 and 2019. Of the 25 events, 21 resulted in death and 4 resulted in injury. Events occurred in products from Companies A, B, and C, with basic (S01 and S03) and deluxe (S02 and S06) inclined sleep products, and product S08 which was sold as a stand-alone sleep product in a larger set by Company C. Sex distribution was 15 males and 10 females. Racial and ethnicity distribution was 15 White, 2 Black, 1 Hispanic, 2 Other, and 5 Not Reported. The average age of the infants at the time of the event was 4.2 ± 1.8 months (adjusted age 4.0 ± 2.1 months), 1.0 months older than the age of infants who experienced supine-supine events ($p=0.081$). One infant was reportedly born pre-term (<37 weeks gestation).

Similar to the *supine-supine* incident analysis, the incidents in which a death occurred when an infant was placed supine and found prone show a few notable trends. First, 4/21 (19%) of the deaths occurred in infants who were currently sick with colds, respiratory symptoms (at least moderate congestion), or fevers. No deaths occurred in infants with significant health problems or chronic health issues. Of the infants who were not suffering from a temporary illness at the time of the death, three were sick within the last month, and five others had findings during the autopsy that indicated mild lung congestion. 1/21 (5%) of infants who died was born premature. A few reports specifically mentioned that the baby had never before rolled unassisted, but most investigations did not contain this information. Similarly, though many reports did not have the information, five parents indicated the inclined sleep product was not the infant’s typical sleeping environment, with one mother stating the infant died the first time the product was used. Nine infants who died were reportedly not buckled into the product, while one was initially buckled, with eleven reports not listing the information. In many of the incidents, the babies were found with their faces in direct contact with the surface, the “pillow” portion, or the seat portion of the inclined sleep product. In the incident where the infant was reportedly initially buckled, it was noted that the caregiver found the infant with the feet in the seat portion of the inclined sleep product, in a “standing” type of prone-lying position within the product. No significant trends were found regarding other demographic or situational data, partly due to incomplete reports across the many categories.

In the United States, it is recommended that infants are put to sleep on their backs, partly based on previous research indicating prone sleeping results in lower oxygen saturation levels in babies (Galland et al., 2000), especially premature babies (Smith et al., 2010). Other peer-reviewed research indicates that at 4 months old, 40% of infants who sleep supine are able to roll (Jantz et al., 1997), with 80% of infants rolling prior to six months of age (Benjamin Neelon et al., 2016). One study reports the age of rolling from front-to-back-to-front is just under six months (Ertem et al., 2018). Once an infant is able to roll on his/her own, the risk of suffocation from prone sleeping may decrease as the infant has increased motor control and has a greater ability to reposition themselves to avoid suffocation. In fact, once an infant is able to roll from supine to prone and prone to supine unassisted, parents are told by the AAP to continue to place the infant to sleep on their backs until 1 year of age, but not to worry or reposition the baby back to supine if the baby rolls to prone on their own during sleep (Moon et al., 2016). This logic likely does not translate to the inclined sleep products because the environment is so different compared to a flat crib mattress. Additionally, other researchers report that the most common risk factor for sleep-related deaths in 4 to 12 month old infants is rolling into other objects in their sleep area such as crib bumpers or pillows (Colvin et al., 2014). This again raises concerns with the inclined sleep products, as the surface is not the same as a crib mattress and often features heavy padding similar to crib bumpers and headrests that are similar to small pillows.

The average age of the infants in these **supine-prone** incidents who experienced events of rolling from supine to prone in an inclined sleep product was 4.2 months (approximately 1.5 months less than average front-to-back-to-front rolling age, Ertem et al., 2018), and many of the reports include statements that the parents had never observed the infant roll on his/her own. It is likely that if an infant experiences a supine to prone roll for the first time in an inclined sleep product, that the baby is put in a position he/she has never before experienced: prone in a non-rigid, concave, and/or heavily padded inclined sleep product. The biomechanical analysis (Section 4) explores these ideas further.

Supine-Other Events

There were four **supine-other** events reported and investigated between 2011 and 2013. Two events were injuries and two were hazards. Events occurred in basic products (S01) from Company A. Sex distribution was two males and two females. Racial and ethnicity distribution was 1 White, 1 Other, and 2 Not Reported. The average age of the infants at the time of the events was 7.0±3.4 months. Restraints were reportedly used in three of the four events (75%). No information on prematurity or health was reported in these events.

These four **supine-other** incidents occurred in infants aged 5 months to 12 months, an older cohort than the other categories. In two incidents, caregivers reported that infants were able to climb out of the product, even when buckled into the harness. One infant was found sitting backwards in the product. In the remaining incident, the infant was found hanging from the product with her leg caught in the harness straps. These four incidents describe events in which babies have maneuvered within or out of the inclined sleep products, resulting in unintended and hazardous positions. A fall from the product to the floor presents a risk of injury for the infant. The incident describing the infant's leg caught in the product presents a risk of serious injury if circulation is cut off for too long; pain and muscle damage are potential outcomes. These events highlight a unique set of risks that are likely specific for older infants who are able to significantly maneuver within or out of the inclined sleep products

Prone-Prone Events

There were three **prone-prone** events reported and investigated between 2013 and 2017. All three events resulted in deaths. Events occurred in products from Company A basic (S01) and

deluxe (S02) inclined sleep products. All three infants were female. Racial and ethnicity distribution was 2 Black and 1 Hispanic. The average age of the infants at the time of the event was 2.3 ± 2.1 months (adjusted age 1.9 ± 2.3 months). One infant was reportedly born pre-term (<37 weeks gestation). At the time of the incidents, one infant was healthy, one was sick, and one was chronically ill. Two parents reported that no restraint was used. While instructions on inclined sleep products indicate that infants should be placed in the supine position, it is clear from these three incidents that those instructions are not always followed by caregivers. The biomechanical analysis (Section 4) will further explore the implications of the prone position in inclined sleep products.

Incident Report Summary

Ninety-one reported incidents of deaths, injuries, and hazards occurred in inclined sleep products from 2010 to 2019. Most incidents fell into two main categories: *supine-supine* and *supine-prone*. The *supine-supine* events occurred in younger infants (average 3.2 months), and many were currently sick, suffering from chronic conditions, or born prematurely. Many reportedly were found with their faces in contact with the sides of the product, and several had blood or mucus on their nose and mouth when they were found, suggesting suffocation as a cause of death. The *supine-prone* events occurred in older infants (average 4.2 months), and sickness, chronic conditions, and prematurity were less prevalent compared to the *supine-supine* events. The three-point harness was used in at least one *supine-prone* event and three of the four *supine-other* events, and many reports indicated that the infant had not been observed to roll alone prior to the incident.

3. PRODUCT ANALYSIS

3.1 Overview

The CPSC provided the research team with 14 different unassembled products that fell into the category of “Inclined Sleep Product.” Most products were frame-type products that were sold alone, but one product (S08) was sold as a part of a set of infant products. Each product was assembled by the research team according to the instructions and was thoroughly examined to ensure no product damage was present.

Each of the 14 inclined sleep products were analyzed and measured using methodology from ASTM F3118-17a: Standard Consumer Safety Specification for Infant Inclined Sleep Products. The research team also identified additional differences in products, and therefore added other measurements as needed. Below is a table of the Measurement, Procedure, and corresponding Photos used to obtain each measurement. A hinged weight gauge infant was also provided by the CPSC. The research team measured and analyzed it to ensure it met the appropriate dimensions prior to using it for measurements.

3.2 Measurement Procedures

Table 1 details the measurements taken for each of the 14 inclined sleep products. Some products allowed for different incline settings, so measurements were taken at both the highest and the lowest settings.

Table 1: Measurements with detailed procedures and photos in a representative inclined sleep product.

Measurement	Procedure	Photos
Minimum Incline at Head	7.10* = Hinged weight gauge-infant centered in product with hinge centered over seat bight line, upper plate on seat back surface. Digital protractor placed (centered) on upper plate to measure top surface seat back angle relative to horizontal.	
Maximum Incline at Head	7.11* = If applicable, repeated with manufacturer's recommended highest incline position	
Minimum Incline at Thigh	Placed as above, for lower plate, to get thigh angle	
Maximum Incline at Thigh	As above, repeated with manufacturer's recommended highest incline position	

<p>Side height (Depth at 11.4")</p>	<p>7.12* = Reference line made at 11.4" from hinge on upper plate. Center point of this reference mark also made. Straight edge with length greater than product width laid across product "rails"/"top", second straight edge placed vertically upwards from reference mark to ensure orthogonal measurement. Vertical distance (d) between underside of straight edge and the upper surface of the hinged weight gauge-infant measured with measuring tape. (Fig. 12, page 13)*</p>	
<p>Usable length (Hinge, to top of backing seam, where the head sits)</p>	<p>7.15* = Hinged weight gauge-infant centered in product with hinge centered over seat bight line, upper plate on seat back surface. Measured, using a tape measure, the distance from intersection of gage plates to top edge of head containment area (top seam above which the head cannot be positioned)</p>	
<p>Width at Shoulder (at 11.4")</p>	<p>Start of additional measurements. Straight edge with length greater than product width laid across product "rails"/"top", second straight edge placed vertically upwards from reference mark to ensure orthogonal measurement. Width of product at this point measured with tape measure</p>	
<p>Width at Hinge</p>	<p>As above, repeated at intersection of upper and lower plate (hinge)</p>	

<p>Width at Knee</p>	<p>As above, repeated at bottom of lower plate</p>	 <p>Width at knee</p>
<p>Maximum Width</p>	<p>Tape measure used to measure maximum width of product (excluding attachments such as electronics or mobile)</p>	 <p>Maximum width</p>
<p>Minimum Width</p>	<p>As above</p>	 <p>Minimum width</p>

<p>Minimum Incline (w/Rock)</p>	<p>Digital protractor placed (centered) on upper plate to measure top surface seat back angle relative to horizontal. Minimum incline w/rock was defined as the angle displayed on protractor with maximum rock/tilt towards head end</p>	<p>Minimum incline angle with rock</p> 
<p>Maximum Incline (w/Rock)</p>	<p>As above, with maximum tilt/rock towards foot end</p>	<p>Maximum incline angle with rock</p> 
<p>Curved / Thick Plastic Molding? (Y/N)</p>	<p>Whether the product had curved/thick plastic molding underneath the surface and/or seat</p>	
<p>Thin Plastic Molding? (Y/N)</p>	<p>As above, but whether the material was a thin deformable plastic</p>	
<p>Side Mesh? (Y/N)</p>	<p>Whether there was side mesh (3.1.9)*</p>	
<p>Plastic</p>	<p>For Reference line (11.4 from hinge), Hinge, and Bottom of lower plate, measurements made along the surface parallel to reference line. This measure is from the center line on the reference line to the "edge" of the plastic molding (if any)</p>	<p>At 11.4"</p>  <p>Distance, along laying surface, to the end/edge of plastic molding from the center of hinged weight-gauge infant</p>

<p>Solid</p>	<p>From the center line to the end/edge of the solid "fabric"</p>	 <p>At 11.4"</p> <p>Distance, along laying surface, to the end/edge of solid "fabric" from the center of hinged weight-gauge infant</p>
<p>Mesh</p>	<p>From the center line to the end/edge of the mesh (if any)</p>	 <p>At 11.4"</p> <p>Distance, along laying surface, to the end of mesh from the center of the hinged weight-gauge infant</p>
<p>End</p>	<p>From the center line to the end/edge of the product, i.e. up to the rail</p>	 <p>At 11.4"</p> <p>Distance, along laying surface, to the end of the product from the center of hinged weight-gauge infant</p>

*These refer to Sections of ASTM F3118-17a: Standard Consumer Safety Specification for Infant Inclined Sleep Products

3.3 Measurement Results

All 14 inclined sleep products were evaluated, and all products exhibited no damage as received. After assembly, product S07 exhibited a slight lateral tilt, and if selected for further biomechanical evaluation, a different product of the exact same model would be purchased to ensure the tilt was not a result of mis-assembly or a manufacturing issue. However, all other results of the product analysis for product S07 would not have changed due to the lateral tilt, therefore the conclusions applicable to product S07 are valid.

Table 2 summarizes the measurements taken defining the design of the product. Products with a “-high” and “-low” row of measurements indicate that they had two incline settings at the head. Blanks (i.e. "x") for “maximum incline” at head or thigh indicates the product did not have an incline adjustable head portion. For products S05, S11 and S12 (i.e. the products with adjustable inclines), the maximum and minimum values are tabulated on the same row (high), and the row below has two blanks since the two values above are the minimum and maximum incline values of the product as a whole. When there is an "x" for min (or max) “incline w/ rock”, that means the product does not rock.

Table 2. Sample measurements and characteristics

Sample	Minimum Incline @ Head (deg)	Maximum Incline @ Head (deg)	Thigh Angle @ Minimum Incline (deg)	Thigh Angle @ Maximum Incline (deg)	Side height (Depth at 11.4") (cm)	Usable length (Hinge, to top of backing seam/ head location) (cm)	Width at Shoulder (at 11.4") (cm)	Width at Hinge (cm)	Width at Knee (cm)	Maximum Width (cm)	Minimum Width (cm)	Minimum Incline (w/Rock) (deg)	Maximum Incline (w/Rock) (deg)	Curved / Thick Plastic Molding? (Y/N)	Thin Plastic molding? (Y/N)	Side Mesh? (Y/N)
S01	27.7	x	44.5	x	13.3	43.2	46.7	43.5	37.1	46.7	32.1	26.2	36.5	Y	N	Y
S02	24.4	x	51.7	x	14.0	45.1	47.3	16.8	38.7	51.8	32.4	23.0	31.7	Y	N	Y
S03	25.5	x	24.3	x	17.1	43.5	39.7	39.7	38.7	41.0	34.0	x	x	N	N	Y
S04	26.0	x	23.9	x	15.6	41.6	40.0	40.6	39.1	40.6	34.3	x	x	N	N	Y
S05-high	12.2	38.7	4.4	1.1	6.7	42.2	34.3	36.8	32.4	36.5	27.9	34.0	41.9	Y	N	Y
S05-low	x	x	x	x	20.0	39.4	30.2	35.6	32.4	x	x	10.7	18.3	x	x	x
S06	31.1	x	22.0	x	11.7	39.4	41.6	43.2	40.6	43.8	30.2	29.1	35.6	N	N	Y
S07	9.3	x	24.5	x	25.1	42.5	51.8	48.6	41.0	51.8	30.2	4.2	15.0	Y	N	Y
S08	31.3	x	38.2	x	3.8	43.5	42.9	40.6	35.2	41.9	18.4	29.8	36.4	N	N	N
S09	20.9	x	52.1	x	14.6	43.5	45.1	43.2	37.8	45.4	31.4	18.8	26.8	Y	N	Y
S10	25.7	x	52.6	x	13.7	44.5	44.5	43.2	38.1	44.5	31.1	24.7	30.0	Y	N	Y
S11-high	11.8	20.5	31.4	22.9	22.2	39.4	50.5	47.3	42.2	51.4	35.6	14.3	17.1	N	Y	Y
S11-low	x	x	x	x	21.9	40.0	49.8	48.9	42.2	x	x	20.3	22.4	x	x	x
S12-high	11.7	25.7	29.0	21.7	23.2	43.5	47.0	46.4	45.1	48.3	22.9	x	x	Y	N	Y
S12-low	x	x	x	x	26.0	43.5	47.3	46.0	43.5	x	x	x	x	x	x	x
S13	21.5	x	25.9	x	14.8	40.0	47.3	43.2	40.6	48.9	41.3	16.8	29.0	Y	N	Y
S14	16.9	x	44.2	x	11.4	44.1	48.3	48.6	43.2	48.9	38.1	10.8	20.6	Y	N	N

Table 3 summarizes the material makeup of the product surface. An "x" along the row for any measurement involving "Plastic", "Solid", "Mesh", and "End" indicates that, at the specific measurement location (11.4", hinge, or knee), the corresponding material is not present, so the first measurement written down is the first material that was available to measure. E.g., S08 has no plastic molding, no solid fabric after the lying surface fabric, and no mesh, and hence the only measurement written down is "End", which indicates a measurement made along the width of the product from the center of the hinged weight-gauge infant to the end (edge) of the product.

Table 4 is descriptive text regarding design and measurement of each product.

Table 3. Distance of different materials on samples from the center, at three locations

Sample	at 11.4"				at hinge				at knee			
	Plastic (cm)	Solid (cm)	Mesh (cm)	End (cm)	Plastic (cm)	Solid (cm)	Mesh (cm)	End (cm)	Plastic (cm)	Solid (cm)	Mesh (cm)	End (cm)
S01	15.2	16.5	22.2	29.2	12.7	14.0	30.8	39.1	x	13.0	21.3	27.9
S02	15.9	19.4	22.2	29.2	12.1	14.9	31.8	38.7	x	14.0	21.6	27.3
S03	x	12.1	24.1	29.2	x	11.1	x	39.4	x	12.7	x	34.9
S04	x	13.0	24.1	29.5	x	11.4	34.0	40.6	x	10.8	28.9	34.9
S05-high	15.2	17.1	20.3	28.9	16.5	20.3	x	34.3	x	x	x	25.4
S05-low	15.2	15.6	19.4	37.8	15.6	19.4	x	33.3	x	x	x	29.2
S06	x	12.1	21.0	27.3	x	10.8	34.6	41.3	x	10.5	29.8	36.2
S07	13.0	14.0	x	40.0	10.2	12.1	34.6	41.9	x	12.7	28.6	37.5
S08	x	x	x	23.5	x	x	x	28.9	x	x	x	21.0
S09	15.9	19.4	21.3	28.3	11.4	14.0	30.5	35.2	x	13.7	20.6	25.1
S10	14.6	19.1	21.0	27.6	10.8	13.7	30.8	35.9	x	14.0	20.3	25.7
S11-high	12.7	20.6	29.8	38.1	12.1	15.2	34.3	43.2	12.7	18.7	27.9	36.2
S11-low	13.3	21.0	30.5	38.7	12.7	15.6	34.9	42.9	12.7	19.1	26.7	34.9
S12-high	16.5	20.0	33.0	41.3	8.3	19.4	37.5	43.2	12.7	16.8	33.0	38.1
S12-low	15.2	18.1	32.4	41.3	10.2	19.1	37.5	43.2	15.9	16.5	33.0	38.1
S13	13.7	14.9	25.1	34.6	x	14.0	28.3	38.1	x	x	23.2	32.4
S14	12.7	23.5	x	30.2	x	28.6	x	34.0	x	19.1	x	26.0

Table 4. Sample measurement notes

Sample	Notes
S01	Additional Padded Head Rest. Plastic Molded Seat sewn in.
S02	Removable plastic molding. Removable head pillow. Removable body cushion. Built-in vibration electronics. Removable toy on harness. Solid headrest. Detachable top (all). Depth at hinge = 25.4 cm - Done because it seems deeper than the rest.
S03	Flaps to cover buttons. No plastic molding. No rocking motion. Mesh at head only.
S04	Removable full length cushion. Collapsible. Toy attached to harness. Attachable vibration electronics. Flaps on either end. Mesh only at head. Side flaps. Measurements done without cushion.
S05	Non-Rock Sitting Incline at head = 47.95°, at thigh = 3.2°. Sleeping incline at head = 21.25°, at thigh = 3.65°. All measurements performed with non-rocking stopper down. Removable head pillow. Difficult to assemble (Assembly instructions unclear). Sitting to sleeping incline shift very difficult. Rocker stopper increases incline for both positions. Thin/short mesh around head and torso. Different (cushion) material on side from bight line down. Product depth at head increases, which increases width of mesh. Removable toy mobile. Minimum width measured above top seam before mesh. Plastic molding is (Y) because it is wood/particle board backing (thin, solid), Aluminium frame, and Seat is plastic molding. At hinge, "Solid" measurement is to the Aluminium frame. "Child" (Hinged weight gage infant) shifted in the product when reclined from sitting to sleeping. Repositioned the best we could, hinge line aligned to seat seam (bight line). At 11.4" for sleeping setting, 19.4 cm is to a second material before mesh, and 37.8" is to end of mesh and this second material.
S06	Side mesh only at head. Flaps on either end. Detachable mobile with toy. Attachable vibration electronics. Detachable head pillow. "Mesh" measurements at hinge and knee are actually of second material.
S07	4.4° Lateral tilt towards the Electronic unit. Flat padded head rest. Head of baby (hinged weight gage infant) flush with the product. Plastic molded seat sewn in. Top removable.
S08	Measuring only the sleeper. Detachable head. Non-detachable head pillow. Embedded electronics under foot end. Fairly small product. No mesh. No plastic molding.
S09	Detachable top (all). Removable plastic molding. Solid head rest. Removable toy on harness.
S10	Detachable top (all). Removable plastic molding. Non-detachable head pillow. Detachable body cushion. Attachable electronics on rail.
S11	Dual folding mechanism (legs and top). Removable body cushion. 2 incline settings. Mobile embedded with toy. Fairly wide product (visually). Measurements done without body cushion.
S12	Standing product. Large base. Fairly heavy. 2 incline settings at head. Detachable body cushion. Attachable electronics on rail.
S13	Removable full length cushion. Collapsible. Mesh only up to just above the seat hinge (bight line). Hard plastic molding in two parts; there is a gap between the two parts at the seat bight line.
S14	Measuring only sleeper. Removable full length cushion, collapsible. No mesh. Has insertable thick plastic molding. Measurements from center to "Solid" Refers to measurement made to the edge of the cushion. Plastic molding ends above seat bight line.

As shown in the product analysis above, products in the Inclined Sleep Product class varied significantly in design. Inclined angles at the head ranged from 12° to 38°, while angles at the thigh ranged from 1° to 53°. Width of the products varied, where some were wider at the shoulders and narrower at the seat, while others exhibited a more consistent width throughout the entire length of the product. Some products rocked approximately 10° while others were stationary, and three products featured different incline settings. The surface of the product was one of the most obvious design differences, with some products featuring thick rigid plastic molding, others no plastic molding, and one with a semi-rigid thin plastic molding. Material selections in the products were just as broad and included thin padding, thick padding, or mesh, in a variety of combinations on the surface and sides of the products.

3.4 Product Selection Rationale

The project team had to select a portion of these inclined sleep products to include in the biomechanical testing, as time limitations prohibited inclusion of all products. Products were selected firstly if any adverse incidents had been reported to the CPSC. Company A's products represented most of the incidents (83), followed by Company B (7), and Company C (1).

The designs of Company A featured rigid plastic molding that conformed into the sides of the products and fell into two categories: basic (S01 and S09) and deluxe (S02 and S10), which featured a pillow or heavily-padded piece. S01 was selected to represent the basic version of Company A and S02 to represent the deluxe version of Company A because several incidents specifically noted these products.

Company B had products with no plastic molding and had basic (S03 and S04) and deluxe versions with padded pillows (S06) as well as a product that featured a maximum incline outside of the range of 10° to 30° (S05). S03 was chosen to represent the basic version of Company B and S06 to represent the deluxe version because incidents were reported in these products.

Company C had two products which were examined (S08 and S13). The incident occurred in product S08, and it was selected since this was the smallest product with an inclined surface made of a single material with no plastic molding or mesh. S13 was also chosen to be included in the biomechanical study because it had a unique design of plastic molding, with the molding split at the seat bight line.

There was room to include one final product in the biomechanical experiment, and a product that was the most different in design to the others and was manufactured by a different company was sought. This left products S07, S11, S12, and S14. Product S14 was received too late to include in testing. S07 and S12 both featured thick plastic molding, not unlike those from Company A, while product S11 had a unique thin plastic molding. S11 also exhibited near maximum product widths at all of the measurement points, making it different than many other products, so S11 from Company D was chosen as the final product.

The final list of products included in further product analysis and biomechanical testing were: S01, S02, S03, S06, S08, S11, and S13.

3.4 Contact Area Analysis

Overview

During the pilot testing of the Biomechanical Analysis experiment (section 4), pressure-mapping sensors (████████████████████) were to be used to record the pressure imparted by infants' palms and forearm when lying prone on the inclined sleep products. The pressure-mapping technology consists of matrices of sensors embedded into elastic fabric mats that permit conformability to three-dimensional deformations and can accurately measure the total force and contact area on the interacting surface, even if heterogeneously loaded across the sensor. The particular sensors used in this study were equipped with 128 individual sensors in an 8 X 16 matrix, with an individual sensor area of 1 cm². However, it was observed that due to a combination of infants' inconsistent arm position during prone time, and the low amount of pressure registered even during proper contact with the sensors, this methodology was not reliable or feasible to control. Figure 2 demonstrates a mockup of this initial setup.



Figure 2. Mockup of prone palm and forearm pressure recording in one product.

Because of the problems with this initial idea, a more consistent methodology was developed to assess the magnitude and distribution of the pressure and contact area recorded on the sensors if a known weight were to be placed orthogonally on the sensors.

Experimental Design

A 2 kg weight was chosen for the controlled testing as it represents approximately 30% of the weight of an average 4-month old infant, a reasonable estimate of the weight a child must bear on their forearms or hands during prone positioning. The calibration weight was placed on a scale to verify its weight (Figure 3). The pressure-mapping sensor was placed on a flat, hard floor and the weight was placed on the sensor to collect the corresponding pressure and contact area

readings. Five repetitions were made for each measurement, Figure 3 demonstrates the experimental setup.



Figure 3. Pressure-mapping sensor on floor with weight placed on top between tape.

During initial product testing with the pressure-mapping sensor, it was observed that the deformation of the sensor, as a result of the pliancy of the inclined sleep products, generated high pressure values when the sensor experienced too much deformation. These unreasonable values did not occur on the crib mattress surface, due to less deformation of the product. Since the magnitude of the values were unreasonable, the contact area experienced by the weight on each product was calculated and used as a measure of deformation.

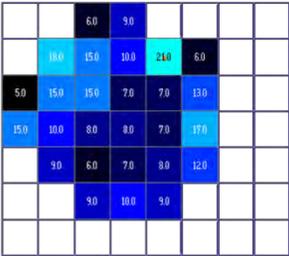


Figure 4. Contact area map of crib mattress product with minimal deformation.

A hinged weight-gauge infant (ASTM F3118-17a) was placed in each product, and the position of the top of the head was used as the indicator for placing the pressure-mapping sensor. Following this, the 2 kg weight was placed on the sensor and the product was tilted as needed so that the weight was sitting orthogonal to the sensor. Five repetitions were made for each measurement. The experimental setup is demonstrated on Figure 5.



Figure 5. Hinged weight-gauge infant and pressure-mapping sensor location determination (A), and 2 kg weight on pressure-mapping sensor on tilted product (B).

Data Analysis

The contact area was calculated as the number of active cells multiplied by the unit cell area (1 cm²). The calculated contact area served as an estimation for the potential of the inclined surface to deform under a load. For example, when a weight is placed on the sensor on a hard surface, no deformation exists due to the rigidity of the surface, so the contact area reading from the pressure sensor is exactly the contact area of weight. Conversely, if a weight is placed on a conforming surface, the sensor deforms with the product, enveloping the sensor such that more surface area of the weight is in contact with the sensor, resulting in a larger contact area reading. Therefore, the larger the contact area, the more deformation. All data analysis was conducted using MATLAB code.

Contact Area Results

Recorded contact area for all inclined sleep products are presented in Table 5 and Figure 6, where the products are categorized by the presence (and type) of plastic molding.

Table 5. Recorded measurements for all inclined sleep products and the crib mattress (at no incline)

Sample	Contact Area (cm ²)	Plastic Molding
Crib Mat	22.4 ± 1.7	No
S03	22.4 ± 2.2	No
S06	33.6 ± 0.9	No
S08	32.6 ± 0.5	No
S11	26.8 ± 1.8	Thin
S01	28.8 ± 0.4	Hard
S02	33.3 ± 1.9	Hard
S13	25.2 ± 0.5	Hard

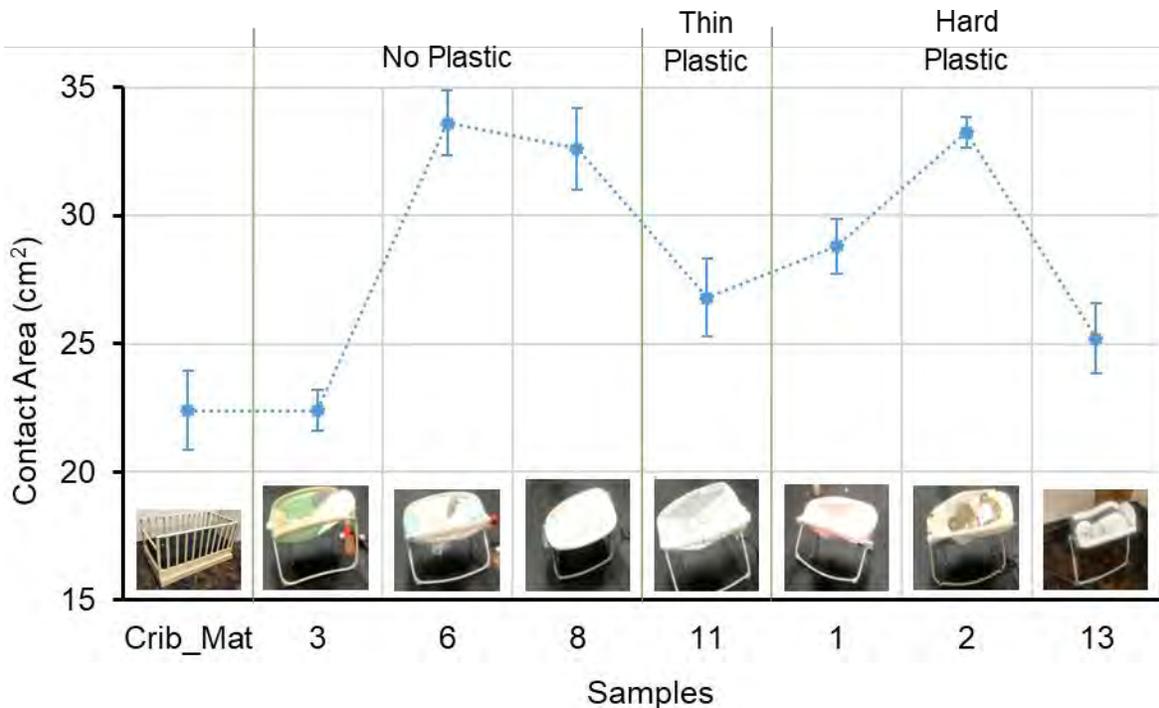


Figure 6. Calculated contact area for crib mattress and inclined sleep products.

Contact areas were highest in products S02, S06, and S08; all products that had a “pillow” or extra cushioning near the head. Product S03 featuring no plastic molding demonstrated contact area characteristics most similar to the crib mattress, and was markedly different from S06 and S08. The principle difference between S03 and both S06 and S08 was the absence of any additional heavy padding material on the product, which likely contributed to the findings.

The product with thin plastic molding, S11, demonstrated contact area characteristics similar to S03, S01, and S13. The slightly higher values demonstrated in S11 are likely due to the higher pliability of the plastic molding (vs. S13), and the presence of a flat full-length cushion on the product (vs. S03).

It is curious that, on average, products with solid plastic molding did not demonstrate significantly different force distribution characteristics compared to products with no plastic molding or thin plastic molding. On closer examination, it was observed that one aspect of this homogeneity is likely the presence of cushioning material near the head on some products. If the findings are examined without the products that have cushioning (i.e. S03 vs. S01 and S13), it is observed that S13’s contact area is closer to S03 than S01. One likely explanation for this may be that S13 has a flat solid plastic molding, while S01’s plastic molding is curved (concave), increasing its potential for a greater contact area as the product shape naturally envelopes the weight.

Beyond the classification criteria, one clear observation can be made of products that were “basic” and “deluxe” versions manufactured by the same company. Both in the case of Company A’s S01 (basic) and S02 (deluxe), and Company B’s S03 (basic) and S06 (deluxe), it is observed that the basic versions have a substantially lower contact area, indicating that the products’ high deformation potential due to extra cushioning may hamper infants’ ability to self-correct if they roll from supine to prone, presenting a safety hazard for babies.

4. BIOMECHANICAL TESTING

4.1 Overview

An *in vivo* experimental biomechanics study was designed to understand how babies move and use their muscles on inclined surfaces and in selected inclined sleep products.

Human Subjects Protections

The Institutional Review Board of the University of Arkansas for Medical Sciences approved this human subjects research study under protocol 228457: *Biomechanical Evaluation of Infants in Inclined Sleep Products*. The study was advertised by word-of-mouth and flyers placed near the University of Arkansas for Medical Sciences in Little Rock, Arkansas. The legal guardians of infants enrolled in this study provided written parental permission and HIPAA agreement prior to testing. Testing took approximately two hours, and caregivers were modestly compensated for their time and effort.

Confidentiality

All caregivers signed a confidentiality agreement in which they agreed to not disclose any details about the testing or any products involved in the study. All branding of the products were covered by duct tape, and products were not referred to by name or company at any time during the experimental session.

Participants

A two-sample *a priori* power analysis performed on normalized mean electromyography (EMG) data collected in an ongoing study of healthy infants indicated a sample size of nine participants would be sufficient to produce significant results ($1-\beta = 0.8$; $\alpha = 0.05$). To exceed this minimum suggested sample size and to align with most human motion pilot study designs, ten infants (even gender distribution within 20%) ages two to six months were recruited for the study (Siddicky, 2019; Mannen, 2018). Efforts were made to represent the racial and ethnic make-up of the United States within the cohort (approximately 70% Caucasian, 20% Hispanic, 10% African American).

Inclusion criteria included:

- healthy infants born >37 weeks gestation,
- currently between 5 and 95 percentile height and weight for age according to the CDC (Kuczmarski et al, 2002),
- between the ages of 2.0 and 5.9 months on the date of testing.

Exclusion criteria included:

- infants born at low birth-weight (<5 lbs 8 oz),
- previous or current diagnosed orthopaedic or neurologic conditions,
- sickness or vaccinations within two-weeks of scheduled data collection.

After a pilot subject was tested (CPSC1 – not reported) to evaluate experimental design, ten additional subjects were enrolled in the study (Table 6). The average age was 4.2 ± 1.2 months (range 2.3 to 5.5 months) and adjusted age (age – (40 weeks – gestational age at birth)) was 4.0 ± 1.4 months (range 1.6 to 5.3 months) with an equal sex distribution and a racial distribution of 80% White, 10% Hispanic, 10% Black. Gestational age at birth was 38.6 ± 1.0 (range 37 to 40 weeks). All babies were within the CDC 5 to 95 percentile for height and weight according to their age, were not considered low birth weight, and had not been sick or received vaccinations within two-weeks prior to testing. No infants had orthopaedic or neurological conditions.

Table 6. Infant participants' demographics.

Subject ID	Age (months)	Gestational Age (weeks)	Race/Ethnicity	Sex (M/F)	Height (cm)	Weight (kg)
CPSC2	3.0	39	White	F	61.0	6.7
CPSC3	4.6	37	White	M	64.5	7.2
CPSC4	5.5	39	Black	M	69.9	8.1
CPSC5	2.6	38	White	M	61.0	6.7
CPSC6	5.5	39	White	F	67.3	7.6
CPSC7	4.9	39	White	M	64.8	7.5
CPSC8	2.3	37	White	F	53.3	4.9
CPSC9	5.1	40	White	F	61.3	7.4
CPSC10	4.2	39	Hispanic	M	61.0	6.0
CPSC11	5.2	39	White	F	54.6	5.2
Mean±SD	4.2±1.2	38.6±1.0	8W/1B/1H	5M/5F	61.8±5.1	6.7±1.1

Experimental Conditions and Product Selection

To test the effect of incline angle on motion and muscle activity, a custom-built inclining crib was designed and built for a 51.7" X 27.3" crib mattress (). The inclining crib was manufactured using medium density fiberboard panels, plywood, whitewood studs, and pine-fir lumber (Figure 7). The crib enabled 0°, 10°, 20°, and 30° inclines which were chosen to represent the range of inclines (10° to 30°) of the product samples and span the allowable inclines detailed in ASTM F3118-17a.



Figure 7. Photos of the four incline settings of the inclining crib

The CPSC provided the research team with 14 unassembled samples of different inclined sleep products. Figure 8 depicts the products chosen to be included in experimentation. Based on a preliminary review of the Incident Reports (Section 3) and results of the Product Analysis (Section 2), seven inclined sleep products were chosen for testing: a basic version from Company A (S01), a deluxe version from Company A (S02), a basic version from Company B (S03), a deluxe version from Company B (S06), a product from Company C (S08), a product from Company D (S11), and a second product from Company C (S13). Detailed analysis of these products and rationale for selection can be found in Product Analysis (Section 2).

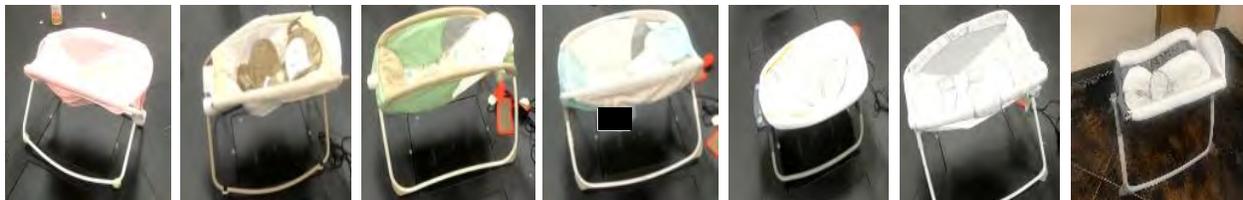


Figure 8. Photos of products used in the biomechanical analysis. From left to right: S01, S02, S03, S06, S08, S11, S13.

During pilot testing, it was observed that the **30° crib incline did not allow for prone or supine lying without the infant sliding down the mattress** (Figure 9). After several attempts, it was determined that the infant was unable to maintain her position (supine and prone), and slid to the bottom of the crib, presenting a hazard for the infant participants. Therefore, the 30° incline crib mattress condition was excluded from all future testing, leaving three crib mattress conditions (0°, 10°, 20°) and seven inclined sleep products, totaling 10 product conditions.



Figure 9. Infant slips downward at 30° incline, presenting a hazard. Therefore, 30° was not included in future testing.

4.2 Experimental Design

Testing occurred at the HipKnee Arkansas Foundation human motion laboratory under the direction of the Principal Investigator. Height, weight, head circumference, birthdate, birth height and weight, gestational age at birth, and race/ethnicity were recorded.

Developmental Screening

No infants enrolled in the study had been diagnosed with any developmental delays at the time of testing. Caregivers were asked to complete an Ages and Stages Questionnaire corresponding with the age of their infant to assess developmental progress, with focus on the Fine Motor and Gross Motor portions of the test (Valleley and Roane, 2010; AAP, 2006). In addition, a pediatric psychologist, evaluated the movements of the infants via video of the biomechanical testing and provided a qualitative assessment of each infant's developmental age based on head control, bilateral kicking and arm movements, hands to midline, kicking or arm movement in response to being spoken to, reaching for items, and loss of newborn reflexes. No infants were excluded from testing or analysis based on the results of the developmental screenings.

Kinematics

Infant motion (kinematics) was recorded using marker-based motion capture. A set of 10 infrared cameras [REDACTED] tracked the position of 21 retro-reflective markers, positioned on specific body segments on the infant, at a sampling rate of 100 Hz. Figure 10 demonstrates the position of these markers, and a schematic of the data capture procedure. The motion capture system included a digital video camera which recorded video at a fixed location at 50 Hz. A [REDACTED] camera ([REDACTED]) mounted on a moveable tripod was used to record the entire data collection process.

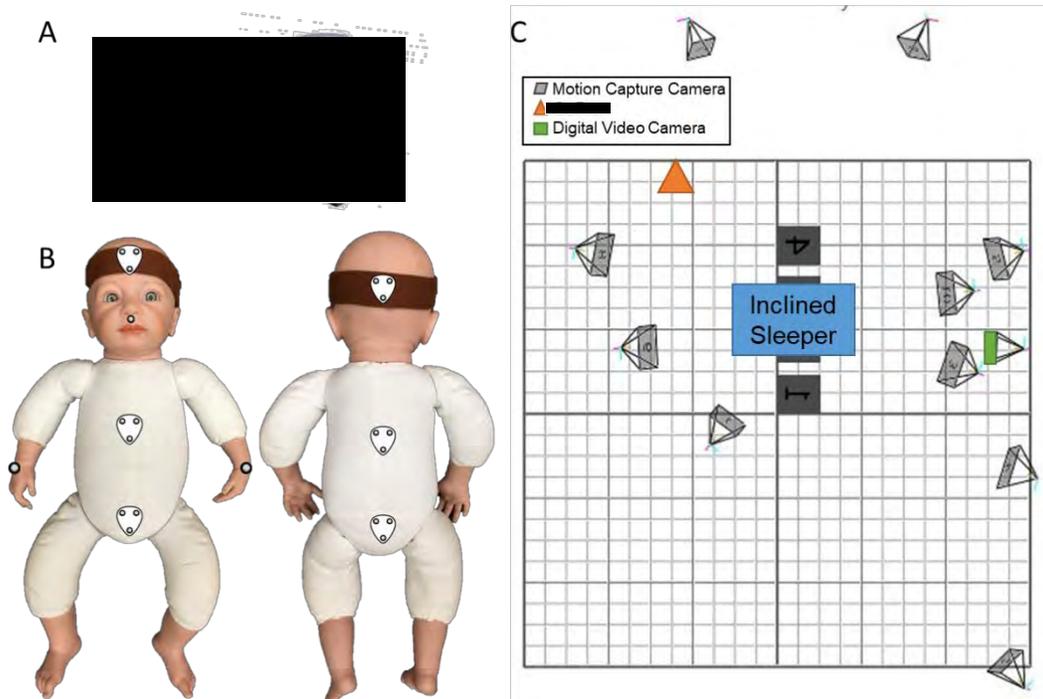


Figure 10. [REDACTED] Cameras (A), front and back view of marker location on infants (B), and schematic of camera positions during testing (C).

Muscle Activity

Infant muscle activity was recorded using surface electromyography (EMG). ████████ wireless EMG sensors (████████████████████) were placed bilaterally on the cervical paraspinal, erector spinae, triceps, pectoralis major, and rectus abdominis muscles of infants. Muscle activity was recorded at 1000 Hz. To avoid possible motion obstructions from the connecting wires between the EMG sensor enclosure and the EMG electrode head, the sensor application sites (i.e. the torso and upper arm) were wrapped with soft cohesive self-adherent wrapping tape. Figure 11 demonstrates the ████████ EMG sensors used in this study, and the anatomical placement locations of these electrodes. Pilot testing revealed that the pectoralis major EMGs were unable to remain in place during testing, so they were removed from the experiment.

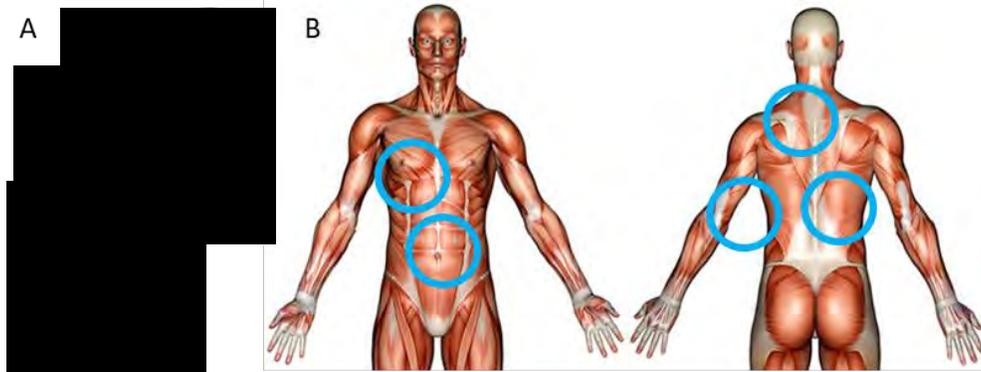


Figure 11. ████████ electrodes (A), and EMG sensor placement locations (B).

Oxygen Saturation

Infants' oxygen saturation (SpO₂) while placed in each product was recorded using a commercial grade and a medical grade pulse oximeter. During pilot testing the commercial grade oximeter ████████████████████ was found to be inappropriate for continuous data logging capabilities because it was highly sensitive to leg movements, with slight movements generating a pop-up window that obscured the SpO₂ display. Therefore, the ████████ was not used during testing.

The medical grade oximeter was the ████████████████████. The onboard data logger recorded time-stamped SpO₂ data at 60 Hz (output at 1 Hz). Figure 12 demonstrates the experimental setup for the placement of the oximeter sensor on the infants' big toe. To avoid motion obstructions and sensor detachment, infants' feet were wrapped in soft cohesive self-adherent wrapping tape. Synchronization between SpO₂ data and the experiment data was maintained by time-syncing the oximeter's internal clock with the laboratory computer's internal clock and noting down the start time of each motion capture/EMG trial on the data collection sheet.

For safety of the testing subjects, a trial was ended if the SpO₂ reading was <95% for at least 5 seconds. To avoid instances of false readings or artifact, video footage of the infants was examined during postprocessing when the SpO₂ readings were <95% to understand the situation which may have led to the low reading.

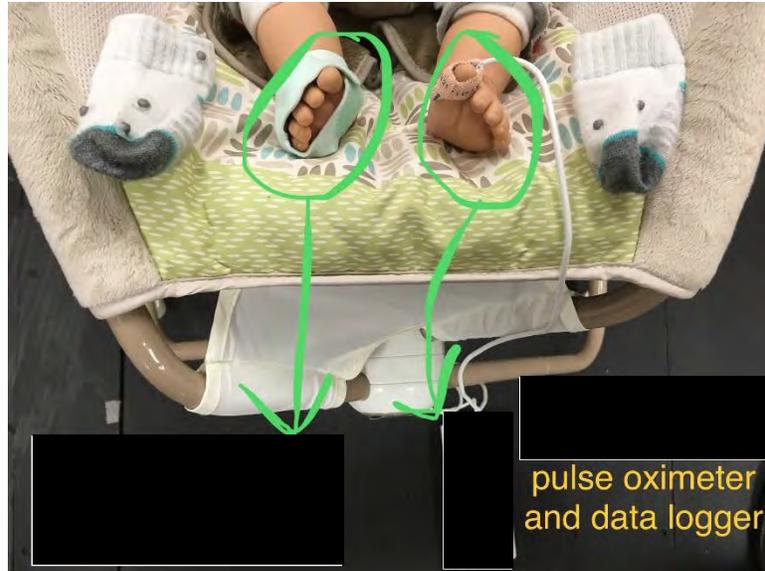


Figure 12. ██████████ SpO₂ sensors placed on the feet of an infant dummy.

Calibration

Calibration of the experimental equipment was conducted prior to each testing session to ensure measurements were accurate. EMG measurements from the prone and supine positions on the Flat Sleeping Surface in this study were compared to a previously collected healthy infant cohort which includes prone and supine positions to ensure reasonableness. If all data from a participant's testing session was found to be errant, the data would be excluded from the analysis and another participant would be recruited.

Testing Procedures

Infants were placed in a random order (Randomizer.org, Urbaniak and Plous, 2013) in each of the 10 testing conditions in both the supine and prone positions for at least 60 seconds (unless the oximeter data fell below 95%, in which case they were removed early to ensure safety, Figure 13). Testing data was considered usable if the infant completed 30 seconds of the task without significant crying or visible distress.

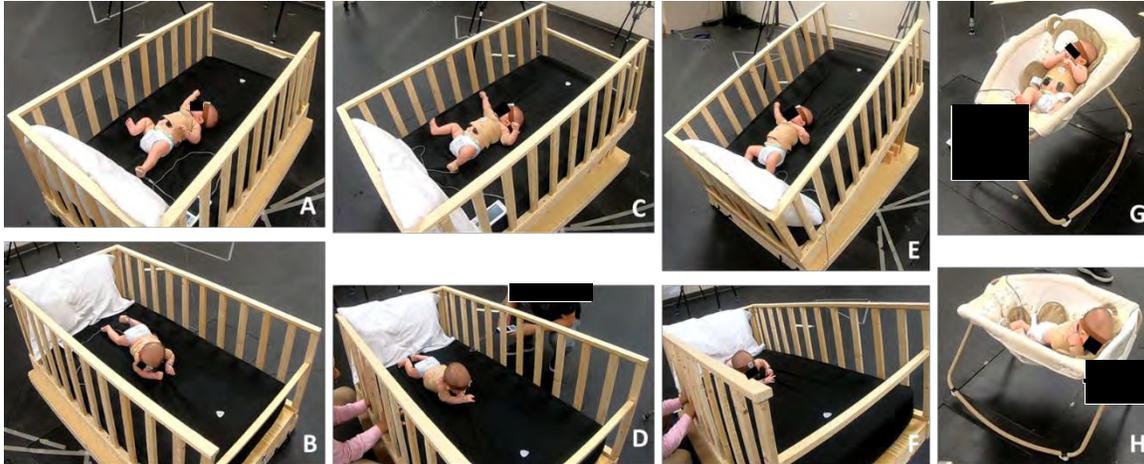


Figure 13. Infant testing setup for: Inclining crib at 0° supine (A), 0° prone (B), 10° supine (C), 10° prone (D), 20° supine (E), 20° prone (F), and an inclined sleep product with infant supine (G), and prone (H).

Sensor Interference with Normal Movement

It is understood that the laboratory environment differs from an infant's natural home environment. Previous studies have determined that small sensors do not interfere with the normal movement of infants (Trujillo-Priego and Smith, 2017). To further assess this concept, a pediatric psychologist qualitatively assessed video footage of the infants for 2 minutes without any sensors and during all testing conditions with the reflective markers and EMG sensors in place to determine if motion or movement of the limbs was hindered by the experimental equipment.

Missing or Incomplete Data

It was expected that not every infant enrolled in the study would successfully complete every activity, but that each infant would complete at least 70% of the planned conditions. By randomizing the order of activities, enough data from the cohort was collected for each condition to make a complete data set. If fewer than seven infants completed a single activity after the collection of ten participants, more subjects would be enrolled in the study.

Data Storage and Reporting

All raw and processed data was de-identified and stored in password-protected and HIPAA-approved secured storage space provided by the University of Arkansas for Medical Sciences.

4.3 Biomechanical Testing Data Analysis

Kinematics

The recorded marker data was used to calculate (1) angular orientation between adjacent body segments, (2) number of times the infants' trunks and necks were raised during prone time, (3) excursion of trunk and hand movements corresponding infants successfully rolling. Angular orientation between adjacent body segments was calculated by using the marker clusters on each body segment to define unit vector matrices forming the axes of local coordinate systems (LCS; Berthouze et al, 2011; Wilk et al., 2006). The element-wise dot product of the LCS unit vector matrices is equivalent to the 3D Cardan rotation matrix representing the relative orientation between the LCS of two adjacent body segments. This calculation is represented in the equation below:

$$R = \begin{bmatrix} c\alpha c\beta & c\alpha s\beta s\gamma - s\alpha c\gamma & c\alpha s\beta s\gamma + s\alpha s\gamma \\ s\alpha c\beta & s\alpha s\beta s\gamma + c\alpha c\gamma & s\alpha s\beta s\gamma - c\alpha s\gamma \\ -s\beta & c\beta s\gamma & c\beta c\gamma \end{bmatrix} = \begin{bmatrix} i.I & j.I & k.I \\ i.J & j.J & k.J \\ i.K & j.K & k.K \end{bmatrix}$$

where [i, j, k] = LCS of body segment 1, [I, J, K] = LCS of body segment 2, c = cosine, s = sine, and [α, β, γ] = rotational angles between the body segments.

Calculations were conducted via custom MATLAB code (MATLAB, Natick, MA). Angular profiles that included data for sagittal plane flexion/extension were calculated for the neck and torso (Figure 14).

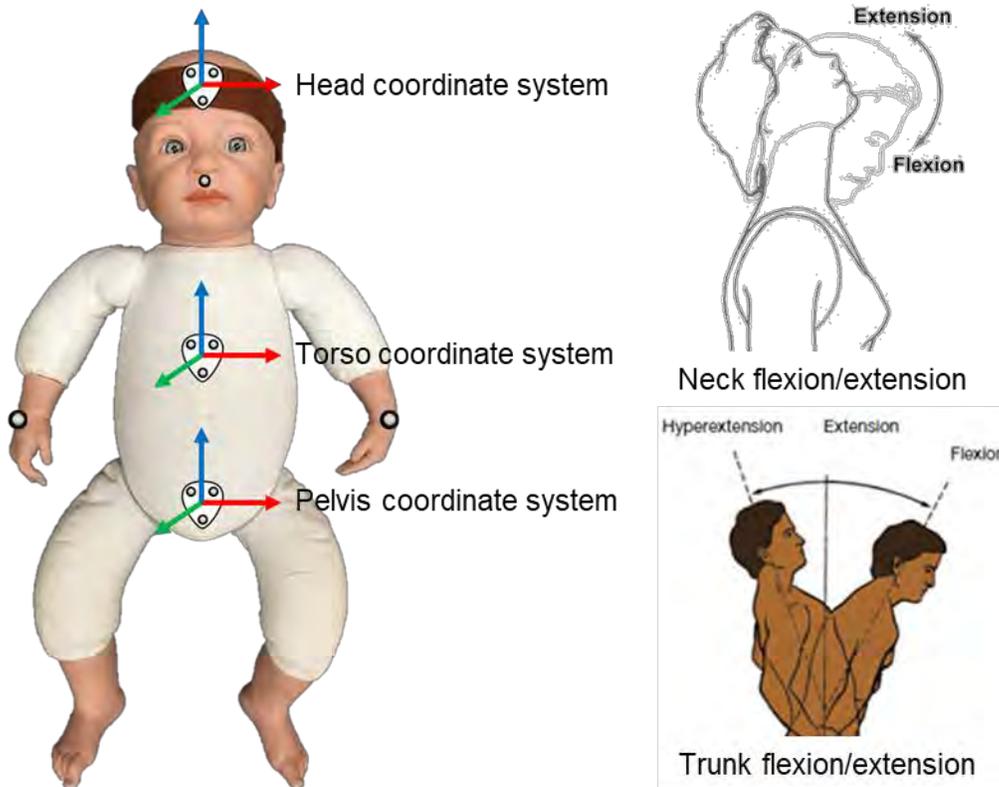


Figure 14. Infant body segment coordinate systems (L), and neck and trunk sagittal plane angles for which ranges of motion were calculated (R)

The neck flexion/extension angular profile was used in conjunction with a peak-finding algorithm to calculate the number of times infants raised their head in each inclined sleep product during the testing duration. The peak-finding algorithm swept through the angular profile data and isolated points in time where the angle value changed by 10° or more. Figure 15 demonstrates a neck extension angular profile with calculated data “peaks” corresponding to head raises.

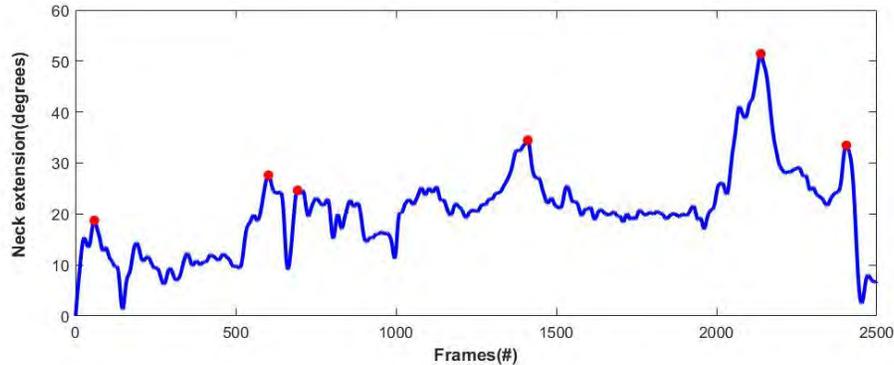


Figure 15. Calculated neck extension angle profile (blue), and data peaks as defined by peak-finder algorithm (red).

Results were compared to the corresponding crib mattress condition (either supine or prone), using paired t-tests ($p=0.05$), and trends were also noted ($p=0.10$). Pairwise comparisons were made for all crib mattress conditions.

Muscle Activity

Raw EMG waveforms were assessed for corrupted data using visual amplitude inspection and power spectral analysis (Boxtel, 2001), and such data (clipped amplitude, low power signal, and abnormal frequency pattern) was excluded from analysis. The raw EMG waveforms were band-pass filtered using a 4th order ██████████ filter between 35 Hz and 400 Hz, to reduce contamination from movement artefacts, electrocardiogram signals (Drake & Callaghan, 2006), and high frequency noise (Hermens et al., 1999). Additionally, to eliminate the effects of signal interference from nearby electronic sources, EMG waveforms were notch-filtered at 60 Hz using a 4th order ██████████ filter. EMG waveforms were then full-wave rectified, demeaned, and subjected to a low-pass 4th order ██████████ filter with a cutoff frequency of 50 Hz to obtain the EMG linear envelope (Hodges & Bui, 1996). The mean value of this linear envelope has been reported in the results. Results were compared to the corresponding 0° crib mattress condition (prone and supine, separately), using paired t-tests ($p<0.05$), and trends were also noted ($p<0.10$). Pairwise comparisons were also made for all prone and supine crib mattress incline angles, and for the prone and supine 0° crib mattress conditions. All data analysis was conducted using custom MATLAB code. All muscle groups were considered for prone conditions, and all muscle groups except the triceps were considered for the supine conditions since the arms were not in contact with the surface or product when babies were lying supine. Results are presented as normalized values to the crib mattress condition (supine or prone).

Space Required to Roll

Infant rolling data was extracted from an existing data set of healthy infants. Using the net excursion of a marker placed on the lateral epicondyle of the knee (Figure 16), the space required for infants to roll on a flat surface was estimated.

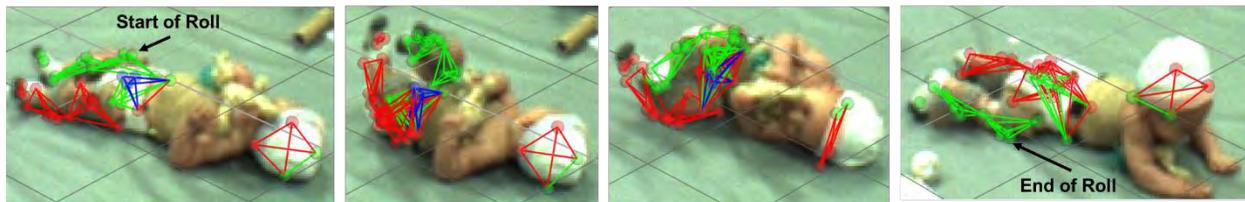


Figure 16. Infant rolling and location trajectory of lateral knee marker

The net excursion of the lateral knee marker was calculated in the transverse/horizontal plane as the resultant of the medial/lateral (x) and anterior/posterior (y) motion of the marker during the roll.

Oxygen Saturation

Retrospectively, SpO₂ data were extracted from the data logger, and the number of times infants registered a below 95% SpO₂ reading for each testing condition was tallied. Video footage was examined when SpO₂ <95% to help determine the cause of the reading.

4.4 Biomechanical Testing Results

All ten infants were able to complete at least 7/10 of the testing conditions, so all babies were included in the study. The qualitative video analysis to determine if the motion capture markers and the EMG sensors interfered with normal motion and movement revealed that sensors did not interfere with any arm or leg movement, agreeing with previously published research. (Trujillo-Priego and Smith, 2017) It was noted a few times during testing when a marker or sensor fell off, but the research team reattached it and testing resumed. Developmental screening, kinematic, EMG, and oxygen saturation results are presented below.

Developmental Screening Results

All 10 infants' caregivers completed the ASQ-3 questionnaire (3 1.0-2.9 months; 3 3.0-4.9 months; 4 5.0-6.9 months). ASQ-3 results indicated below average or delayed behavior for: Gross Motor 1/10 and Fine Motor 4/10. Video assessment revealed below average motor behavior in 4/10 infants. Because no babies had been previously diagnosed with developmental delays, all babies were included in the study.

4.4.1 Kinematic Results

Effect of Inclined Crib Mattress during Prone Positioning

No significant changes in sagittal plane range trunk or neck range of motion (ROM) were found (Figure 17). A significant trend toward an increased number of neck peaks was found for 20° as compared to 10° ($p = 0.08$). The inclined angles of the crib surfaces did not affect the number of neck and trunk angle peaks.

Neck and Trunk ROM and Movement on Crib Mattress at Various Incline Angles: Prone Position

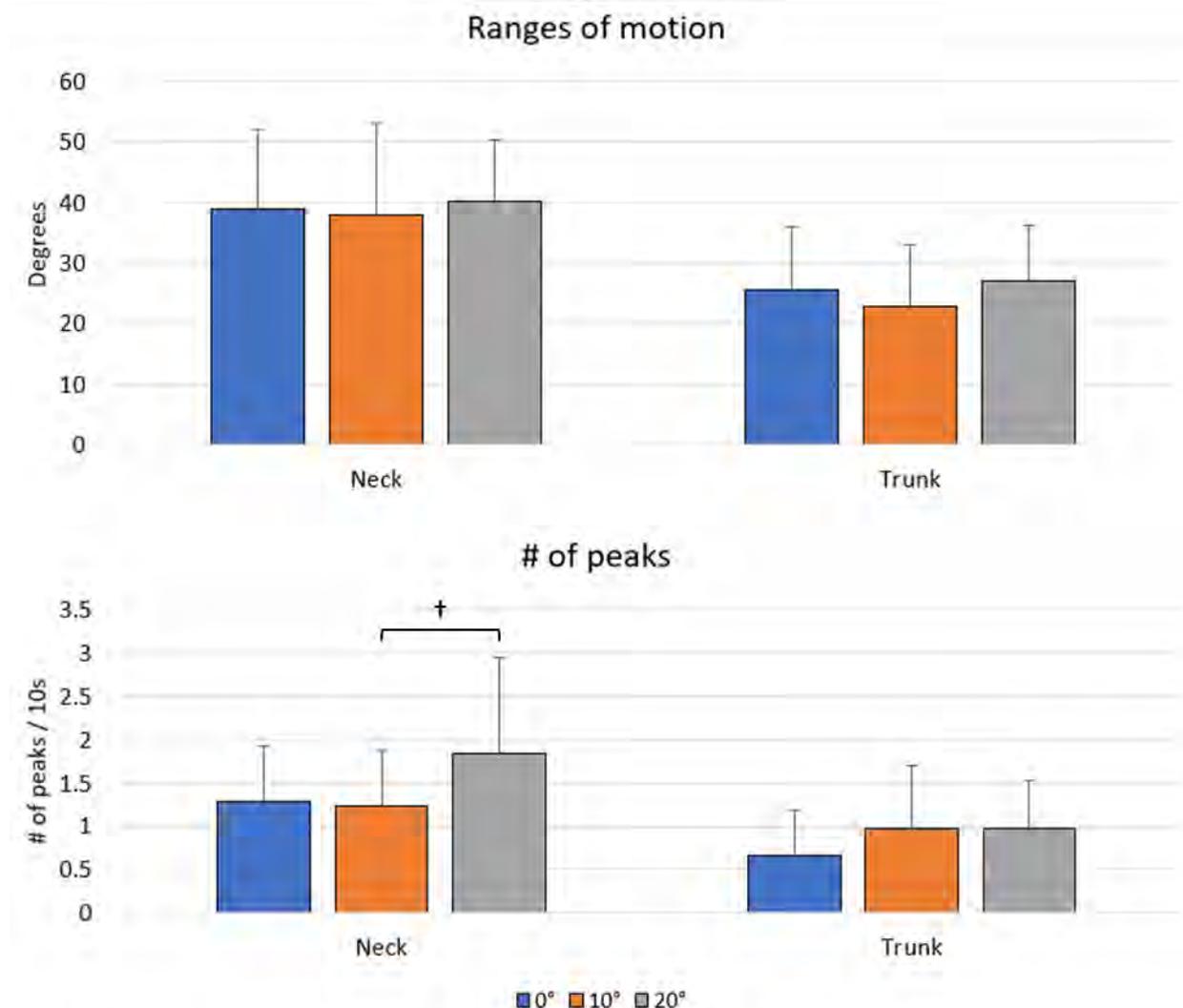


Figure 17. Effect of inclined crib mattress surface (0° vs. 10° vs. 20°) during prone positioning on (a) ranges of motion and (b) number of peaks [neck: number of times an infants raised heads relative to trunks; trunk: number of times infants raised trunks relative to pelvises]. † $p < 0.1$.

Kinematic parameters during prone positioning were not sensitive to different inclined angles of the crib surfaces. Greater inclined angles (20°) may increase neck movement (the number of angle peaks) during prone positioning, meaning that infants may be lifting their heads more often

at a 20° incline, but this did not reach statistical significance. The incline angle alone also does not appear to significantly impact trunk or neck range-of-motion during prone positioning.

Effect of Inclined Sleep Products during Prone Positioning

Although incline angle alone did not impact trunk or neck ROM, several inclined sleep products did (Figure 18). S03 resulted in increased neck ROMs as compared to the 0° crib mattress (p = 0.04). S03, S06, S08 increased trunk ROMs as compared to the 0° crib mattress (p = 0.03, p = 0.01, p = 0.04)

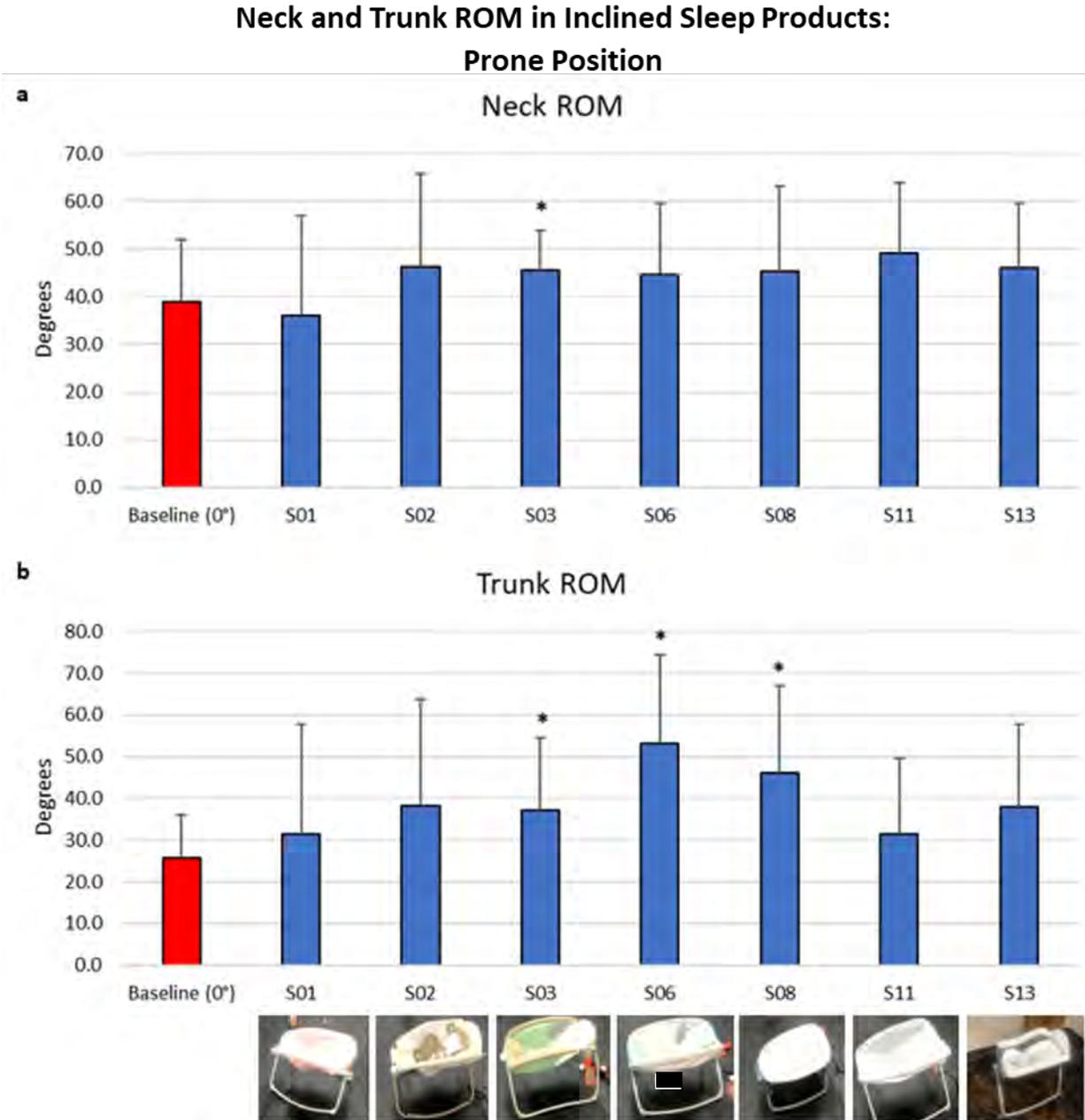


Figure 18. Effect of inclined sleep products during prone positioning on (a) neck and (b) trunk ranges of motion (ROM). *p<0.05 when compared to 0° crib mattress (Baseline).

S03, S06, and S08 are all products that do not have any plastic support underneath the surface (see Product Analysis section 3.3 for details). It appears that trunk and neck movement increases (up to 25°) during prone positioning in inclined sleep products without plastic support at the surface, which differs from the crib mattress incline results which showed no differences. The conformity of these particular products with no rigid support likely causes more movement as infants must work harder to position their bodies. The meaning of these kinematic results will be discussed in more detail after the EMG results are presented below (section 3.1.4).

Neck and Trunk Movement in Inclined Sleep Products:

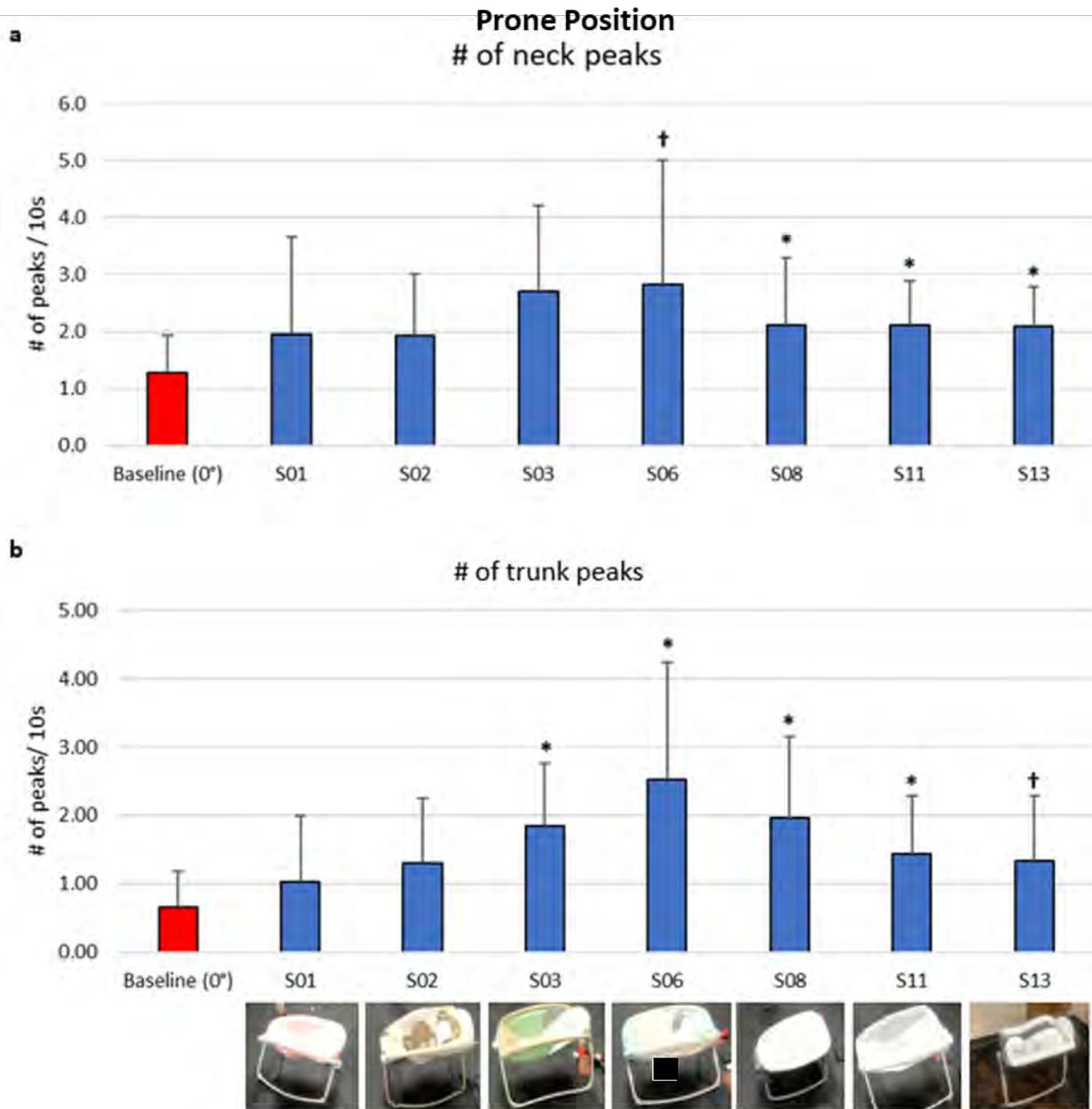


Figure 19. Effect of inclined sleep products during prone positioning on number of (a) neck and (b) trunk peaks [neck: number of times infants raised heads relative to trunks; trunk: number of times infants raised trunks relative to pelvises]. *p<0.05 and †p<0.1 when compared to 0° crib mattress (Baseline).

The number of trunk angle peaks was significantly increased for S8, S11, and S13 as compared to 0° (Figure 19, $p = 0.05$, $p = 0.02$, $p = 0.01$). Similarly, S03, S06, S08, and S11 showed an increased number of trunk angle peaks as compared to 0° ($p = 0.04$, $p = 0.01$, $p = 0.01$, $p = 0.02$).

These results tell a similar story as the ROM results: inclined sleep products result in different movement patterns during prone positioning compared to a flat crib mattress surface. Interestingly, products without any plastic surface support (S03, S06, and S08) caused babies to move more often as they worked against the pliant product to move their bodies compared to the firm and flat crib mattress. These peak results also show that products with a thin plastic surface (S11 and S13) also caused more movement. Only the products with a rigid plastic surface (S01 and S02) showed no difference in the number of times the babies lifted their trunk or neck compared to prone lying on a flat crib mattress. The meaning of these results will be discussed in more detail after EMG results are presented.

Effect of Inclined Crib Mattress during Supine Positioning

Neck ROM was significantly, though only slightly, increased for the 20° surface as compared to 0° surface (Figure 20, p=0.02) while no changes in trunk ROMs were found. Number of neck angle peaks were significantly increased when comparing 20° to 0° and 10° (p=0.02, p=0.01). No changes in trunk ROMs and number of trunk angle peaks were found.

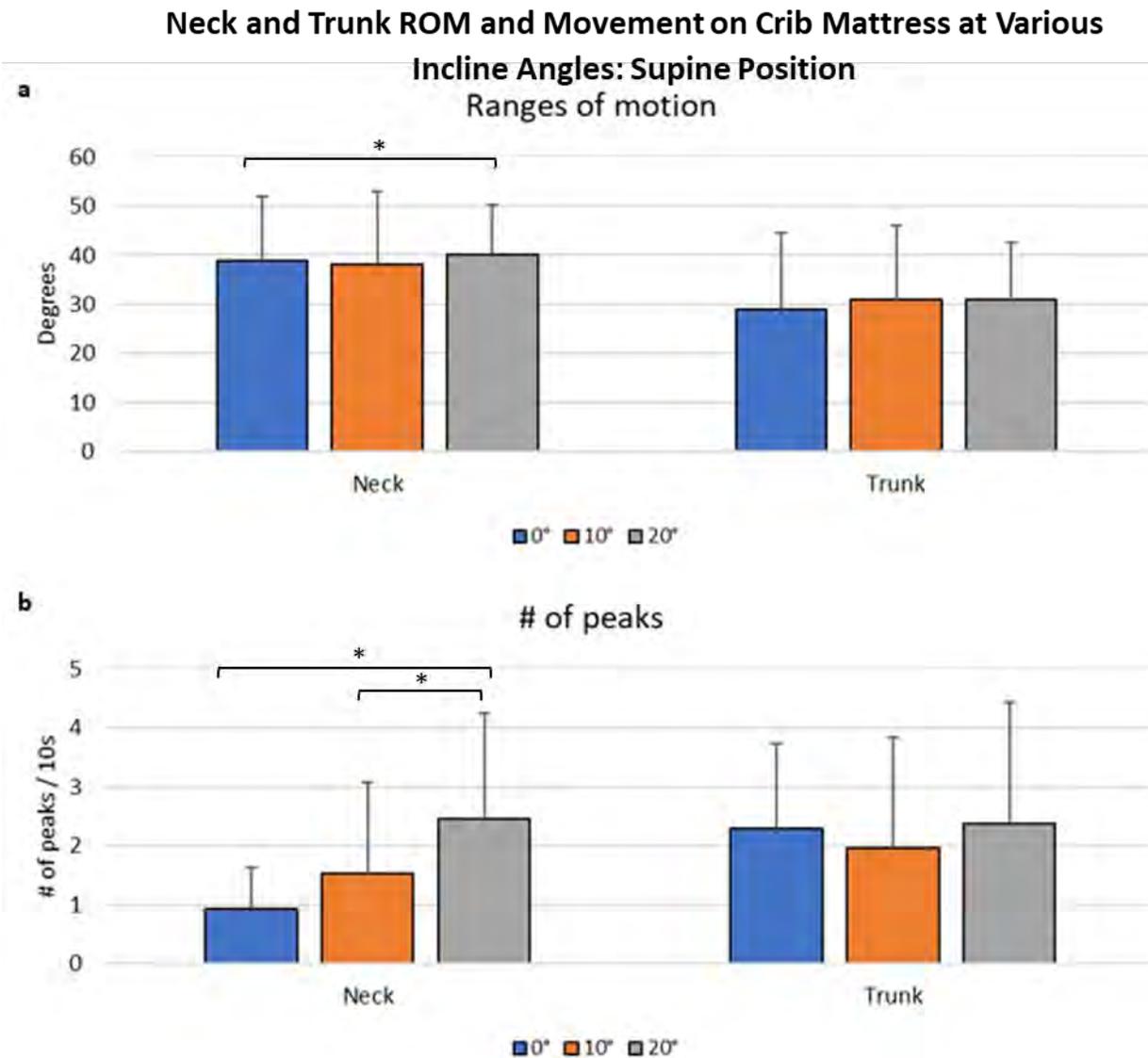


Figure 20. Effect of inclined crib mattress surface (0° vs. 10° vs. 20°) during supine positioning on (a) ranges of motion and (b) number of peaks [neck: number of times an infants raised their heads relative to their trunks; trunk: number of times infants raised their trunks relative to their pelvises]. * p<0.05.

Inclined surface angles slightly increased neck motion while trunk motion remained unchanged during the supine position. Babies lifted their heads 2.5 times more often at the 20° incline compared to the flat surface. These results will be discussed in detail in conjunction with the EMG results below.

Effect of Inclined Sleep Products during Supine Positioning

No significant differences in neck ROM were found (Figure 21). S01 and S02 resulted in decreased trunk ROMs as compared to 0° (p=0.03, p=0.08).

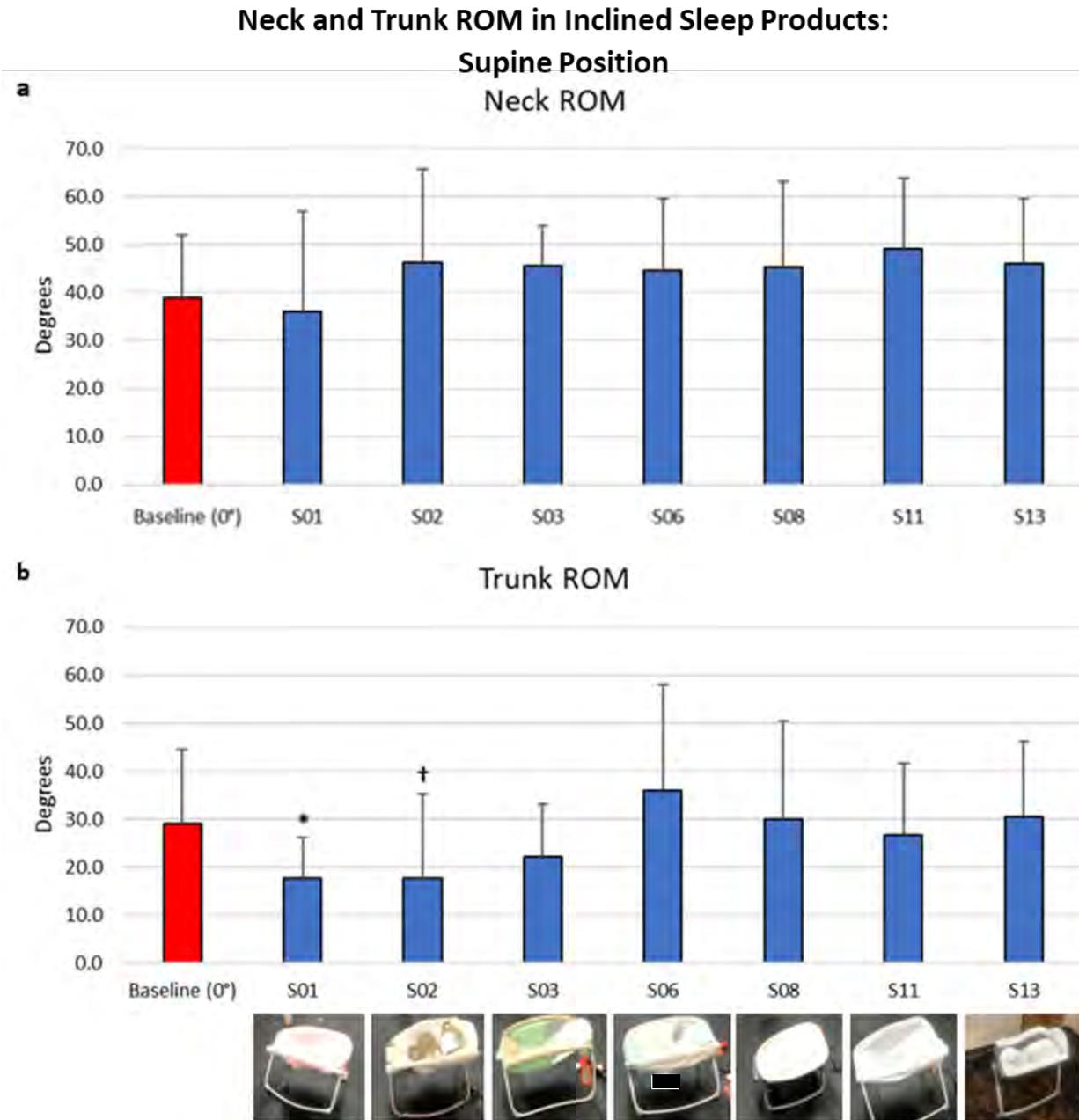


Figure 21. Effect of inclined sleep products during supine lying on (a) neck and (b) trunk ranges of motion (ROM). *p<0.05 and †p<0.10 when compared to 0° crib mattress (Baseline).

S01 and S02 showed decreased trunk motion as compared to 0° surface. These two products have a hard plastic surface, which may prevent babies from extending their trunks during supine lying, resulting in a lower range-of-motion.

No changes in the number of neck angle peaks were found (Figure 22). The number of trunk angle peaks was decreased up to 4 times for S02, S06, S11, and S13 ($p = 0.06$, $p = 0.07$, $p = 0.01$, $p = 0.05$)

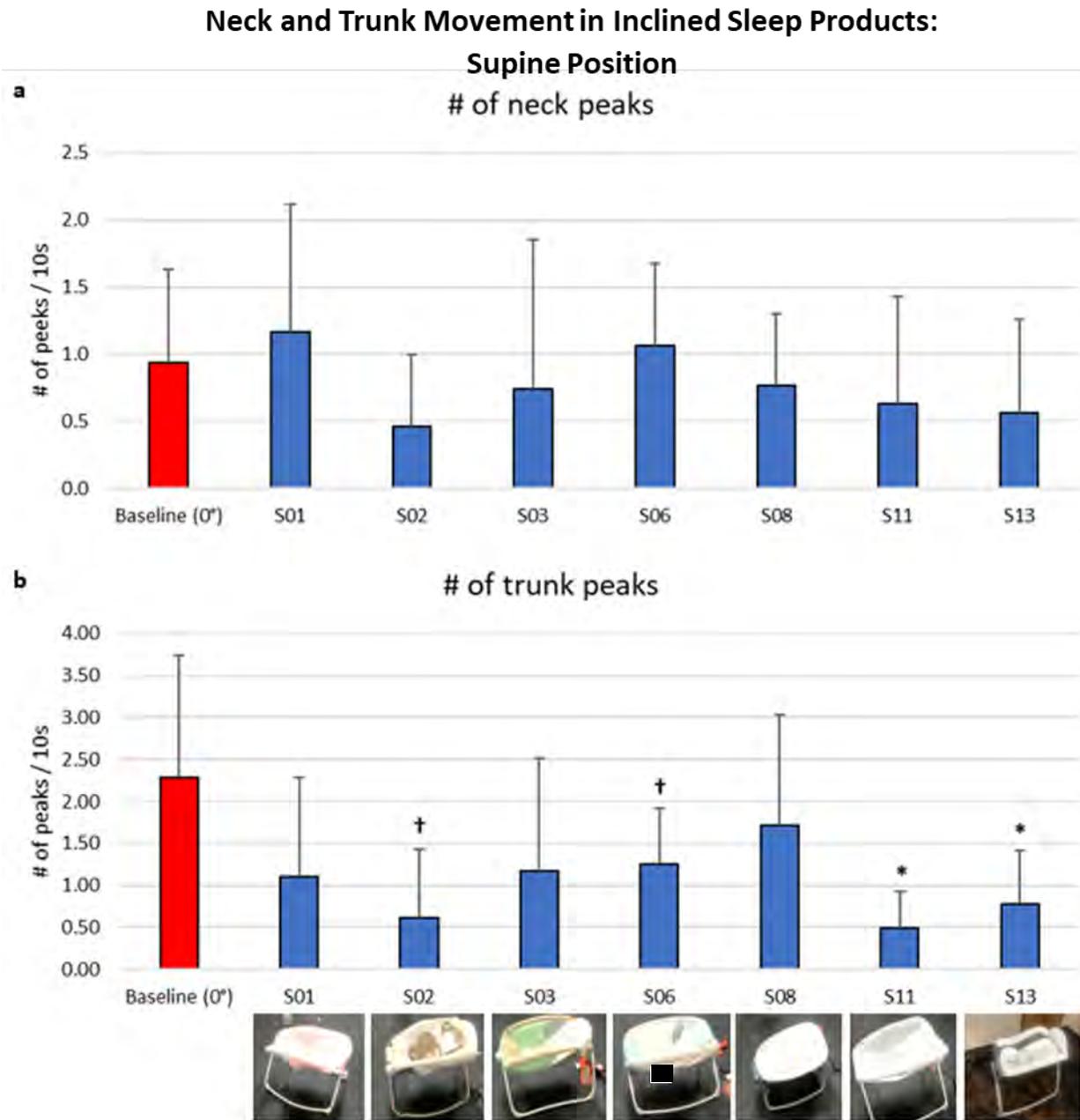


Figure 22. Effect of inclined sleep product during supine lying on (a) neck and (b) trunk peaks [neck: number of times an infants raised heads relative to trunks; trunk: number of times infants raised trunks relative to pelvises]. * $p < 0.05$ and † $p < 0.1$ when compared to 0° crib mattress (Baseline).

Contrary to the results of the crib mattress incline portion of this study, babies showed no difference in the number of times they lifted their heads in the inclined products but had significantly fewer trunk movements in the products during supine lying. This shows that something about the design of the inclined sleep products is preventing trunk motion during supine lying in a way that an inclined crib mattress surface does not. Decreased trunk movement was measured in all types of inclined sleep products (various angles, various plastic/ no plastic surfaces, various padding). One reason for this observation may be that when babies are positioned supine in the products, some conformity occurs (either due to no rigid plastic surface or due to heavy padding). The conformity causes an increased trunk flexion that does not occur on an inclined crib mattress surface. Because the babies are already in a flexed position, further flexion is more difficult to achieve and therefore they do not move as often. These results will be discussed in conjunction with the EMG results below.

4.4.2 EMG Results

Effect of Inclined Crib Mattress during Prone Positioning

The inclined crib mattress significantly impacted muscle activity of the infants (Figure 23, presented as normalized values). Erector spinae EMG activity was significantly decreased when comparing 10° and 20° to 0° ($p = 0.04$, $p = 0.01$, respectively). Cervical paraspinal EMG activity was significantly decreased for 20° as compared to 0° ($p = 0.02$). Abdominal muscle activity was significantly increased when comparing 10° and 20° to 0° ($p = 0.02$, $p = 0.01$) as well as when comparing 20° to 10° ($p = 0.04$). Triceps EMG activity was significantly decreased for 20° as compared to 0° ($p = 0.02$).

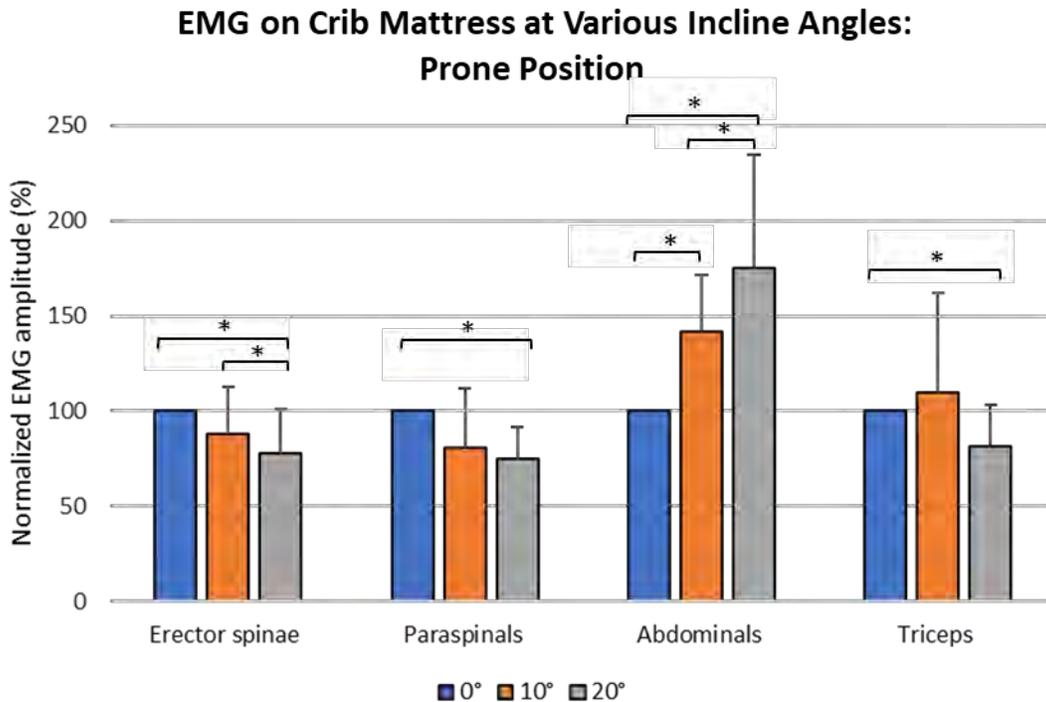


Figure 23. Effect of crib mattress surface at various inclines (0° vs. 10° vs. 20°) on EMG: erector spinae, cervical paraspinals, abdominals, and triceps during prone. * $p < 0.05$.

These results indicate that inclined surfaces (especially 20°) require greater abdominal muscle activity while decreasing erector spinae, cervical paraspinal, and triceps muscle activities. In other words, to maintain a prone lying position, an infant must use and coordinate their muscles differently when on an inclined surface; babies must depend more on their abdominal muscles to maintain a lying position. In particular, the core muscles (abdominals) require 70% more activity to maintain a prone lying position, indicating that **muscle fatigue of the abdominals would occur more quickly at an incline compared to a flat surface**. Rather than depending on many muscles to maintain a prone position on a flat surface, the inclined surface increases the effort required of the core muscles. Postural adjustments and core muscle strength are closely related, so the role of abdominal muscles in changing position is critical and is impacted by incline angle.

When analyzed in conjunction with the kinematic results above, the narrative is supported; babies are not moving their heads or trunks more or less often in the prone position on an inclined crib mattress surface, yet the muscle activity profile is significantly different. Further, the decrease in neck and back muscle activity does not result in a decrease in neck or back movement, indicating

that the abdominals must play a significant role in body movement during prone lying on an incline. Because the abdominal muscles are critical for body control and movement, it is likely that an incline makes it more difficult for infants to roll from prone to supine when compared to a flat surface due to the increased demand on their abdominal muscles to maintain a prone position.

Effect of Inclined Sleep Products during Prone Positioning

Erector spinae muscle activity was significantly decreased for S02, S03, and S08 as compared to 0° baseline (Figure 24, $p = 0.007$, $p = 0.05$, $p = 0.005$). Significant trends (i.e. $p < 0.1$) toward decreased erector spinae muscle activity was found for S01 and S11. No significant changes and trends in cervical paraspinals were found.

EMG in Inclined Sleep Products:

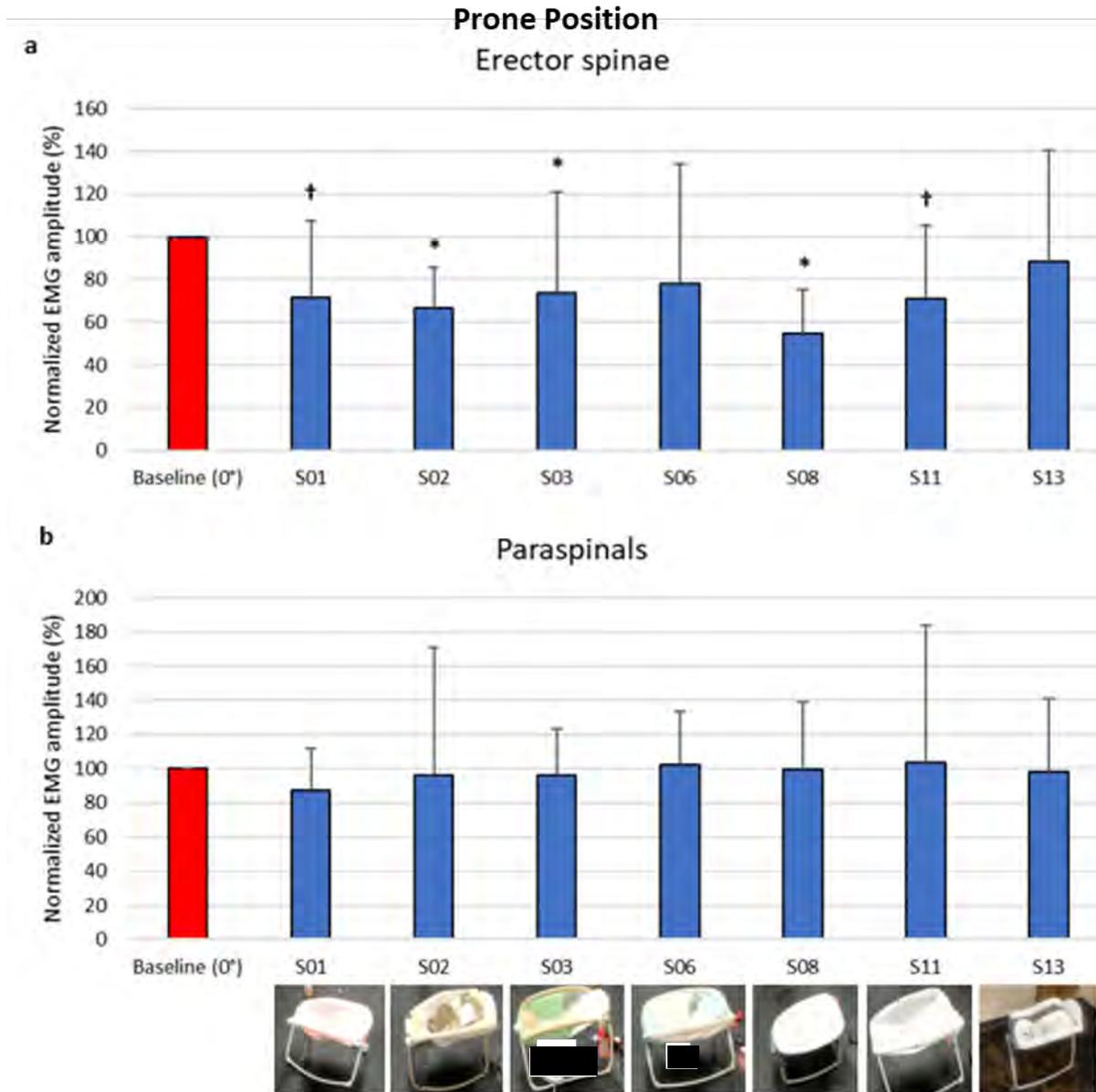


Figure 24. Effect of inclined sleep products during prone positioning on EMG activity of the (a) erector spinae and (b) cervical paraspinals. * $p < 0.05$ and † $p < 0.10$ when compared to 0° crib mattress (Baseline).

S01, S02, S03, S08, and S11 products resulted in decreased trunk extensor muscle activity during prone lying (as compared 0° crib mattress surface). S06 and S13 also showed decreased erector spinae activity but did not show significant changes due to high variability. These results agree with those of the 20° crib surface, showing less erector spinae muscle activity required to maintain

a prone position. It is not surprising that the cervical paraspinal activity exhibited high variability. Observationally, babies rested their heads during prone tasks, while others appeared to move their heads continuously, resulting in high variability.

Abdominal EMG activity was increased for S02, S06, and S08 as compared to 0° baseline (Figure 25, $p = 0.03$, $p = 0.01$, $p = 0.05$). A significant trend for S03 (increased abdominal activity) was found ($p = 0.08$). No significant differences in triceps EMG were found.

EMG in Inclined Sleep Products:

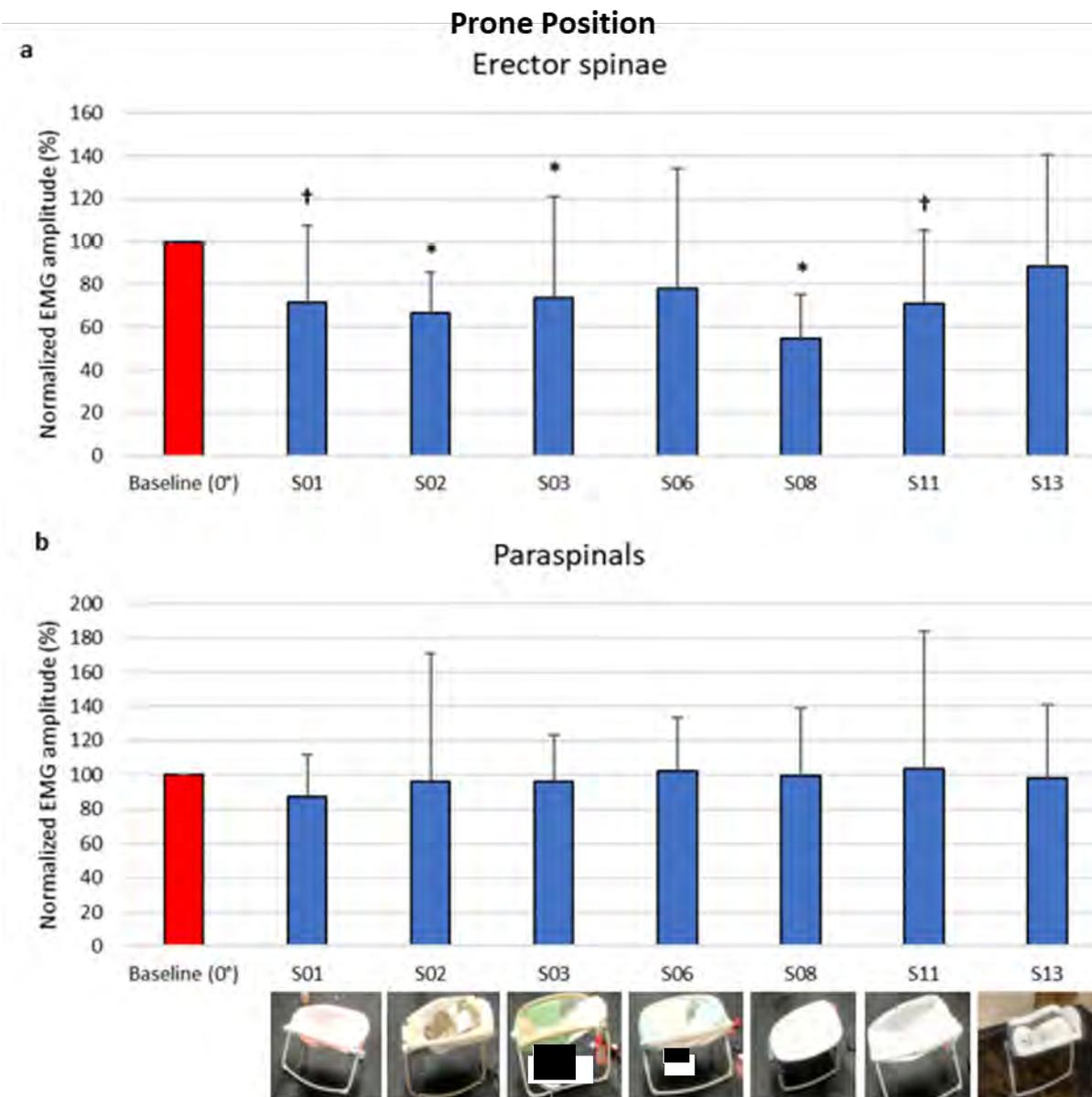


Figure 25. Effect of inclined sleep product during prone positioning on EMG activity of (a) abdominals and (b) triceps. * $p < 0.05$ and † $p < 0.1$ when compared to 0° crib mattress (Baseline).

Similar to the inclined crib mattress testing, infants used their abdominal muscles significantly more when lying prone in the inclined sleep products compared to the flat crib mattress surface. In particular, it was noted that products with the thickest padding (S02, S06, and S08) exhibited increases in abdominal muscle activity of 186%, 245% and 191%, respectively. **This suggests that the combination of incline angle and product design requires infants to use significantly more core effort (abdominal strength) to maintain a prone position compared to a flat surface.** If an infant rolls within an inclined sleep product, the product design of limited horizontal space and a non-rigid concave surface makes rolling prone to supine difficult or impossible. Therefore, infants attempt to maintain a safe prone posture, which the EMG results suggest places an increased demand on the core muscles.

Similar to the cervical paraspinal muscles, it is not surprising that the triceps muscle activity exhibited high variability. Observationally, some babies actively used their arms during prone positioning, while others appeared to utilize their legs to attempt repositioning, resulting in high variability. However, the consistent abdominal and erector spinae data indicate that babies rely on these muscle groups to reposition themselves regardless of variability in technique.

When considered with the kinematic results (section 3.1.3), back muscle activity decreases while the trunk motion actually increases, indicating that different muscles (abdominals) are being recruited to initiate movement during prone positioning in inclined sleep products, **presenting a significant hazard to babies if a roll from supine to prone in an inclined sleep product occurs.** Although babies may receive adequate practice in tummy time on a flat surface, a roll from supine to prone in an inclined sleep product would likely be the first time they have ever experienced a position that required muscles to work together in this particular way – with a significant need for abdominal strength. This situation would likely result in expedited muscle fatigue as the baby attempts to reposition and self-correct.

The role of abdominal muscles during breathing have been previously studied, though not on an inclined surface. In general, the contraction of the abdominal muscles, which normally play a role in breathing and are accessory muscles of respiration, stabilize the chest wall and push up on the abdominal contents, giving the diaphragm something to contract against, thus improving its function. Abdominal muscles are also expiratory accessory muscles that aid in forced expiration (exhalation) against obstructed airways (Campbell and Green, 1953; Martin and De Troyer, 1982). However, there is some evidence in infants that contraction of the abdominal muscles leads to decreased lung volume and hypoxic episodes (Boliver et al., 1995). So, an infant with increased abdominal muscle activity could have restricted rib cage expansion and low lung volumes or hypoxemia.

Effect of Inclined Crib Mattress during Supine Positioning

Erector spinae activity was increased for 20° as compared to 10° (Figure 26, p=0.04) though no changes were found when comparing 20° to 0°. For abdominals and cervical paraspinal muscles, there were no significant changes or trends across 0°, 10°, and 20° inclined surfaces.

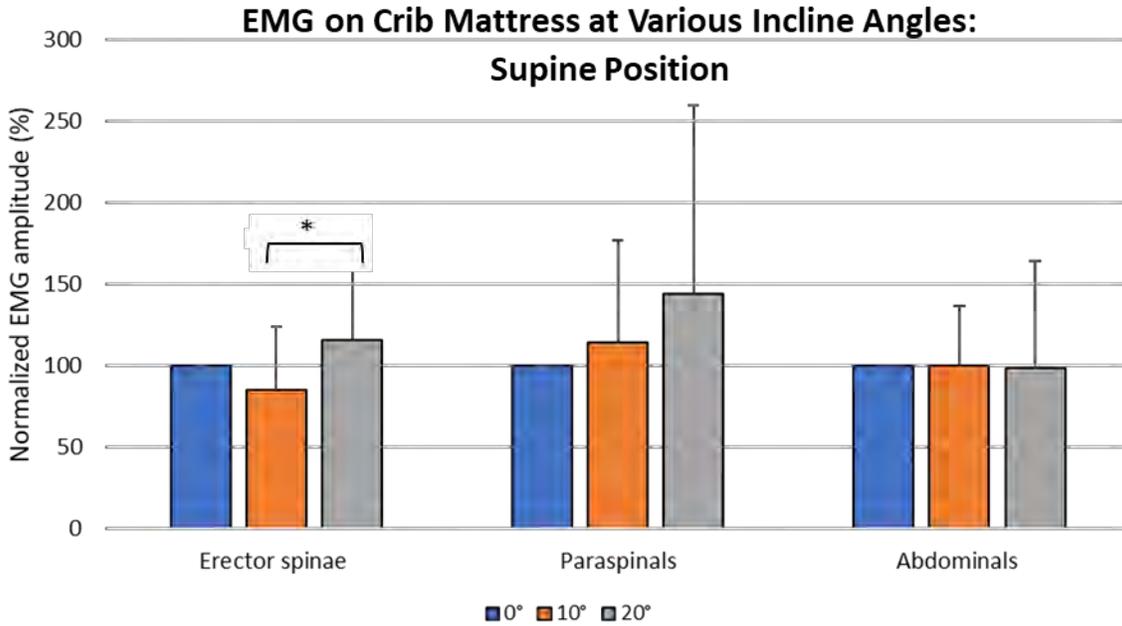


Figure 26. Effect of crib mattress at various incline angles (0° vs. 10° vs. 20°) during supine lying on EMG activity: erector spinae, cervical paraspinals, and abdominals. *p<0.05

Taken alone, these results suggest that an incline angle does not impact how infants are using their muscles during supine lying. However, when reviewed in conjunction with kinematic data (section 3.1.3), these EMG results become meaningful. The increased incline angle resulted in more neck motion, yet the EMG results mostly do not indicate an increase in muscle activity. Therefore, at an incline, it is easier for babies to move their heads in the supine position as compared to lying on a flat surface.

Effect of Inclined Sleep Products during Supine Positioning

Erector spinae EMG activity was significantly decreased for S06 as compared to 0°(baseline) (Figure 27, p=0.01). S02 also showed a significant trend toward decreased muscle activity when compared to 0° (p=0.07). Most inclined sleep product conditions tended to decrease erector spinae muscle activity when compared to 0°. No significant differences and trends in cervical paraspinal EMG were found.

EMG in Inclined Sleep Products:

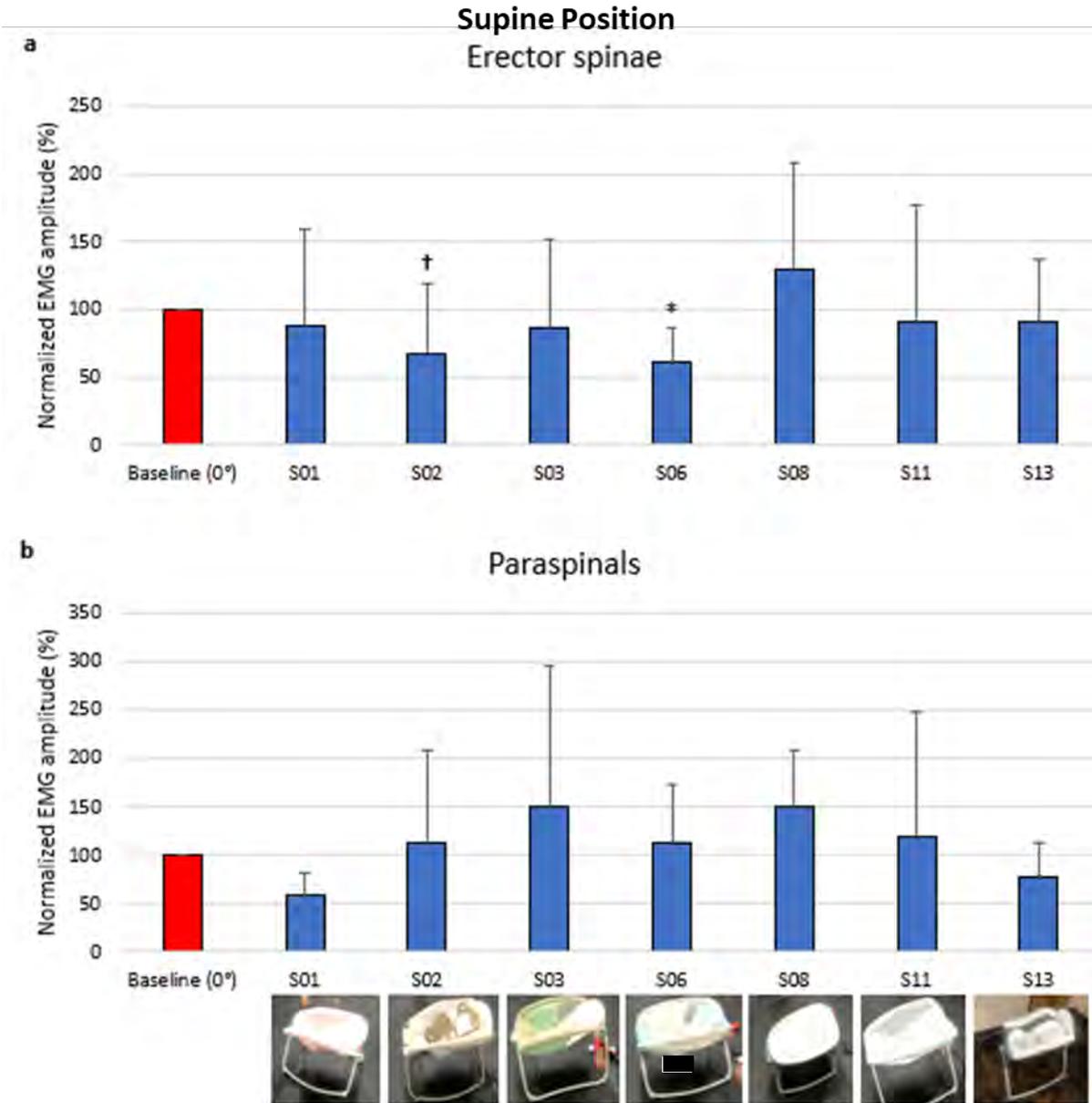


Figure 27. Effect of inclined sleep product during supine positioning on (a) erector spinae and (b) abdominals. * p<0.05 and †p<0.1 when compared to 0° crib mattress (Baseline).

Infants used their back muscles less during supine lying in products S02 and S06, two “deluxe” versions of products which exhibit significant padding. The heavy padding may conform to the infant during supine lying more than other products, resulting in a more flexed trunk which requires

less muscle activity to maintain the position. It is also reasonable that the conforming products offer comfort to infants, resulting in less movement and muscle activity. Across all products, EMG activity was highly variable and not significantly different than the baseline 0° condition during supine lying for both erector spinae and paraspinal muscle groups. When considered with the results of the kinematic analysis (section 3.3.1), infants move their trunks less and use their back muscles less in some inclined sleep products.

No significant changes in abdominal EMG activity during supine lying was found (Figure 28). These results suggest that infants are not using their abdominal muscles differently when positioned supine in an inclined sleep product.

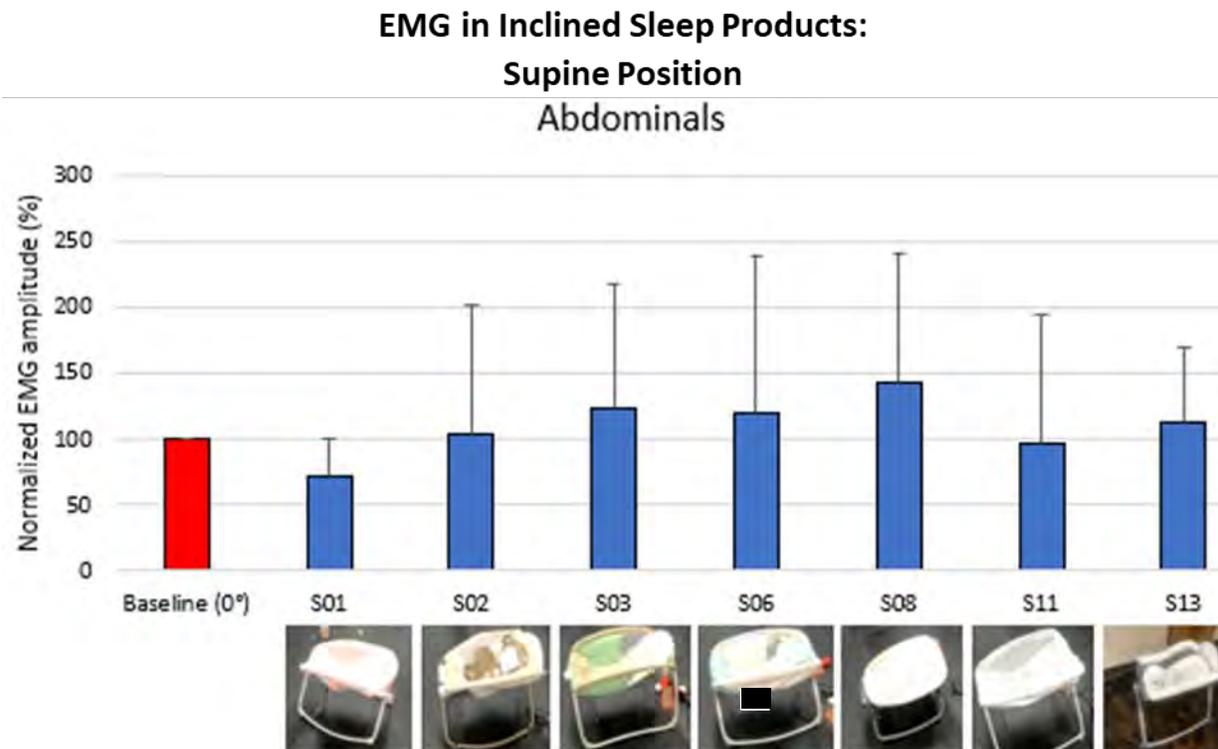


Figure 28. Effect of inclined sleep products during supine positioning on EMG activity of the abdominals.

While it is not fully understood how infants achieve a roll from supine to prone, the head represents a significantly higher percentage of total body weight in an infant compared to an adult. Therefore, head motion (in addition to other coordinated movements) likely plays a role in providing momentum and achieving a roll from supine to side-lying or supine to prone. The three incidents of supine to prone rolling that occurred on a flat surface during testing were analyzed, and it was found that the rolling mechanism was initiated by the fetal tuck (hip and trunk flexion) which requires a co-activation from the abdominal muscles and erector spinae as an agonist-antagonist pair. Because the conformity of the inclined sleep products naturally puts the infants in a more flexed hip and trunk position, it may be easier for infants to achieve the fetal tuck position to roll from supine to prone. Regardless if a roll from supine to prone is easier or more difficult to achieve on an inclined surface or in an inclined sleep product, it is fair to say that an inclined sleep product represents a different environment than a flat crib mattress or even a crib mattress at an incline. In particular, the most significant differences in supine lying occurred in the mostly heavily padded products (S02 and S06).

Prone v. Supine EMG Activity

EMG activity of the cervical paraspinals, erector spinae, and abdominal muscle groups were compared between prone and supine lying on a flat crib mattress. Results showed no difference between abdominal muscle activity in prone and supine lying, but 3 times more erector spinae ($p < 0.001$) and 5 times more cervical paraspinal ($p = 0.004$) muscle activity during prone lying compared to supine lying (Figure 29). In other words, while the abdominal effort may not change between prone and supine lying on a flat surface, the trunk extensor muscle groups (cervical paraspinals and erector spinae) are much more active in the prone position on a flat surface.

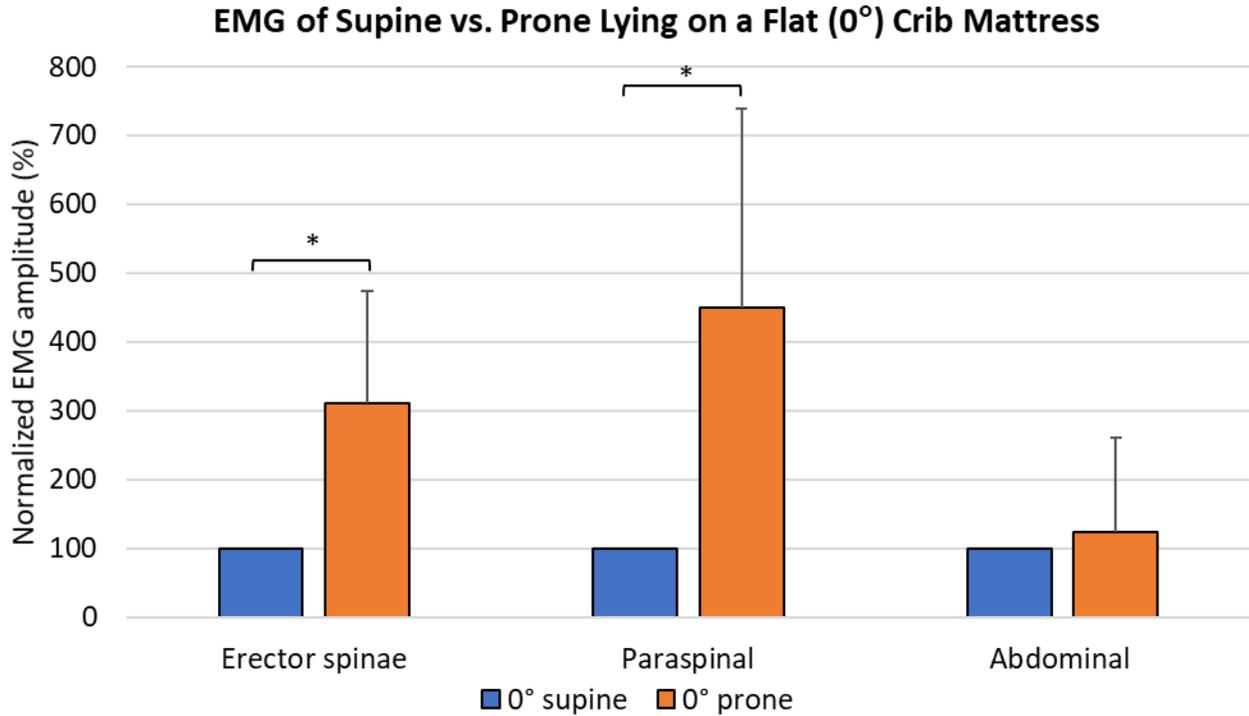


Figure 29. EMG activity (erector spinae, paraspinal, and abdominals) during flat (0°) crib mattress supine compared to flat (0°) crib mattress prone lying, with EMG amplitudes normalized to the supine condition. * $p < 0.05$.

When taken together with the results that show less extensor, more abdominal muscle activity, and more movement during inclined prone positioning compared to lying prone on a flat surface, it is clear that muscle synergies (i.e. how muscles work together) to achieve mobility and postural changes on a flat surface are not the same when an incline is introduced. The fact that abdominal muscle activity increased by nearly 250% in some inclined sleep products suggests that more effort than is ever needed for flat surface supine or prone lying is required when prone in an inclined sleep product (Figure 30). Positions that demand much more of muscles will also fatigue them more quickly, so if a baby experiences a roll, the baby is in a hazardous and unfamiliar position that requires efforts they have likely never experienced, presenting a risk factor that may contribute to suffocation if self-correction from prone to supine does not occur.

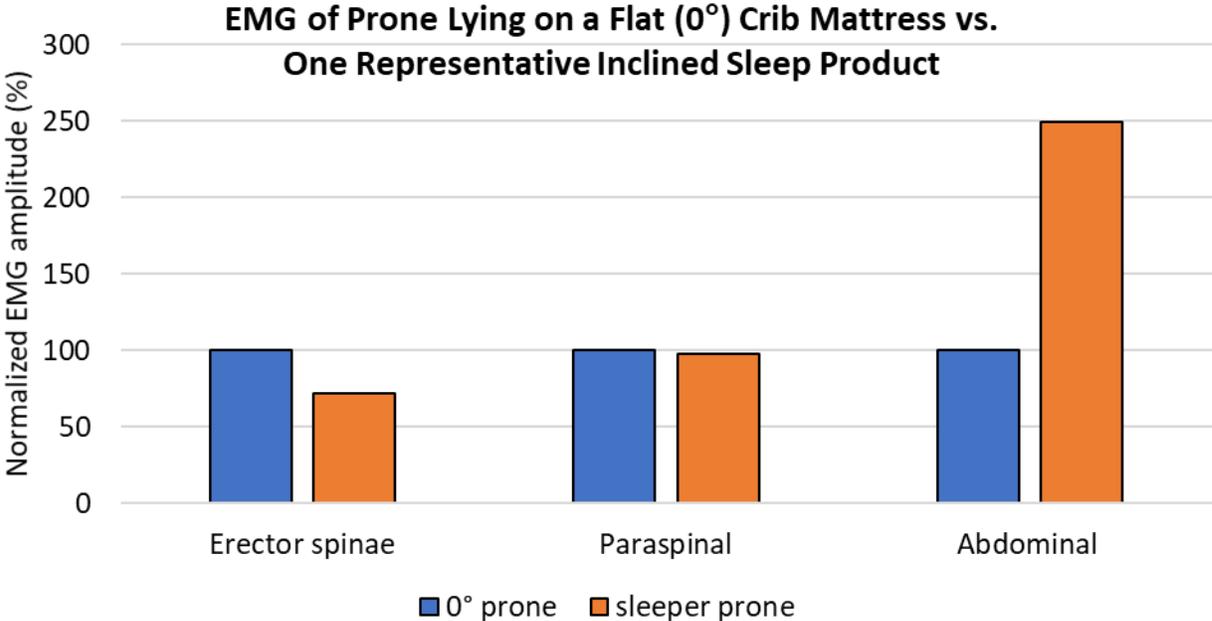


Figure 30: EMG activity (erector spinae, paraspinal, and abdominals) during flat (0°) crib mattress prone lying (blue) and with one representative inclined sleep product during prone lying (orange).

4.4.3 Space Required to Roll

Our dataset contained three full supine-prone rolls with visible marker data. All these rolls occurred on the flat crib mattress and were initiated by the fetal tuck (hip flexion) which drove trunk rotation after the lateral knee contacted the surface. Therefore, the excursion of the lateral knee marker was used to define the horizontal space of a roll. The mean space required to roll (at the knee) was 47.1 cm (range: 27.9 cm – 63.6 cm). However, the product analysis (Section 3.3) confirms that every inclined sleep product analyzed had a knee width less than 47.1 cm.

While in theory, a product narrower than the average space required for a roll on a flat surface should reduce or eliminate the ability of an infant to roll, as evidenced in the 33 incident reports of supine to prone rolls in Section 2, other factors are at play that allow infants to roll even though the width of many of the products appear to be prohibitive. Inclined sleep products have added factors of pliancy, concavity, and inclined surfaces, all of which may reduce the horizontal space required to achieve a supine to prone roll. In addition, every inclined sleep product is different, so space required to roll likely varies between products.

The infants who rolled on the flat surface had a mean knee-to-knee distance (infant's body size at knee) of 21.5 cm (range: 18.5 – 27.0 cm) while lying supine, prior to initiating the roll. Based on the mean space required to roll on the flat surface (47.1 cm), the distance from the outer knee to the side of a flat product should not exceed 12.8 cm if rolling is to be avoided.

If the goal is to avoid any supine to prone rolling in an inclined sleep product, the distance from the lateral aspect of the knee to the side of the product should be minimized when the infant is lying supine. However, due to the range of designs of inclined sleep products (conformity, pliancy, and incline angle) which likely all have an impact on space required to roll, it is difficult to state a width that will prevent rolling in this diverse product class.

4.4.4 Oxygen Saturation Results

The number of trials that each baby experienced a drop in oxygen saturation (SpO₂) <95% during the 60 second testing conditions were tallied. Nine of ten babies experienced at least one SpO₂ event during testing. No babies experienced problems in any supine-lying condition.

There were 18 total prone-lying trials that ended early due to SpO₂ readings of <95% (Table 7). Upon video analysis, in each instance where SpO₂ readings of <95% were found, the baby’s face appeared to be in contact with the surface of the product, both on the crib mattress and in the inclined sleep products (Figure 31). Product S06 (deluxe version of Company B) resulted in four babies experiencing SpO₂ readings of <95%. S06 has no plastic molding, a plush thick pillow, and the largest incline angle at the head portion of the product. Product S13 (Company C) was the next highest with 3 babies experiencing SpO₂ readings of <95%. S13 has a rigid plastic molding that is split into two parts, making the product unstable if a force is applied to the surface. Products S01 and S02 (basic and deluxe versions from Company A) and S03 (basic version from Company B) each had 2 babies experience SpO₂ readings of <95%. One infant experienced SpO₂ readings of <95% in each of the other testing conditions (0°, 10°, 20° crib mattress; inclined sleep products S08 and S11). S08 features a low incline with low side heights and a uniform thick plush material. S11 is the widest of all products examined and has a thin plastic molding on the bottom surface.

Table 7. Number of events (SpO₂<95%) for prone lying on crib mattress and inclined sleep product conditions for each participant (CPSC 2 through CPSC 11).

	0°	10°	20°	S01	S02	S03	S06	S08	S11	S13
CPSC2	√	√		√		√				
CPSC 3				√			√	√		
CPSC 4					√					
CPSC 5					√	√	√			
CPSC 6							√			
CPSC 7										
CPSC 8							√			√
CPSC 9										
CPSC 10			√							√
CPSC 11									√	√
Total	1	1	1	2	2	2	4	1	1	3



Figure 31: Examples of infants' faces in contact with crib mattress and inclined sleep product surfaces prior to low SpO₂ events from left to right: crib mattress, S13, S02, and S08.

When considering all crib conditions v. all inclined sleep product conditions, oxygen saturation concerns were found in 10% of crib mattress trials compared to 21% of inclined sleep product trials. In other words, **babies were more than twice as likely to experience SpO₂ readings of <95% while lying prone in an inclined sleep product compared to prone on a crib mattress.** The differences between a crib mattress and an inclined sleep product are vast and include more space to maneuver, no fabric materials on the sides of the product, little conformity with force application, and a flat product design featuring no concavity. These main differences likely contribute to fewer SpO₂ incidents in the crib mattress conditions compared to the inclined sleep product conditions.

Although no previous research has been done regarding the impact of inclined surfaces on breathing, these results agree with previous literature looking at prone compared to supine lying on a flat surface. Galland et al. (2000) compared the response of 3-month-old infants to asphyxia in the prone vs. supine position in quiet vs. active sleep. Three-month-old infants responded to asphyxia equally well in prone vs. supine position during quiet sleep. **However, during active sleep (REM equivalent in infants), 3-month-old infants had a poorer (reduced) ventilatory sensitivity to asphyxia in the prone position compared to the supine position.** This suggests that 3-month-old infants sleeping prone, in active sleep, would likely respond less to an asphyxia challenge compared to infants the same age in the supine position. This is particularly meaningful when considering that most of the incidents in the inclined sleep products occurred during naptime or overnight sleeping, when babies were less awake and possibly even experiencing active sleep.

It is critical to remember that the low oxygen saturation events in this study occurred within 60 seconds of being placed prone in each condition. Therefore, dangerous and fatal oxygen saturation levels could be reached in babies who roll from supine to prone in an inclined sleep product in a short amount of time.

Analyzing the results of this oxygen saturation portion of the study, in conjunction with the biomechanical analysis which showed differences in how muscles must work together to achieve a prone lying position with an increased demand on the core muscles in inclined sleep products, it is clear that **prone lying in a product in the class of Inclined Sleep Products evaluated in this study is a dangerous position that puts an infant's life at risk,** likely within only a few minutes after the roll occurs. These results also have implications for caregivers who may place infants to sleep prone within an inclined sleep product (as evidenced by three of the deaths from the incident analysis); prone positioning in an inclined sleep product, whether due to the infant rolling from supine to prone or due to the caregiver placing the infant prone in the product, is not safe for infants.

4.5 Study Limitations

This study is not without limitations. Infant biomechanics is grossly understudied compared to older children and adults. For that reason, established methodology for infant biomechanical studies is scarce. The project team has developed methods to analyze infant position and muscle activity by adapting widely accepted methodology for use in an infant population (Siddicky, 2019; Mannen, 2018). Specifically, the trunk-neck-head angular changes were analyzed to avoid the limitation of finding exact anatomical locations on which to place retroreflective markers. Exact placement of these markers is crucial to achieve high fidelity estimates of body segment kinematics, and the necessary landmarks are not always fully developed in infants. The method of using local coordinate systems on each body segment used in this study avoids the errors of lack of anatomical landmarks in babies and has been used in the spinal biomechanical analyses of children (Wilk et al., 2006).

Furthermore, there are inherent limitations in using surface electromyography (EMG) sensors on adults or children. While fine-wire EMG is more accurate, it is invasive and hence not feasible in a study on healthy infants. Surface EMG is used widely in older child and adult biomechanical studies, so similar methods and smaller EMG sensors were used to account for the infant population. One criticism of EMG technology is crosstalk between muscle groups. Since paired analyses were performed and were not specifically interested in one muscle but rather muscle groups, the results of this study accurately explain muscle use in various conditions. While other muscle groups may be important in achieving a roll, the experimental limitations did not allow for all muscles to be analyzed, and muscle groups were chosen based on preliminary data in the laboratory and knowledge of the field.

Oximetry technology is not without error. For this study, a medical grade handheld device commonly used in hospitals to detect oxygen saturation levels was used. Each event was examined to determine if the infant's face was in contact with a surface or if the reading was possibly false. In all 18 events, the infant's face was observed to be contacting a surface, giving confidence in the results.

Enrolling and testing enough participants for a biomechanical study can be challenging, particularly when considering the critical and expedited timeline for this study. The power analysis was based on EMG data from a previous study, and more subjects were tested than was suggested by the power analysis for achieving sufficient power to detect a significant difference in muscle activity between conditions. While the data showed several significant differences, especially between 0° and 20° crib mattress positions and between 0° crib mattress and inclined sleep products, a larger sample size may give more statistically significant evidence in other comparisons.

Though necessary for high-tech biomechanical testing, the laboratory environment is not the same as a home environment, but efforts were made to keep the temperature warm and the ambiance calm in the laboratory. Challenges of fussiness, crying, and sleeping were overcome by encouraging the caregiver to take an active role in the experiment. Data was included for analysis in this study if the baby was awake and not crying. Caregivers were given unlimited time to calm, feed, or change their infant's diapers to help testing go as smoothly as possible and to replicate a home environment. Experimental constraints also limited the time of testing to 60 seconds per condition, which is less time that infants would spend in these products in a home environment. The fact that biomechanical changes and differences in oxygen saturation levels were seen in this short period of time shows that even short amounts of time in inclined sleep products impacts an infant's ability to move and breathe.

Our testing was conducted on infants who were awake and not recently sleeping. This of course differs from the conditions reported to the CPSC where most infants were put into the inclined sleep products for a nap or for overnight sleep, so those infants were likely sleepier than the infants in the current study. An infant who is not wide awake may have less focus and energy to expend compared to the wide-awake infants in this study. So, while the muscle use and motion may be similar, it is likely that infants who find themselves in a compromised position in an inclined sleep product during a nap or overnight sleep may not have enough energy or alertness to achieve self-correction and may succumb to suffocation earlier or more easily than infants who are fully awake.

4.6 Summary of Biomechanical Analysis

An *in vivo* biomechanical study utilizing motion capture and EMG to evaluate the impact of an inclined crib mattress and inclined sleep products on an infant's ability to move and use their muscles to achieve movement was conducted.

Table 8 summarizes the main findings of the biomechanical study on incline angle of a crib mattress. During prone positioning, an increase in crib mattress incline angle resulted in a decrease in neck and back muscle activity and an increase in abdominal and triceps muscle activity, completely altering the normal muscle synergies that babies use to achieve a prone position when compared to the flat surface. Fewer changes were observed during supine positioning, with the most significant difference being an increase in head motion without the corresponding increase in muscle activity, indicating that the incline makes it easier for babies to lift and move their heads.

Table 8. Summary of EMG and Kinematic Results for Inclined Crib Mattress . Wide orange arrows indicate $p < 0.05$ and narrow blue arrows indicate $p < 0.10$.

During prone position			
Parameters	0° vs. 10°	10° vs. 20°	0° vs. 20°
Erector spinae	-	↓	↓
Cervical paraspinals	-	-	↓
Abdominals	↑	↑	↑
Triceps	-	-	↑
Neck ROM	-	-	-
Trunk ROM	-	-	-
# of neck peaks	-	↑	-
# of trunk peaks	-	-	-
During Supine position			
Erector spinae	-	↑	-
Cervical paraspinals	-	-	-
Abdominals	-	-	-
Neck ROM	-	-	↑
Trunk ROM	-	-	-
# of neck peaks	-	↑	↑
# of trunk peaks	-	-	-

Table 9 summarizes the main findings of the biomechanical study of the inclined sleep products. In general, babies moved their trunks more and more often while positioned prone in products with little or no hard plastic support surface. They also required more abdominal effort and less erector spinae effort to maintain a prone position. During supine lying, products with a hard or semi-rigid plastic support surface decreased trunk motion, and erector spinae muscle activity was significantly lower for products with heavy padding.

Table 9. Summary of EMG and kinematic parameters of each inclined sleep product when compared to 0° surface (baseline). Wide orange arrows indicate $p < 0.05$ and narrow blue arrows indicate $p < 0.10$.

During prone position							
Parameters	S01	S02	S03	S06	S08	S11	S13
Erector spinae	↓	↓	↓	-	↓	↓	-
Cervical paraspinals	-	-	-	-	-	-	-
Abdominals	-	↑	↑	↑	↑	-	-
Triceps	-	-	-	-	-	-	-
Neck ROM	-	-	↑	-	-	-	-
Trunk ROM	-	-	↑	↑	↑	-	-
# of neck peaks	-	-	-	↑	↑	↑	↑
# of trunk peaks	-	-	↑	↑	↑	↑	↑
During supine position							
Erector spinae	-	↓	-	↓	-	-	-
Cervical paraspinals	-	-	-	-	-	-	-
Abdominals	-	-	-	-	-	-	-
Neck ROM	-	-	-	-	-	-	-
Trunk ROM	↓	↓	-	-	-	-	-
# of neck peaks	-	-	-	-	-	-	-
# of trunk peaks	-	↓	-	↓	-	↓	↓

The key findings of the biomechanics study are:

1. Inclined surfaces and inclined sleep products resulted in significantly higher muscle activity of the trunk core muscle (abdominals), which may lead to quicker fatigue and suffocation if an infant finds themselves prone in an inclined sleep product.
2. Muscle synergies (i.e how muscles work together) are significantly different in inclined sleep products. If an infant rolls from supine to prone in an inclined sleep product, it is likely the first time the baby has experienced the position of lying prone within an inclined sleep product and the demands the position requires of the muscles.
3. Some inclined sleep products require greater neck and trunk adjustments during prone positioning, indicating that infants may struggle to adjust their posture to enable breathing and attempt to self-correct if a roll from supine to prone occurs.
4. Prone lying in the inclined sleep product puts infants at higher risk of suffocation as evidenced by oxygen saturation results.
5. Some evidence was found that supports the idea that the inclined sleep products allow the babies to roll more easily from supine to prone. The flexed trunk and ease of head lifting during supine lying in an inclined sleep product may indicate that supine to prone rolling is achieved more easily.
6. If babies roll from supine to prone in an inclined sleep product, then, due to the high musculoskeletal demands necessary to maintain safe posture to prevent suffocation, babies would fatigue faster than they would on a stable, flat surface.

5. SUMMARY OF FINDINGS

5.1 Overall Results

The overall goal of this study was to inform the CPSC on whether the designs of Inclined Sleep Products impact an infant's ability to move within the products, and whether those designs directly impact safety or present a risk factor contributing to suffocation of an infant.

To meet this goal, the following studies were conducted:

1. An analysis of the incident reports related to Inclined Sleep Products to qualitatively assess trends, similarities, or differences in the incidents that may inform product safety.
2. A thorough product analysis of various Inclined Sleep Products within the product class to identify differences in design.
3. A non-invasive *in vivo* biomechanics study of infants 2-6 months of age to determine:
 - (a) the strength and space requirements for infants to move their heads and/or roll from the supine to the prone position in Inclined Sleep Products compared to a Flat Sleep Product,
 - (b) the strength and space requirements for infants to lift their heads and/or roll from the prone to the supine position in Inclined Sleep Products compared to a Flat Sleep Product.

Based on the results of the biomechanical testing, product analysis, and incident report analysis, **none of the Inclined Sleep Products that were tested and evaluated as a part of this study are safe for infant sleep.**

Ninety-one incidents (death, injury, hazard) were reported in inclined sleep products between 2010 and 2019. The majority of the incidents with adequate information supplied in the reports to analyze the events were supine-supine (53%) or supine-prone (35%) events. The supine-supine incidents occurred in younger infants (average 3.2 months), while supine-prone incidents occurred in older infants (average 4.2 months). Many supine-supine deaths occurred in infants who were currently sick, chronically ill, or born premature. Because these infants have higher mortality rates compared to healthy babies, for most incidents, it cannot be confirmed if the event was related to the condition or the product design. However, many reports indicate the infant was found with his/her face contacting the side of the inclined sleep product and that mucus or blood was found on the infant's face, suggesting suffocation was the cause of death. In combination with the product analysis which showed the sides were made of heavy padding or a combination of padding and plastic, it is likely that suffocation in the side of the product contributed to the deaths or injuries of these infants. Future work should consider the materials used on the product sides to reduce the risk of carbon dioxide rebreathing.

The current warning on inclined sleep products suggests that parents should stop using the product once the infant can roll, but the results of this study suggest that the first observed infant roll can occur in the product and can result in a fatal suffocation event evidenced by data within the incident reports. Further supporting that idea are results from the biomechanical analysis. During supine lying within an inclined sleep product, babies moved their trunks less and exhibited less erector spinae muscle activity, likely due to a combination of conformity of the products and the lack of rigidity as quantified in the product analysis. During supine lying, babies' trunks are more flexed solely due to the product design. Coupled with the lack of a rigid surface to move against in many of the inclined sleep products, babies are exposed to a much different environment than a crib mattress or even a crib mattress on a similar incline. The flexed trunk position in combination with flexed hips due to the design of the seat portion of the inclined sleep products puts babies closer to the fetal tuck position that is often used to achieve a supine to prone roll when compared to a flat or inclined crib mattress. This is further supported because the

average age of infants who experienced supine-prone events analyzed in the incident reports was slightly less than the average age of rolling, suggesting that babies who died or were injured in inclined sleep products may have been able to roll more easily in the inclined sleep products than on a flat rigid surface. It is likely a combination of all of these factors that allow babies to roll supine to prone in inclined sleep products, despite the narrow width of the products that may otherwise prohibit rolling.

In the prone position within an inclined sleep product (whether from a roll from supine to prone or from being initially placed prone), infants are required to use their muscles differently and move their body in unusual and unfamiliar ways simply to maintain the prone posture and lift their heads to breathe. In particular, the demands of the core muscles are likely some of the highest that they have ever been exposed to, resulting in increased fatigue rates as the infant tries to self-correct. It is likely that in incidents where babies were found deceased in the prone position, that a roll occurred, and after some amount of struggling, the baby was fatigued and could no longer move into a position to prevent suffocation. This is further supported by the product analysis, which showed inclined sleep products have more deformation with force application compared to a crib mattress, resulting in a pliant surface that distributes force differently than a rigid surface. Therefore, when infants attempt to self-correct in inclined sleep products, their movements are less effective compared to a more rigid surface. Additionally, the oxygen saturation events from the biomechanics analysis indicated that infants in this study experienced <95% SpO₂ twice as often when lying prone in inclined sleep products compared to lying prone on a crib mattress. The combination of incline angle, rigidity of the surface, curvature of the surface, and material selection of a plastic surface with padding all contribute to an increased risk of suffocation if infants are positioned prone in an inclined sleep product. The unfamiliar movement requirements coupled with a product design that does not allow for the same force distribution of a flat crib mattress results in a situation in which infants may be unable to self-correct.

While there were differences in the product designs and the biomechanical results of infants within the products, no product that was examined in this study was found to be safe for infant sleep. **All products in the class of Inclined Sleep Products that were tested and evaluated in this study are unsafe for infants.** If this product class remains, ASTM F3118-17a should be rewritten and implemented as a mandatory standard to mitigate hazards posed by and prevent future incidents with Inclined Sleep Products.

5.2 Future Considerations

1. Future analysis should seek to understand if 15 degrees is a suitable angle for an inclined sleeping surface, or if movement and muscle activity are significantly different at this angle compared to a flat surface. The research team recommended testing 10 more infants in a biomechanical study at various inclined angles (0, 5, 10, 15, 20) to more specifically identify a safe incline angle for infant sleep.
2. CO₂ rebreathing, or breathability of the products, should be quantitatively assessed. The project team recommends utilizing the model by Maltese et al. (2019) (Figure 27) to understand how material selection and product design may impact CO₂ rebreathing, and the likelihood of suffocation. As noted in several of the supine-supine incidents, suffocation appeared to have occurred without significant movement within the product. This may be attributed partly to product design. In the same way that infants are not recommended to stay in a car seat for extended amounts of time, a breathability study may further quantify the time that is safe for babies to remain in an inclined sleep product.

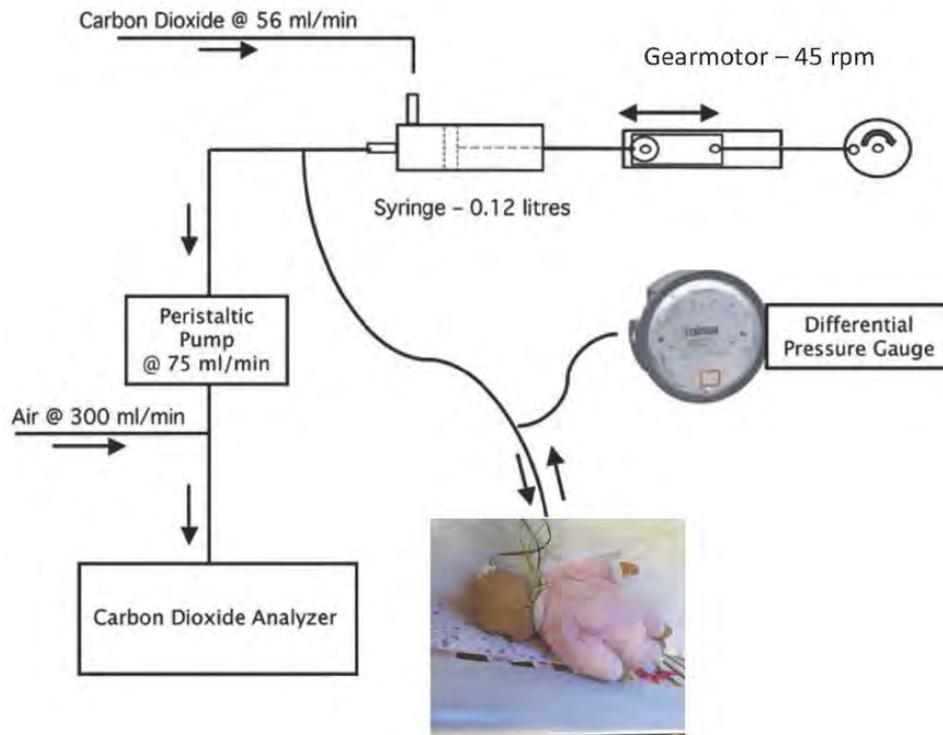


Figure 31. Infant CO₂ rebreathing setup used by Maltese and Leshner (Maltese et al., 2019)

3. A similar study should be conducted to evaluate the safety of seated products for infants by understanding how babies use their muscles to move within the confines of other common infant products.

6. ASTM RECOMMENDATIONS

With the findings of the biomechanical study, the product analysis, and the incident report analysis, the team reviewed, analyzed, and interpreted the safety and design of specific Inclined Sleep Products. The project team examined other Inclined Sleep Products per the CPSC's requests to determine whether the design specifications in ASTM F3118-17a are appropriate to prevent accidental deaths. **The team believes that no inclined sleep products that were examined as a part of this study are currently safe for infant sleep. The product category should be completely eliminated, or the ASTM standard significantly modified to ensure a safe environment and mitigate risk.**

When analyzing specific design considerations, particular attention was paid to the following: seatback incline angle, surface guidelines, minimum side barrier height and material, and maximum width. Specifically, the following are addressed: (a) the safety or hazard presented by a 30-degree incline, (b) the characteristics of Inclined Sleep Products that may diminish respiration and ways to minimize the hazard, and (c) recommendations to improve the ASTM standard to minimize injuries and deaths in Inclined Sleep Products.

6.1 Incline Angle

30-Degree Incline Does Not Allow for a Lying Posture

Based on the results of the biomechanical study, it was revealed that a 30-degree angle should not be considered a lying position for an infant. Infants could not maintain a lying posture at the 30-degree crib mattress incline and began to slide off the mattress. For this reason, 30-degrees is too steep of an incline for a lying or sleeping product.

20-Degree Incline Puts Infants at Risk for Muscle Fatigue

Based on the results of the biomechanical study, the 20-degree mattress incline resulted in significantly different muscle activity for the infants compared to the zero-degree incline surface. The increased demand on the abdominal muscles could lead to increased fatigue and suffocation if an infant is unable to reposition themselves after a roll from supine to prone occurs.

10-Degree Incline May Not Significantly Impact Infant Motion or Muscle Activity

Based on the results of the biomechanical study, fewer differences in muscle activity or lying posture were revealed at a 10-degree mattress incline compared to the zero-incline surface. 10 degrees is likely a safe incline for sleep on a crib mattress type of surface.

Inclines Between 10- and 20-Degrees Should Be More Thoroughly Studied

The experimental design of this study did not examine the angles between 10- and 20-degrees, so future work should focus on understanding which, if any, angles between 10- and 20-degrees may be safe for infant sleep.

Recommendation: An incline angle of 10-degrees is likely safe for an infant Inclined Sleep Product, and an incline of 20-degrees or greater is not safe. In order to determine if angles between 10- and 20-degrees are safe, additional biomechanical testing is required.

6.2 Surface

Lying Surface Rigidity should be Standardized

The results of the biomechanical testing revealed that infants moved differently when lying prone in Inclined Sleep Products compared to an inclined crib mattress. This difference is likely due in part to the lack of surface rigidity of the Inclined Sleep Products. The product analysis revealed

varying designs for the lying surface (hard plastic, malleable plastic, or no plastic with little to heavy padding). Regardless of the rigidity of the underlying plastic surface, the added padding of many of the Inclined Sleep Products resulted in a highly compliant surface, which could result in the inability of infants who have rolled to self-correct as they are unable to apply the force required to lift their head to breathe or perform a roll. It is also important to recognize that the biomechanical testing in this study was done with awake and alert infants; it is likely that infants who are recently aroused from a deep sleep may not have the same amount of effort to expend as fully awake infants, further decreasing the likelihood of self-correction if a roll occurs. For these reasons, specific recommendations for the surface rigidity of the Inclined Sleep Product need to be formulated. In the worst-case scenario, when infants are unable to self-correct after a roll and are lying prone on the product, the maximum allowable deformation of the Inclined Sleep Product surface should not exceed one-half of the infant's head radius. According to the WHO Child Growth Standard (WHO, 2006), a 5th percentile newborn's weight and head circumference are 2.6 kg and 32.2 cm respectively (male and female values averaged). Considering that an infant's head is 25% of the total body weight, the head weight of the 5th percentile newborn is 0.64 kg. From the head circumference measurement, one-half of the head radius of the 5th percentile newborn is 2.6 cm. The maximum allowable deformation on the Inclined Sleep Product surface should be 2.6 cm (1 inch) when a 0.64 kg (1.4 lb.) weight (i.e. a 6.25 N load) is placed on the surface. In order to obtain more robust parameters for the ASTM standard, future work on product surface deformation analyses are recommended.

Lying Surface Shape should be Flat

Product analysis of some of the Inclined Sleep Products revealed that the sleeping surface is either not flat or not flat with added weight. Concave curvature either in the back or the seat portion of the product increases the suffocation risk for babies who have experienced a roll, as the surface envelopes their face, increasing the risk for rebreathing and suffocation if self-correction is not achieved. Therefore, the surface of the Inclined Sleep Product should be flat with no curvature to the surface either with or without added doll weight. It would be beneficial to adapt a flatness test in the Inclined Sleep Products ASTM standard similar to the flatness test currently in the Bassinets and Cradles standard (F2194-16e1; Section 6.7).

Surface Material should be Standardized

The incident report analysis revealed that many of the infant deaths occurred in products with heavy plush padding on the surface of the products (S02 and S06). There were also differences in material of the sides of the products, varying from heavy plush to lightweight mesh. The surface of the Inclined Sleep Products should meet the standard used for Crib Mattresses (ASTM F2933-19). Therefore, recommendations for the surface material of the Inclined Sleep Products need to be formulated. In that regard, carbon dioxide rebreathing analyses are recommended to inform material recommendations for the sides of the Inclined Sleep Products. (Paluszynska et al., 2004; Carleton et al, 1998)

Surface Width should Prevent Supine to Prone Rolling

If all other recommendations regarding the surface are implemented, the concern of suffocation due to a roll from supine to prone will be significantly minimized. However, if the goal is for supine to prone rolling to be completely prevented, the product width should be minimized based on preliminary data from a flat crib mattress rolling.

Recommendation: The surface of the Inclined Sleep Product should have a minimum rigidity, should exhibit no curvature, and should meet material recommendations to minimize rebreathing. If roll prevention is still a concern, the maximum product width should minimize the distance from the lateral knee to the side of the product during supine lying.

6.3 Sides

Material and Height Minimum of the Sides should be Further Studied

Our study did not quantitatively evaluate safety of materials used for the sides of the Inclined Sleep Products. However, the products evaluated exhibited vastly different side materials. While a breathable side material is necessary, future work should focus specifically on carbon dioxide rebreathing of various materials or material combinations to quantify the level of breathability required for safety. This study also did not provide data to guide the heights of the sides of the product to avoid falling, so future work is required to define the minimum safe height.

Recommendation: Additional research should be done to understand the minimum height of the sides of the Inclined Sleep Product. Additional research is required to clearly define the threshold of carbon dioxide rebreathing to inform safe product design.

6.4 Warnings for Use

Caregivers of Infants Who are Sick, Chronically Ill, or were Born Prematurely Should Exercise Additional Caution when Using Inclined Sleep Products

The incident report analysis revealed that several of the supine-supine deaths occurred with infants who had chronic conditions, were experiencing sickness, or were born premature. Because these are risk factors for increased rates of infant mortality, it cannot be confirmed if the inclined sleep product contributed to the incidents for these vulnerable infants. One likely explanation for these incidents is that babies who already had a risk factor for increased mortality experienced suffocation in the sides of the products as many of their faces were found in contact or close contact with the product. A safe sleeping product may be even more important for infants who have previous risk factors for infant mortality. Additional research should be made into crafting and implementing warnings for inclined sleep products and other products regarding infants with sickness, chronic illness, or prematurity.

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Appendix A: STUDY TEAM

Principal Investigator:

Dr. Erin Mannen has a Ph.D. in mechanical engineering from the University of Kansas and specializes in biomechanics with over ten years of research experience in the field. As Principal Investigator, she was responsible for oversight of the entire project. Dr. Mannen led the design of the biomechanics experiment, oversaw data collections, managed data analysis, interpreted results, prepared reports, conducted meetings, ensured data quality, and managed all aspects of the project. Dr. Mannen has also served as Principal Investigator on similar projects studying biomechanics of infants in various infant products.

Co-Investigators:

Dr. John Carroll is a medical doctor specializing in pediatric pulmonology. He is a graduate of the University of Texas Southwestern Medical School, completed Pediatrics residency at the State University of New York, Upstate Medical Center, and completed Pediatric Pulmonology fellowship at the University of Arizona and McGill University. Dr. Carroll is board certified in Pediatrics and Pediatric Pulmonology and is currently an investigator on several NIH-supported projects. As a Clinical Co-Investigator, Dr. Carroll provided clinical guidance on experimental design and data interpretation, focusing on the respiratory aspects of the project. He provided analysis on the supine-supine incidents to help determine if external factors may have caused the events. Dr. Carroll has extensive experience in pediatric pulmonary clinical research.

Dr. David Bumpass is a board-certified orthopaedic surgeon specializing in pediatric spine. He is a graduate of the University of Virginia School of Medicine and completed his orthopaedic and spine surgery training at Washington University in St. Louis. He specializes in complex pediatric spinal deformity surgery. As a Clinical Co-Investigator, Dr. Bumpass provided clinical insight into experimental design and data interpretation, focusing on understanding an infant's ability to move based on typical motor development milestones. Dr. Bumpass's familiarity with biomechanics research allowed him to help interpret the results of the biomechanical studies from a clinical perspective.

Dr. Brien Rabenhorst is a board-certified pediatric orthopaedic surgeon specializing in pediatric hip development. He is a graduate of Louisiana State University School of Medicine. He completed an orthopaedic residency at Texas Tech Health Science Center, and a pediatric orthopaedic fellowship at the Children's Hospital of Colorado. As a Clinical Co-Investigator, Dr. Rabenhorst contributed to the experimental design and data interpretation, focusing on the strength and coordination required of infants to move from compromised positions. Dr. Rabenhorst's familiarity with biomechanics research allowed him to help interpret the results of the biomechanical studies from a clinical perspective.

Dr. Brandi Whitaker is a psychologist working extensively over the past seven in the areas of psychological assessment and treatment of infants and young children. She earned her Ph.D. in the Psychology from Washington State University and completed a Post-Doctoral Fellowship in Pediatric Psychology. As a Co-Investigator, Dr. Whitaker provided guidance on proper selection of a developmental measure for the subjects. She led the effort in analyzing and interpreting the developmental data and offered interpretation of the results from a developmental perspective.

Dr. Junsig Wang is a postdoctoral fellow specializing in infant biomechanics. He earned his Ph.D. in Kinesiology from Iowa State University where he specialized in biomechanical research involving human motion data collection and analysis and completed further training as a

postdoctoral fellow in the Department of Orthopaedics at the University of Arizona. Dr. Wang carried out the experimental testing, data analysis, data processing, quality control, and report preparation.

Dr. Safeer Siddicky is a postdoctoral fellow specializing in infant biomechanics. He earned his Ph.D. in Engineering and Biomedical Informatics from the University of Missouri-Kansas City, where he specialized in biomechanical research involving human motion data collection and analysis. Dr. Siddicky provided technical support through IRB adherence, data collections, data processing, data analysis, and assisted with report preparation and data quality control.

Organizational Structure:

The multi-disciplinary project team consists of investigators with doctoral degrees in mechanical engineering and kinesiology specializing in biomechanics and psychology specializing in pediatrics, and medical doctors in the fields of pediatric pulmonology and pediatric orthopaedics. This team had the technical ability to carefully design and execute the work and interpreted the results from both an engineering and a medical viewpoint.

Dr. Mannen met with the CPSC regularly (every 2-4 weeks) to give updates on the progress of the project. The entire team met as needed throughout the project timeframe to meet goals and discuss outcomes.

Appendix B: FACILITIES AND EQUIPMENT

Laboratory: The HipKnee Arkansas motion laboratory at which testing will take place is equipped with state-of-the art validated experimental equipment costing over \$250,000. Service contracts are in place to ensure all equipment is calibrated and functional.

Environment: UAMS is a research and teaching institution, fostering this collaborative team of engineers, researchers, and clinicians in a variety of specialties. As faculty, both research and clinical, we are encouraged and expected to participate in translational, meaningful projects. We are supported by a team of professionals in the UAMS Office of Research and Sponsored Programs to aid in the administrative requirements of a government contract.

IT: UAMS has a team of professionals to handle all technical issues that may arise relating to internet connectivity, computers, telephones, video-conferencing, email, and HIPAA-secured cloud storage space.

Office Space: The PI and Co-Investigators have their own computers and private offices. Members of the Project Support Team each has their own personal workspace and computer. There are private meeting rooms available to use as needed.

Appendix D: Incident Report Summary

Data is summarized from all 91 incidents investigated by the CPSC related to inclined sleep products occurring from 2010 to May 2019. Data is separated into incident types: *supine-supine*, *supine-prone*, *supine-other*, *prone-prone*, *other circumstances*, and *not enough information*. The tables include:

- [REDACTED]
- [REDACTED]
- Incident Date: date of the incident,
- Age (months): age of the infant at the time of the incident,
- Death/Injury/Hazard: type of incident,
- Restraint Use (Y/N/UNK): indicates if the buckle was used in the product prior to the incident [Y=yes; N=no; UNK=unknown],
- Healthy/Sick/Chronic/UNK: indicates if the state of health of the infant at the time of the incident [healthy, sick (includes colds, fevers, respiratory congestion), chronic (includes serious health issues such as sickle cell), UNK=unknown],
- Premature <37 weeks (Y/N/UNK): indicates if the infant was born prematurely (<37 weeks gestational age) [Y=yes; N=no; UNK=unknown].

Table D1: Supine-Supine Incidents (2011 to 2018)

	Incident Date	Age (months)	Death/Injury /Hazard	Restraint Use (Y/N/UNK)	Healthy/Sick/Chronic/UNK	Premature <37 weeks (Y/N/UNK)
	09/23/11	3.3	Death	N	Sick	Y
	10/01/11	2.0	Injury	UNK	UNK	UNK
	01/21/13	1.0	Injury	UNK	UNK	UNK
	10/19/13	2.5	Death	UNK	Sick	N
	10/14/14	4.0	Hazard	Y	UNK	UNK
	11/07/14	3.3	Death	N	Healthy	Y
	12/23/14	2.1	Death	Y	Healthy	UNK
	04/13/15	1.1	Death	UNK	Sick	N
	05/16/15	1.5	Death	Y	Healthy	N
	05/25/15	0.2	Injury	UNK	UNK	UNK
	09/23/15	4.2	Death	N	Sick	UNK
	09/24/15	3.7	Death	UNK	Healthy	UNK
	09/26/15	8.7	Death	UNK	UNK	UNK
	10/27/15	2.6	Death	N	Healthy	UNK
	04/21/16	0.2	Death	Y	Healthy	UNK
	09/09/16	4.0	Death	N	Sick	N
	09/11/16	2.3	Injury	Y	UNK	UNK
	12/08/16	5.0	Death	UNK	Sick	UNK
	01/05/17	4.8	Death	UNK	Sick	UNK
	05/05/17	0.5	Death	UNK	Sick	N
	06/11/17	10.1	Death	N	Chronic	UNK
	07/31/17	3.3	Death	Y	Chronic	N
	08/01/17	3.4	Death	UNK	Healthy	Y
	09/15/17	1.2	Death	UNK	Sick	UNK
	12/23/17	2.8	Death	UNK	Healthy	UNK
	01/12/18	6.1	Death	N	Healthy	UNK
	03/10/18	4.5	Death	Y	Healthy	N
	03/14/18	3.1	Death	UNK	Healthy	Y
	03/21/18	1.7	Death	N	Healthy	N
	04/01/18	0.3	Death	N	Healthy	N
	04/24/18	5.1	Death	N	Chronic	UNK
	07/08/18	5.1	Death	UNK	Healthy	N
	08/15/18	1.3	Death	UNK	Healthy	UNK
	09/21/18	3.0	Death	UNK	Chronic	N
	10/20/18	4.3	Death	Y	Healthy	N
	11/15/18	1.3	Death	UNK	Sick	Y
	12/04/18	2.7	Death	N	Healthy	N
	03/01/19	7.0	Death	N	Healthy	Y

Table D2: Supine-Prone Incidents (2010 to 2019)

Incident Date	Age (months)	Death/Injury /Hazard	Restraint Use (Y/N/UNK)	Healthy/Sick/ Chronic/UNK	Premature <37 weeks (Y/N/UNK)
11/08/10	3.2	Death	UNK	Healthy	UNK
06/03/13	2.8	Death	N	Healthy	N
06/19/14	8.7	Death	UNK	UNK	N
07/25/14	1.6	Injury	N	Healthy	UNK
02/22/15	6.8	Death	UNK	Sick	Y
08/10/15	4.0	Death	UNK	Healthy	UNK
09/23/15	3.0	Death	N	Healthy	N
12/14/15	3.0	Death	UNK	Healthy	UNK
07/16/16	3.3	Death	UNK	Healthy	UNK
09/16/16	3.0	Death	N	Healthy	N
11/26/16	4.0	Injury	UNK	UNK	UNK
12/04/16	1.0	Injury	Y	Healthy	UNK
04/17/17	2.9	Death	UNK	UNK	UNK
06/12/17	1.9	Death	UNK	Healthy	N
06/15/17	5.3	Death	N	Healthy	UNK
07/17/17	4.0	Injury	Y	UNK	UNK
09/03/17	4.8	Death	N	Healthy	UNK
12/22/17	5.4	Death	Y	Healthy	N
01/06/18	6.0	Death	UNK	Sick	UNK
01/11/18	4.1	Death	N	Healthy	N
04/10/18	4.8	Death	N	Healthy	N
04/25/18	5.9	Death	N	Healthy	UNK
12/13/18	6.9	Death	N	Sick	N
03/26/19	3.0	Death	UNK	Sick	UNK
05/02/19	5.4	Death	UNK	UNK	N

Table D3: Supine-Other Incidents (2011 to 2013)

Incident Date	Age (months)	Death/Injury /Hazard	Restraint Use (Y/N/UNK)	Healthy/Sick/C hronic/UNK	Premature <37 weeks (Y/N/UNK)
09/04/11	5.0	Hazard	Y	UNK	UNK
09/08/12	5.0	Injury	Y	UNK	UNK
04/19/13	12.0	Hazard	Y	UNK	UNK
06/17/13	6.0	Injury	UNK	UNK	UNK

Table D4: Prone-Prone Incidents (2013 to 2017)

Incident Date	Age (months)	Death/Injury /Hazard	Restraint Use (Y/N/UNK)	Healthy/Sick/C hronic/UNK	Premature <37 weeks (Y/N/UNK)
02/27/13	2.0	Death	N	Healthy	N
04/17/17	4.5	Death	UNK	Chronic	Y
07/03/17	0.3	Death	N	Sick	N

Table D5: Other Circumstances (2016 to 2018)

Incident Date	Age (months)	Death/Injury /Hazard	Restraint Use (Y/N/UNK)	Healthy/Sick/C hronic/UNK	Premature <37 weeks (Y/N/UNK)
08/26/16	2.2	Death	UNK	Healthy	UNK
03/16/18	3.0	Injury	Y	Healthy	N

Table D6: Not Enough Information (2014 to 2019)

[REDACTED]	Incident Date	Age (months)	Death/Injury /Hazard	Restraint Use (Y/N/UNK)	Healthy/Sick/Chronic/UNK	Premature <37 weeks (Y/N/UNK)
[REDACTED]	12/01/14	1.6	Injury	N	Healthy	UNK
[REDACTED]	12/16/14	7.6	Death	UNK	Healthy	UNK
[REDACTED]	01/25/15	4.2	Death	UNK	UNK	UNK
[REDACTED]	04/18/15	4.0	Injury	UNK	UNK	UNK
[REDACTED]	08/31/16	UNK	Death	UNK	UNK	UNK
[REDACTED]	10/17/16	1.0	Injury	UNK	UNK	UNK
[REDACTED]	11/19/16	1.7	Death	UNK	UNK	UNK
[REDACTED]	02/27/18	3.0	Death	UNK	UNK	UNK
[REDACTED]	04/18/18	UNK	Death	UNK	UNK	UNK
[REDACTED]	07/08/18	5.0	Death	UNK	UNK	UNK
[REDACTED]	09/28/18	2.8	Death	UNK	UNK	UNK
[REDACTED]	10/27/18	4.4	Death	UNK	UNK	UNK
[REDACTED]	01/02/19	2.3	Death	UNK	UNK	UNK
[REDACTED]	02/10/19	3.2	Death	UNK	UNK	UNK
[REDACTED]	02/20/19	3.1	Death	UNK	UNK	UNK
[REDACTED]	03/02/19	3.4	Death	UNK	UNK	UNK
[REDACTED]	03/21/19	1.2	Death	Y	Healthy	UNK
[REDACTED]	04/09/19	2.9	Death	UNK	UNK	UNK
[REDACTED]	05/13/19	UNK	Death	UNK	UNK	UNK

TAB C: Staff’s Review and Evaluation of ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, for Incorporation by Reference into Staff’s Draft Supplemental Notice of Proposed Rulemaking

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

Memorandum

Date: October 1, 2019

To: Celestine T. Kish
Infant Inclined Sleep Products Project Manager
Directorate for Engineering Sciences

Through: Mark Kumagai, Division Director
Division of Mechanical and Combustion Engineering
Directorate for Engineering Sciences

From: Kevin Lee, Mechanical Engineer
Division of Mechanical and Combustion Engineering
Directorate for Engineering Sciences

Subject: Staff's Review and Evaluation of ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, for Incorporation by Reference into Staff's Draft Supplemental Notice of Proposed Rulemaking

I. INTRODUCTION

In accordance with the Danny Keysar Child Product Safety Notification Act (section 104) of the Consumer Product Safety Improvement Act (CPSIA), this memorandum assesses the effectiveness of ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products* (ASTM F3118), and outlines staff's recommendation to propose to incorporate by reference this standard (ASTM F3118-17a)¹ into a mandatory rule for infant sleep products.

¹ Current edition approved on September 1, 2017, Published October 2017. This is the fourth revision to the standard originally published in May 2015.

II. PRODUCT DESCRIPTION

An infant inclined sleep product and a newborn inclined sleep product are defined in ASTM F3118-17a, Section 3 as:

3.1.3 *infant inclined sleep product, n*—a freestanding product, intended to provide a sleeping accommodations for an infant up to approximately 5 months of age, that is generally supported by a stationary or rocker base with one or more inclined sleep surface positions for the seat back that are greater than 10° and do not exceed 30° from the horizontal.

3.1.4 *newborn inclined sleep product, n*—a free standing product, intended to provide sleeping accommodations for a newborn up to approximately 3 months of age, that is supported by a stationary or rocker base with one or more inclined sleep surface positions for the seat back that are greater than 10° and do not exceed 30° from the horizontal and whose seat back length, measured from the bight, is not greater than 17 in. (432 mm).

Inclined sleep products can be categorized as frame-type, hammock, compact, and inclined sleep product accessory. The types of products within the scope of this standard are described, as follows:

Frame-Type Inclined Sleep Products

Frame-type inclined sleep products (Figure 1) are elevated, intended to be placed on the floor, and are self-supporting. Typically, this design uses a metal frame covered by a fabric insert that contains the occupant. Some frame-type products have a rigid plastic insert under the sleeping surface, and/or extra padding with head positioning cushions.

The base may be stationary or allow side-to-side/head-to-toe rocking. This type of product could have a fixed incline or be adjustable, but it must have at least one position between a 10° and a 30° angle. Frame-type products can be intended for use by newborns or infants, or both, depending on the size of the product.



Figure 1: Frame-Type Inclined Sleep Product

Hammocks



Support from Above



Side Support

Figure 2: Hammock Support

Hammocks are typically constructed of fabric and suspended from one or two points, either above or on either side (Figure 2). Hammock products are constructed of various materials and generally conform to the shape of the child when placed in the product. However, some hammock designs use a mat, mattress, or other type of pad to provide a semi-rigid sleeping surface that maintains the product's form (Figure 3). Hammocks are intended to be suspended and can be supported by a frame or other structure, such as a ceiling.



Figure 3: Semi-Rigid Sleep Surface

Compact Inclined Sleep Products

Compact inclined sleep products (Figure 4) are freestanding, with the bottom of the seat a maximum of 6 inches (152 mm) above the floor. These products tend to be constructed of foam, with a fixed seat back angle between 10° and 30°. These products are intended to be used on the floor.



Figure 4: Compact Inclined Sleep Product

Accessory Inclined Sleep Products

An accessory inclined sleep product is intended to provide sleeping accommodations for infants or newborns and are attached to, or supported in some way, by another product (Figure 5a). These products can be fixed or adjustable, but they must have at least one seat back position with an angle between 10° and 30°. An inclined sleep accessory is typically a rigid-frame product that has a stationary or fixed base and, in some cases, inclined sleep product accessories may be removed and used independently (Figure 5b).



Figure 5a: Play Yard with Inclined Sleep Accessory



Figure 5b: Incline Sleep Accessory Used Independently

III. ADEQUACY OF ASTM F3118-17a TO ADDRESS IDENTIFIED HAZARD PATTERNS

Biomechanical Study

During the development of this Supplemental NPR briefing package, staff received reports of 451 new incidents, 59 of which were deaths that occurred in an infant inclined sleep product. Commission staff contracted with Dr. Erin Mannen, Ph.D., a mechanical engineer with a biomechanics specialization, to conduct infant testing to evaluate the design of inclined sleep products. The study examined how 10 infants move and use their muscles on flat, inclined surfaces, and in selected inclined sleep products, and whether those designs directly impact safety or present a risk factor that could contribute to the suffocation of an infant. Testing

compared infants' muscle movement and oxygen saturation on a flat crib mattress at 0°, 10°, and 20° versus seven different inclined sleep products. Researchers recorded infant muscle activity using surface electromyography (EMG), and recorded oxygen saturation using a medical grade pulse oximeter. Researchers placed infants in a random order in each of the 10 testing conditions, in both the supine and prone positions, for at least 60 seconds (unless the oximeter data fell below 95%, in which case they were removed early to ensure safety).

Key findings state:

- “Inclined surfaces and incline sleep products resulted in significantly higher muscle activity of the turn core muscle (abdominals), which may lead to quicker fatigue and suffocation if an infant finds themselves prone in an incline sleep product.
- Muscle synergies (*i.e.*, how muscles work together) are significantly different in inclined sleep products. If an infant rolls from supine to prone in an inclined sleep product, it is likely the first time the baby has experienced the position and the demands the position requires of the muscles.
- Some inclined sleep products require greater neck and trunk adjustments during prone positioning, indicating that infants may struggle to adjust their posture to enable breathing and attempt to self-correct if a roll from supine to prone occurs.
- Prone lying in the incline sleep products puts infant at higher risk of suffocation as evidenced by oxygen saturation results.
- Some evidence was found that supports the idea that the inclined sleep products make the babies roll more easily from supine to prone. The flexed trunk and ease of head lifting during supine lying in an inclined sleep product may indicate that supine to prone rolling is achieved more easily.
- If babies roll from supine to prone in an inclined sleep product, then, due to the high musculoskeletal demands necessary to maintain safe posture to prevent suffocation, babies would fatigue faster than they would on a stable, flat surface.
- None of the inclined sleep products that were tested and evaluated as a part of this study are safe for infant sleep.”

Additionally, Dr. Mannen's study stated:

20-Degree Incline Puts Infants at Risk for Muscle Fatigue

Based on the results of the biomechanical study, the 20-degree incline resulted in significantly different muscle activity for the infants compared to the zero-degree incline surface. The increased demand on the abdominal muscles could lead to increased fatigue and suffocation if an infant is unable to reposition themselves after an accidental roll from supine to prone occurs.

10-Degree Incline Does Not Significantly Impact Infant Motion or Muscle Activity

Based on the results of the biomechanical study, fewer differences in muscle activity or lying posture were revealed at a 10-degree mattress incline compared to the zero-degree incline surface. Ten degrees is a safe incline for sleep on a crib mattress surface.

Inclines Between 10 and 20 Degrees Should Be More Thoroughly Studied

The experimental design of this study did not examine the angles between 10 and 20 degrees, so future work should focus on understanding which, if any, angles between 10 and 20 degrees may be safe for infant sleep.

Dr. Mannen states, “It is likely that in incidents where babies were found deceased in the prone position, that an accidental roll occurred, and after some amount of struggling, the baby was fatigued and could no longer move into a position to prevent suffocation.” Dr. Mannen concludes that an incline of 20 degrees or more puts an infant at risk compared to a 0-10 degree incline. Although her study did not test infants on inclines between 10-20 degrees, and thus did not offer conclusions for these angles, CPSC staff does not believe additional testing on inclines between 10-20 degrees is necessary because we conclude that a flat surface that does not exceed 10 degrees offers the safest sleep environment for infants. This conclusion comports with our recommendation to remove “inclined” from the standard and to require that all sleep products not otherwise specified as cribs (full-size or non-full-size), play yards, or bedside sleepers meet the requirements in 16 CFR 1218 Safety Standard for Bassinets and Cradles, which, among other requirements, mandates that the seat back surface angle intended for sleep be 10 degrees or less.

Based on these findings, staff determined that ASTM F3118-17a is not adequate because the standard allows for products with a seat back angle greater than 10 degrees. Staff recommends more stringent requirements in the standard to further reduce the risk of injury associated with these products. Staff recommends that the Commission incorporate by reference ASTM F3118-17a with modifications to address the potential hazards of an infant sleeping on an inclined surface.

Staff’s Recommended Modification to ASTM F3118-17a

The following are staff’s recommended modifications to ASTM F3118-17a with the double underlined text being additions and the text with strikethroughs being deletions:

Modification to the Introduction

Delete the text: ~~This consumer safety specification is intended to cover normal use and reasonably foreseeable misuse or abuse of inclined sleep products. This specification does not cover inclined sleep products that are blatantly misused or used in a careless manner that disregards the safety instructions and warnings provided with each inclined sleep product~~

Add the following text: The purpose of the standard is to address infant sleep products not already covered by traditional sleep product standards and to prevent deaths due to the use of Infant Sleep Products with a seat back angle greater than 10° from the horizontal.

Modifications to the Scope (section 1)

Delete the term ~~inclined~~ sleep products and change to infant sleep products.

Add the following text to section 1.3:

1.3 This consumer safety performance specification covers products that are not covered by other ASTM standards such as:

- ASTM F1169 Standard Consumer Safety Specification for Full-Size Baby Cribs
- ASTM F406 Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards
- ASTM F2194 Standard Consumer Safety Specification for Bassinets and Cradles
- ASTM F2906 Standard Consumer Safety Specification for Bedside Sleepers

Delete the following ~~text~~ from section 1.3

~~For example, an inclined sleep product that can have the recline angle adjusted below 10° shall also comply with the applicable requirements of Consumer Safety Specification F2194.~~

Modifications to Reference Documents (section 2)

Delete all references and FIG. 1-2 except F2194 Consumer Safety Specification for Bassinets and Cradles.

Add the following references:

F1169 Standard Consumer Safety Specification for Full-Size Baby Cribs
F406 Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards
F2906 Standard Consumer Safety Specification for Bedside Sleepers
16 CFR 1219 - Safety Standard for Full-Size Baby Cribs
16 CFR 1220 - Safety Standard for Non-Full-Size Baby Cribs
16 CFR 1221 - Safety Standard for Play Yards
16 CFR 1222 - Safety Standard for Bedside Sleepers
16 CFR 1218 - Safety Standard for Bassinets and Cradles

Modifications to Terminology (section 3)

For all items identified with the name “inclined sleep product,” delete the term *inclined sleep product* and replace it with *sleep product*.

Delete sections ~~3.1.3 – 3.1.6~~

Modify ~~3.1.7~~ and ~~3.1.10~~ to:

~~3.1.7.1.3~~ infant *inclined sleep product*, n—a freestanding product...supported by a stationary or rocker base and that is not subject to any of the following standards: ~~with one or~~

~~more inclined sleep surface positions for the seat back that are greater than 10° and do not exceed 30° from the horizontal.~~

- 16 CFR 1219 – Safety Standard for Full-Size Baby Cribs
- 16 CFR 1220 and 1221 – Safety Standard for Non-Full-Size Baby Cribs and Play Yards
- 16 CFR 1222 – Safety Standard for Bedside Sleepers
- 16 CFR 1218 – Safety Standard for Bassinets and Cradles

~~3.1.103.1.4 newborn *inclined sleep product, n*—a freestanding product...supported by a stationary or rocker base with one or more inclined sleep surface positions for the seat back that are greater than 10° and do not exceed 30° from the horizontal and whose seat back length, measured from the bight, is not greater than 17 in. (432 mm) and that is not subject to any of the following standards:~~

- 16 CFR 1219 – Safety Standard for Full-Size Baby Cribs
- 16 CFR 1220 and 1221 – Safety Standard for Non-Full-Size Baby Cribs and Play Yards
- 16 CFR 1222 – Safety Standard for Bedside Sleepers
- 16 CFR 1218 – Safety Standard for Bassinets and Cradles

Delete sections ~~3.1.7.1, 3., 3.1.8 – 3.1.9, 3.1.11- 3.1.13~~

Renumber ~~3.1.14-seat bight line...~~ to 3.1.5 and FIG. ~~3~~ to FIG. 1.

Modifications to General Requirements (section 5) – Delete this section and figure 4.

Modifications to Performance Requirements (section 6)

Delete section ~~6.1 – 6.8 and 6.10 – 6.14~~ and FIG. ~~5~~

Modify section 6.9, 6.9.1 and 6.9.2 to:

~~6.9.1~~ 6.9.1 *Maximum Seat Back Angle Incline:*

~~6.9.1 5.1.1 Accessory, Compact, and Infant Inclined Sleep Product and Infant Inclined Sleep Product Accessory~~—The angle of the seat back surface intended for sleep along the occupants head to toe axis relative to the horizontal shall not exceed ~~30~~10° when tested in accordance with ~~7.11.2~~ 6.1.2.

~~6.9.2 5.1.2 Accessory, Compact, and Newborn Inclined Sleep Product and Newborn Inclined Sleep Product Accessory~~—The angle of the seat back surface intended for sleep along the occupants head to toe axis relative to the horizontal shall not exceed ~~30~~10° when tested in accordance with ~~7.11.3~~ 6.1.3.

Add the following new requirement:

5.2 Accessory, Compact, Infant Sleep Products, and Newborn Sleep Products - shall meet requirements of 16 CFR 1218 Safety Standard for Bassinets and Cradles.

Modifications to Test Methods (section 7)

Delete section ~~7.1 - 7.10~~ and FIG. ~~7-10~~.

Delete the term *Incline* and *Inclined* from the text

Renumber section ~~7.11 – 7.11.3.2~~ to 6.1 – 6.1.3.2

Modify section ~~7.11.2~~ and ~~7.11.3~~ (renumbered to 6.1.2 and 6.1.3) to include *Accessory, Compact, Infant Sleep Products, and Newborn Sleep Products*

Modify section 7.11.2 to:

~~7.11.2.1~~6.1.2.1 If applicable, place the product in the manufacturer’s recommended highest ~~incline~~ seat back angle position intended for sleep.

Delete sections ~~7.12 - 7.15~~, ~~8 - 9~~ and associated FIG. ~~12- 16~~

APPENDIX - delete this section.

Electrical Hazard.

Staff determined that 127 of the 451 new incidents are related to electrical issues. The electrical-related issues included battery leakage, electric shock, and overheating of components. Some inclined sleep products have accessories that provide music, rocking motion, or vibration, which are either battery or a/c powered, however, F3118-17a does not include any performance requirements for electrical components. Other juvenile products that have similar features include performance requirements that could apply for infant sleep products. CPSC staff has raised this issue with and is working with the ASTM Ad Hoc task group to develop performance requirements to address electrical hazards across juvenile products. Performance requirements will apply to other children’s product standards such as bouncers, swings, and bassinets. Because these requirements are currently being developed, CPSC staff recommends not proposing electrical requirements in this SNPR, but to continue working with applicable ASTM subcommittees to develop electrical requirements for all applicable durable infant or toddler products with electrical components.

IV. RECOMMENDATIONS

Staff recommends that the Commission publish the draft supplemental NPR that incorporates by reference the requirements contained in ASTM F3118-17a with modifications. These modifications include:

1. Modify the introduction and scope of the standard to state the purpose of the standard is to address infant sleep products not already covered by traditional sleep product standards.
2. Modify the definition of accessory, compact, infant sleep products, and newborn sleep products to remove the term “inclined.”
3. Modify seat back angle so the maximum allowable seat back angle must be equal to or less than 10° in all sleep recommended positions.
4. Add new requirement – accessory, compact, infant sleep products, and newborn sleep products must meet 16 CFR 1218 Safety Standard for Bassinets and Cradles.
5. Remove all the performance requirements except for the above new or modified requirements.

6. Remove all test methods except for maximum seat back angle.

Based on the incident reports and Dr. Mannen's study, staff concludes this draft Supplemental NPR will address incidents and reduce the number of injuries and deaths from infant sleep products. Staff's recommendation would establish more stringent requirements than ASTM F3118-17a. The suggested requirements would further reduce the risk of injury associated with infant sleep products.

**TAB D: Human Factors Assessment of ASTM 3118-17a
Requirements for Infant Sleep Products (CPSIA Section
104)**

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

Memorandum

DATE: October 1, 2019

TO: Celestine T. Kish, Project Manager, Infant Inclined Sleep Products Rulemaking,
Division of Human Factors, Directorate for Engineering Sciences

THROUGH: Rana Balci-Sinha, Ph.D., Division Director
Division of Human Factors
Directorate for Engineering Sciences

FROM: Zachary Foster, Industrial Engineer,
Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Human Factors Assessment of ASTM F3118-17a Requirements for Infant Sleep Products (CPSIA Section 104)

BACKGROUND

The ASTM International (ASTM) voluntary standard ASTM F3118, *Standard Consumer Safety Specification Infant Inclined Sleep Products*, establishes requirements for infant inclined sleep products (referred to here as inclined sleep products) in the United States, and is intended to minimize the hazards associated with the reasonably foreseeable use and misuse, or abuse, of these products. ASTM developed this voluntary standard in response to incident data supplied by staff of the U.S. Consumer Product Safety Commission (CPSC). The current published version of the voluntary standard is ASTM F3118-17a.

Staff recommends that infant sleep products have a maximum seat back angle of 10 degrees and that infant sleep products be required to meet 16 CFR 1218 Safety Standard for Bassinets and Cradles. According to 16 CFR 1218, bassinets and cradles must comply with ASTM F2194, *Standard Consumer Safety Specification for Bassinets and Cradles*.

Both ASTM F3117-17a and F2194-16e1 standards specify marking and labeling requirements, which include warning statements that must appear on each infant sleep product. Both standards also specify the instructional literature that must be provided with each product. This memorandum, prepared by staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF), assesses the adequacy of these sections of both voluntary standards in addressing the risk of injuries and deaths associated with the use of infant sleep products.

DISCUSSION

ASTM F3118-17a WARNING AND INSTRUCTIONAL REQUIREMENTS

Section 8, Marking and Labeling of ASTM F3118-17a specifies labeling and warning requirements for inclined sleep products. In short, all inclined sleep products must include warnings on the product about the risk of fall and suffocation hazards. Due to the wide variety of inclined sleep products currently allowable by F3118, the voluntary standard provides eight warning labels for manufacturers to use based on their product(s) design.

On-product warning labels that meet the requirements in the F3118-17a (see Figure 1) address numerous warning format issues related to capturing consumer attention, improving readability, and increasing hazard perception and avoidance behavior. Additionally, HF staff believes that the warning informs consumers of the fall and suffocation hazards, consequences of the hazards, and instructions on how to reduce the risks of injury and death due to falls and suffocation.



Figure 1: Sample label per F3118-17a

Section 9, Instructional Literature of ASTM F3118-17a specifies that instructions that are easy to read and understand must be provided with the product. The on-product warnings are also required in the instructions. Additionally, a warning that addresses the strangulation hazard from strings is required in the instructions.

FOCUS GROUP OF CAREGIVERS PERCEPTIONS AND REACTIONS TO SAFE SLEEP

In focus groups conducted by Fors Marsh Group on caregivers' perceptions and reactions to safety messaging¹, nearly all of the participants reported that they were aware of the warning label presented as part of the activity (Figure 2). Additionally, participants reported that the label looked similar and contained comparable information to labels that they would find on products that they had purchased. Some participants reported that they tended to gloss over warning labels, as they believe the language to be the same on every label. Regarding the purpose of warning labels, some participants reported that they thought the main message was to be careful and keep an eye on their infant, while a few participants believed that warning labels were used as a means for manufacturers to protect themselves from liability or litigation. Participants' recommendations to improve warning labels included making the labels more concise and making the labels "stand out."



Figure 2: Warning label shown in focus group activity

The findings of the focus group indicate a shared perception among participants that warning labels contain similar information across a wide range of sleep products. Therefore, staff believes that the use of eight distinct warning labels provided in F3118 is unnecessary, as consumers will foreseeably perceive these labels to contain identical information. Instead, warning labels should present concise, direct messaging about general safe sleep practices.

¹ Fors Marsh Group under contract: "Consumer Product Safety Commission (CPSC): Caregiver Perceptions and Reactions to Safety Messaging Final Report," August 12, 2019, pp 24-26.

ASTM F2194-16e1 WARNING AND INSTRUCTIONAL REQUIREMENTS

Section 8, Marking and Labeling of ASTM F2194-16e1 specifies labeling and warning requirements for bassinets and cradles. In short, all bassinets and cradles must include warnings on the product about the risk of fall and suffocation hazards. Bassinets and cradles must also include a warning about Sudden Infant Death Syndrome (SIDS) and a recommendation that healthy infants are placed on their backs to sleep unless advised otherwise by a physician. Bassinets and cradles also require an additional warning for products that use sheets that instructs consumers to only use the sheet provided by the manufacturer or one specifically designed to fit the dimension of the product. CPSC staff is working with the Bassinet Subcommittee to incorporate the Ad Hoc formatting recommendations into ASTM F2194.

Section 9, Instructional Literature of ASTM F2194-16e1 specifies that instructions that are easy to read and understand must be provided with the product. The on-product warnings are also required in the instructions. Additionally, a warning addressing the strangulation hazard from strings is required in the instructions.

CONCLUSIONS

ESHF staff recommends removing the requirements in Sections 8 and 9 of the ASTM F3118-17a that relate to Marking and Labeling and Instructional Literature. Staff recommends that infant sleep products must meet 16 CFR 1218 Safety Standard for Bassinets and Cradles, including that standard's requirements for warnings and instructions, ESHF staff believes the warning and instructional requirements in ASTM F2194-16e1 adequately address the risk of injuries and deaths associated with the use of infant sleep products; staff is working with the bassinet subcommittee to incorporate the Ad Hoc formatting recommendations into ASTM F2194.

TAB E: Directorate for Health Sciences response to consumer complaints that the sleep product caused plagiocephaly (flat head syndrome), and torticollis (twisted neck syndrome) or both conditions.

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

Date: January 30, 2017

TO : Celestine T. Kish, MA, Infant Inclined Sleep Products Project Manager,
Division of Human Factors, Directorate for Engineering Sciences

THROUGH: Alice Thaler, D.V.M., MS Bioethics, Associate Executive Director
Directorate for Health Sciences
Jacqueline Ferrante, Ph.D., Division Director
Division of Pharmacology and Physiology
Directorate for Health Sciences

FROM : Suad Wanna-Nakamura Ph.D., Physiologist
Division of Pharmacology and Physiology
Directorate for Health Sciences

SUBJECT : Directorate for Health Sciences response to consumer complaints that the sleep product caused plagiocephaly (flat head syndrome), and torticollis (twisted neck syndrome) or both conditions.

I. BACKGROUND

CPSC incident data indicate that some parents believe use of an inclined sleep product caused plagiocephaly (flat head syndrome) and torticollis (a term used to describe the tilting/rotation of an infant's head to one side). Parents also expressed concerns that these morphological changes can have lasting effects on the child's appearance and might have lasting effects on normal development. In this memorandum, Health Sciences (HS) staff describes the various underlying causes of "flattened heads" in infants, and explains that the recent increased incidence of post-natal flattening of infant's head is not unique to inclined sleep products, and also explains that the post-natal head flattening associated with infant sleep position is unlikely to have any lasting negative impact on mental function and developmental capability.

II. DISCUSSION:

A. Etiology of Plagiocephaly:

Plagiocephaly¹ is a term used to describe cranial asymmetry, where one surface of the skull appears flattened. It is commonly applied to describe infants who have a flattened area of their occipital bone, which is the bone located in the lower part of the posterior region of the skull

¹ Plagiocephaly means "oblique head" (Greek origin, "plagios," meaning oblique and "kephalê," meaning head).

(i.e., at the back of the head). To allow passage through the birth canal during delivery, and allow for brain growth in early childhood, an infant's skull is soft and pliable at birth, and it gradually hardens over the first 4 years of life. Plagiocephaly in infants can result from different causes, and the appropriate treatment may differ significantly according to cause.

1. Positional Plagiocephaly:

Positional plagiocephaly, otherwise known as “*flat head syndrome*,” is a visible flattening of one side of the skull of an infant due to maintained external pressure exerted on the head. It is the also the most common type of cranial asymmetry in infancy. This deformity may be present at birth, due to mechanical constraint of fetal movement in the womb during pregnancy, mainly from intrauterine crowding (as in the case of multiple births).¹ For example, in twins, the 55.6 percent prevalence of plagiocephaly is more than four times greater than with singletons.^{2,3} It may also result from using vacuum or forceps during assisted deliveries with extraneous pressure on the infant skull. Plagiocephaly is common in premature infants.

Plagiocephaly may also develop during the first few months following birth,^{4,5} when an infant's skull remains relatively soft and pliable. Post-natal skull deformity or head molding is due primarily to sustained pressure on the back of the head that can occur while the baby is placed in a supine sleeping position. Similar pressure on the skull can occur when an infant is placed in a reclined infant carrier/seat. Premature infants are particularly vulnerable because their skull development lags behind a full term infant and therefore have softer skulls for a longer period following birth.

Although the incidence of post-natal plagiocephaly is not uncommon, there has been a six-fold increase in the number of reported incidents since the early 1990s.⁶⁻¹² Studies have suggested that this may be a consequence of American Association of Pediatrics' (AAP) recommendation in 1992 that infants be put to sleep in the supine (back) rather than prone position. While that recommendation has been credited with a dramatic decline in incidence of Sudden Infant Death Syndrome (SIDS), an unintended consequence is that the positioning of an infant in the supine position overnight places added pressure to the back of the pliable skull, which increases the risk of plagiocephaly.^{4,5}

Although the flattened appearance of an infant's head can be alarming to parents, no scientific evidence suggests that positional plagiocephaly interferes with brain development or function. The condition appears to be preventable and reversible when appropriately treated. The only lasting effect is on the physical shape/deformity of the head.^{13-27, 34} Strategies exist to reduce the development of plagiocephaly that largely involve methods for minimizing the pressures on the skull leading to the deformity. Pediatricians should inform parents of the following possible interventions:

- Varying the position of the sleeping infant's head by turning it to the left or right side^{11, 13,26} so that the non-flattened side rests on the sleeping surface (ideally a firm crib mattress).
- Increasing the amount of supervised “tummy time” during the infant's waking hours,¹¹ which helps strengthen muscles of the upper body, arms, and neck.

- Increasing the time the baby is held by parents/caregivers, which also helps strengthen the baby's neck muscle.
- Physiotherapy and repositioning to help align and attain shoulder girdle strength^{27,28} and alleviate discomfort.
- In some cases that do not respond adequately to these interventions, pediatricians may recommend a customized orthotic helmet^{15, 19, 31} to help reshape the infant's head.

2. Plagiocephaly due to Craniosynostosis:

Craniosynostosis is a more serious condition where an infant's misshapen head results from premature hardening and fusion of the skull bones' sutures [ossification of fibrous junctions (sutures) separating skull bones].^{20, 30-35} This can result in insufficient space to accommodate an infant's growing brain, which has very serious consequences. This type of birth defect is a much less common cause of plagiocephaly, but cannot be self-corrected in response to the behavioral interventions listed above. It requires surgical intervention during the first year of life to avoid significant, permanent consequences. The infant's misshapen skull may be present at birth or could develop during the first few months of life. Therefore, it is extremely important for pediatricians to carefully evaluate infants with plagiocephaly in order to differentiate between the underlying causes as early as possible.^{10, 11} Accurate diagnosis is critical for reducing morbidity and optimizing management strategies.

B. Torticollis:

Torticollis² (twisted neck) can be present at birth or it may develop in the first 6 to 8 weeks of life. Muscular torticollis is a musculoskeletal condition characterized by shortening of the *sternocleidomastoid*, [the muscle that extends from the jawbone (mastoid) to the clavicle (collarbone) and sternum (breastbone), on the side of the neck.]³⁴⁻³⁸ Clinical signs include a head tilt and a strong preference to look to one side.

Torticollis can be congenital or acquired with the former condition being more prevalent. Congenital torticollis is often associated with positional plagiocephaly because both are caused by constraint of head and neck movement. Facial asymmetry is a characteristic feature of congenital torticollis and often used to distinguish it from acquired torticollis. For most babies, stretch exercises and simple changes in how the infant is held or positioned that are aimed at gradually lengthening the muscle should help correct the problem.

Acquired torticollis on the other hand is not a diagnosis but rather a presentation of other underlying illnesses usually either muscular or neurological in nature.³⁶⁻³⁸ They can include skeletal abnormalities (abnormal shape of body parts), damage to the spinal cord induced by trauma and malignancies (exerted pressure by tumors in the neck and the base of the skull). Other causes of acquired torticollis include infection ocular and psychiatric disorders. These conditions require specialized treatments.

² The word torticollis (twisted neck) is derived from the Latin words "torus" means "twisted" and "collum" means "neck."

III. SUMMARY

The development of positional plagiocephaly and torticollis are not exclusively attributable to the use of infant inclined sleep products, and the conditions are not addressable with performance standards. Staff is not recommending any modifications to the voluntary standard to address these issues.

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TAB F: Initial Regulatory Flexibility Analysis of the Draft Supplemental Notice of Proposed Rulemaking for Infant Sleep Products, the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Infant Sleep Products Standard, and the Impact of the Product Registration Rule

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

Memorandum

Date: September 25, 2019

TO : Celestine T. Kish
Project Manager, Infant Inclined Sleep Products
Division of Human Factors
Directorate for Engineering Sciences

THROUGH: Gregory B. Rodgers, Ph.D.
Associate Executive Director
Directorate for Economic Analysis

Robert L. Franklin
Senior Staff Coordinator
Directorate for Economic Analysis

FROM : Jill L. Jenkins, Ph.D.
Economist
Directorate for Economic Analysis

SUBJECT : Initial Regulatory Flexibility Analysis of the Draft Supplemental Notice of Proposed Rulemaking for Infant Sleep Products and the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Infant Sleep Products Standard

I. Introduction

ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, is the current ASTM International (ASTM) standard for infant inclined sleep products (inclined sleep products). Staff recommends that the U.S. Consumer Product Safety Commission (CPSC) issue a supplemental notice of proposed rulemaking (NPR) under the requirements of the Danny Keysar Child Product Safety Notification Act (section 104) of the Consumer Product Safety Improvement Act (CPSIA). Staff recommends that the supplemental NPR propose to incorporate by reference the most recent ASTM standard for infant inclined sleep products, but change the introduction and scope, and delete large portions of the standard. The supplemental NPR would limit the seat back angle for any infant product intended for sleep, for infants five months old or younger, to 10 degrees or less, and require that any such product meet the mandatory bassinet standard.

As required by the Regulatory Flexibility Act (RFA),¹ this memorandum evaluates the potential economic impact the draft supplemental proposed rule would have on small entities, including small businesses. Section 603 of the RFA requires that agencies prepare an initial regulatory flexibility analysis (IRFA) and make it available to the public for comment when the general NPR is published, unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. As explained below, the draft supplemental proposed rule could have a significant impact on small firms that currently manufacture or import infant inclined sleep products, as well as small firms whose products may have difficulty meeting the bassinet standard's requirements.

The IRFA must describe the impact of the proposed rule on small entities and identify significant alternatives that accomplish the statutory objective and minimize any significant economic impact. Specifically, the IRFA must contain:

1. a description of the reasons why action by the agency is being considered;
2. a succinct statement of the objectives of, and legal basis for, the proposed rule;
3. a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
4. a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements and the type of professional skills necessary for the preparation of reports or records; and
5. an identification, to the extent practicable, of all relevant federal rules that may duplicate, overlap, or conflict with the proposed rule.

II. The Product

The draft supplemental proposed rule would impact any infant product with an inclined sleep surface (*i.e.*, position “primarily intended and marketed² to provide sleeping accommodations”) that is designed for infants five months old or younger and that is not covered by another standard for sleeping accommodations.³ This includes the inclined sleep products that currently fall under the scope of the voluntary standard ASTM F3118-17a, which covers inclined sleep products “with one or more inclined sleep surface positions for the seat back that are greater than 10° and do not exceed 30° from the horizontal.” The draft supplemental proposed rule would also cover products with inclined sleep surfaces greater than 30 degrees and less than 10 degrees, if they are intended or marketed for children under 5 months of age for sleep purposes, and they are not subject to another sleep product standard. For example, the draft supplemental proposed rule would include the hammock-style crib accessory shown in Figure 1. It appears to have an incline of 10 degrees or less, but does not fall under another sleep category.

¹ 5 U.S.C. §§ 601-612.

² This would include marketing information (such as on websites or in ad campaigns), product and retail package labeling, as well as supplier statements about the product.

³ These include: Safety Standard for Full-Size Baby Cribs (16 CFR 1219); Safety Standard for Non-Full-Size Baby Cribs and Ply Yards (16 CFR 1220 and 1221); Safety Standard for Bedside Sleepers (16 CFR 1222); and Safety Standard for Bassinets and Cradles (16 CFR 1218).



Figure 1. Crib Accessory – Hammock-Style

In general, products with adjustable seat back positions that are covered by other mandatory or voluntary standards in inclined position(s), such as bouncers, rockers, hand-held carriers, or infant swings, would not be impacted by the draft supplemental proposed rule unless they have a seat back angle that is specifically marketed for sleep for children 5 months or younger. So far, staff has found one bouncer on the market with an inclined position marketed for sleep for children in this age range.

Inclined infant sleep products sell on the U.S. market for approximately: \$65 for a frame-style inclined sleeper, \$110 for a compact sleeper, \$165 for an infant hammock,⁴ and \$236 for a play yard with an inclined sleeper accessory.⁵ The hammock-style crib accessory that would be impacted by the draft supplemental proposed rule (but does not currently fall under the voluntary inclined sleeper standard or another sleep standard) sells for approximately \$50.

Several product categories would not fall under the scope of the draft supplemental proposed rule: (1) positioners; (2) sleep wedges, many of which are marketed as medical devices, putting them under the jurisdiction of the Food and Drug Administration; and (3) miniature infant hammocks marketed exclusively for use as photographic props (*i.e.*, photos of newborn babies).

Staff requests comments on products likely to be impacted by the draft supplemental proposed rule. This includes both product categories discussed above and any additional types of products that commenters feel may be impacted by the draft supplemental proposed rule.

III. Reason for Agency Action and Legal Basis for the Draft Supplemental Proposed Rule

Section 104 of the CPSIA requires the CPSC to examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products and promulgate consumer product safety standards that are substantially the same as the voluntary standards or more stringent than the voluntary standards if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the products. Although a number of sleep products were specifically mentioned as a durable infant or toddler product in section 104(f)(2), including cribs and bassinets, inclined sleep products were not.

⁴ Note that the average price for an infant hammock supplied by a home-based manufacturer is approximately \$200. Home-based manufacturers will be discussed further in Section VI.

⁵ Prices are averaged across all models of a particular type found. Shipping costs for a few hammock models delivered from overseas suppliers have been ignored as unknown, which means that the average cost for an infant hammock may be a low estimate, depending upon how many hammocks are entering the U.S. via these overseas suppliers.

Inclined sleep products were not recognized as a distinct product category until relatively recently. In January 2010, a series of fatalities in infant hammocks came to the attention of CPSC staff and an effort was made to include these products in the bassinets and cradles rulemaking that was being developed at the time. However, bassinets have flat sleep surfaces and it was impossible to make infant hammocks, which are inherently inclined, conform to that standard without fundamentally changing them (*i.e.*, making them flat rather than inclined). Additionally, other inclined sleeping products for infants and toddlers entered the market, making it more effective to address the inclined products together, as a new product type. Therefore, CPSC staff began working with ASTM to develop a voluntary standard that would cover the wide array of products on the market that provide infants and toddlers with inclined sleeping environments. In 2016, the Commission issued an NPR proposing to incorporate by reference the voluntary standard as a mandatory standard.

Since the 2016 NPR was issued, CPSC has become aware of additional deaths in inclined sleep products and several major suppliers of infant inclined sleep products have been recalled. Staff is unaware of any evidence that suggests that an incline greater than 10 degrees is safe for infant sleep, and the results of a CPSC contractor's biomechanical study state that 20 degrees is not safe. As a result, staff developed a draft supplemental proposed rule that would require all infant products intended and marketed for sleep by children 5 months of age or younger, that are not already subject to another sleep standard, to test sleep surface(s) for the degree of incline, as described in Section IV below. Those products with sleep surface angles greater than 10 degrees would fail the test and be prohibited from sale in the United States. Staff concludes that requiring sleep surface angles of 10 degrees or less will address injuries and deaths associated with inclined sleep products.

IV. Requirements of the Draft Supplemental Proposed Rule

The draft supplemental proposed rule would incorporate by reference the voluntary standard for inclined sleep products (ASTM F3118-17a) with significant changes (as described in Section IV.A. below). If adopted by the Commission as a final rule, it would become a mandatory consumer product safety standard under section 104 of the CPSIA. If it becomes a mandatory standard, firms with a sleep product that is subject to the rule would need to evaluate their product, determine what changes would be required to meet the standard, and modify the product so that it complies with the standard or cease supplying the product to the U.S. market. The manufacture or importation of noncompliant products would be prohibited after the effective date of the standard.

This section lays out the requirements of the draft supplemental proposed rule and considers the implications on all firms, large and small. Section VI then continues the discussion, focusing exclusively on the small business impacts.

A. Draft Supplemental Proposed Rule

The draft supplemental proposed rule would eliminate all of the requirements of the voluntary standard, except those listed below (modifications to the remaining requirements are presented in italics):⁶

- The maximum seat back angle requirement and test procedure—intended to ensure that the sleep surface does not exceed the range determined to be safe. *The test procedure applies to all positions recommended for sleep, and the criteria for failure has been changed from more than 30 degrees to more than 10 degrees.*
- *Accessory, Compact, Infant Sleep Products, and Newborn Sleep Products—a new requirement has been added whereby any product that passes the maximum seat back angle requirement/test would be required to meet all of the requirements of the mandatory bassinet standard.*⁷

The draft supplemental proposed rule would also *create definitions for infant sleep products*, based on the existing definitions of an infant inclined sleep product, a newborn inclined sleep product, an accessory inclined sleep product, and a compact inclined sleep product. *It would change the name of the covered products from “inclined sleep products” to “infant sleep products” and modify the scope to specify that the standard includes products not covered by ASTM standards such as those for full-size cribs, non-full-size cribs and play yards, bedside sleepers,⁸ and bassinets and cradles.*

The draft supplemental proposed rule would require all infant sleep products intended for children five months or younger, that are not subject to another sleep accommodation standard, to test all of their seat back angles recommended for sleep to the maximum seat back angle requirement. Those with sleep surfaces greater than 10 degrees would fail and be prohibited for sale in the United States. Those with sleep surfaces less than or equal to 10 degrees would be required to meet all of the requirements of the mandatory bassinet standard.

All products with inclined sleep surface angles greater than 10 degrees would fail the maximum angle test (this includes the inclined sleepers covered by the scope of the current voluntary standard and any products with sleep surfaces greater than 30 degrees) *if they are intended for children 5 months or younger.*⁹ These firms will all need to decide whether to redesign or drop their current products. Alternatively, some firms may change the marketing of their impacted products to change the intended user age or remove any suggestion that the product is intended for sleep.¹⁰ The latter is similar to the Canadian approach to inclined sleep products; many of the inclined sleepers sold in the U.S. are also sold in Canada but without any

⁶ The Introduction to the voluntary standard has also been modified, but that would not have an economic impact on firms, so it has been left out here. See Lee (2019) for more information.

16 C.F.R. part 1218.

⁸ Bedside sleepers are fundamentally considered bassinets and must also be tested to the bassinet standard, but do have a standard with additional requirements and are therefore listed separately here.

⁹ See Section II for a breakout of the product groups expected to be impacted by the draft supplemental proposed rule.

¹⁰ For importers, redesign would involve either working with their existing supplier(s) or finding alternative suppliers willing to assist them.

reference to overnight sleep in the marketing.^{11, 12} CPSC staff believes that any mention of sleep, including “napping,” should be considered “primarily intended and marketed to provide sleeping accommodations.”

Any firm that wants to continue marketing products with an inclined sleep surface for children 5 months or younger would need to redesign them to a 10 degree or less incline *and* meet all of the requirements in the mandatory bassinet standard. Redesign costs are likely to vary for different products, based on the difficulty of modifying the sleep surface incline (some infant hammocks could find this more difficult) and the extent of changes required to meet the bassinet standard (the hammock-style crib accessory shown in Figure 6 would probably have difficulty meeting the bassinet side height requirements, for example). To provide some perspective on the magnitude of potential redesign costs, we previously estimated that the cost of redesigning a bassinet to comply with the standard could be up to \$500,000, depending upon the extent of the changes required.¹³

Alternatively, suppliers might simply change their marketing. They could only label existing surfaces of 10 degrees or less for sleep or, if none exists, change their marketing of the product to eliminate any mention of sleep, and focus on other uses. Suppliers could also opt to change the age range for which their existing products are marketed, targeting children older than 5 months. Changes in marketing do not remove a firm’s obligation to comply with existing regulations; they merely modify the applicable standard. For example, a product currently marketed as an inclined sleep product/rocker could be marketed to focus exclusively on the product’s rocker function. The product would still need to meet applicable standards, in this case ASTM F3084 (*Standard Consumer Safety Specification for Infant and Infant/Toddler Rockers*). Staff cannot predict whether a particular product will be remarketed, how it will be remarketed, and whether any compliance costs would be associated with the remarketing.

Finally, suppliers have the option simply to withdraw their noncomplying products from the U.S. market.

In all cases, the economic impact will depend upon two factors: (1) the compliance effect, the cost of bringing a product into compliance with the standard; and (2) the demand effect, how demand is affected by the changes made (such as marketing or design changes)¹⁴ and how the firm’s revenue is affected (*i.e.*, the importance of the revenue the product generates for the firm). If consumers value a sleep surface with an incline of 10 degrees or less equivalently to a product

¹¹ In some cases, much of the marketing materials available in the U.S. also do not mention sleep uses, even when the product is known to test for compliance with the ASTM inclined sleeper voluntary standard.

¹² A review of a major Canadian retailer’s website for products similar to the inclined sleepers sold in the U.S. found several marketing approaches. Some focused on “rest” or “naps,” while others focused instead on alternative uses, like rocking. These are approaches taken by first party sellers and are, therefore, considered likely to be acceptable under the Canadian standard. The approaches taken by some third party sellers (such as simply avoiding marketing materials entirely and saying nothing about what the product should be used for) could be violations of Canadian regulations, depending upon how closely Canadian officials monitor these sites.

¹³ See memorandum from Jill L. Jenkins, Ph.D., Economist, Directorate for Economic Analysis, dated July 16, 2012, Subject: Initial Regulatory Flexibility Analysis of Staff-Recommended Proposed Standard for Bassinets and Cradles. See

https://www.cpsc.gov/Newsroom/FOIA/ReportList?field_nfr_date_value%5Bvalue%5D%5Bmonth%5D=8&field_nfr_date_value_1%5Bvalue%5D%5Byear%5D=2012&field_nfr_type_value=commission&title=&=Apply for a link to the briefing package with this memorandum.

¹⁴ For dropped products, a lack of supply would be equivalent to the result from no demand, although there might still be a positive demand for the product dropped.

with an incline of more than 10 degrees, no demand effect would occur from the draft supplemental proposed rule. If consumers value the product the same, whether or not it is marketed for sleep use, no demand effect would occur. This might be the case if consumers are not intending to use the product for sleep or if consumers are indifferent about marketing strategies (e.g., if consumers consider the product still usable for sleep regardless of the product's marketing).¹⁵ In addition, if consumers value the product equally, regardless of the target age group (or if consumers ignore the target age group marketing in making their purchases), no demand effect would occur. To the extent that any of the product changes is viewed as less desirable by consumers, demand for a product would decrease and the firm would be negatively impacted. Staff lacks the information required to determine how the demand for the infant sleep products of any of the current suppliers might be impacted by the draft supplemental proposed rule.

Staff requests comment on how firms with inclined sleep surfaces will likely respond to the draft supplemental proposed rule, including suppliers of products with inclines above 10 degrees and products with inclines less than or equal to 10 degrees that do not already comply with the bassinet standard. We would also appreciate any information on the possible responses of consumers to changes in marketing. Additionally, any information on the approximate percentage of revenue attributable to these types of products would be valuable. Finally, staff requests any information regarding the safety of sleep angles in excess of 10 degrees but less than 20 degrees.

B. Third Party Testing

Under section 14 of the CPSA, if the draft supplemental proposed rule becomes effective, all suppliers will be subject to the third party testing and certification requirements under the CPSA and the Testing and Labeling Pertaining to Product Certification rule (16 CFR part 1107), which requires that manufacturers and importers certify that their products comply with the applicable children's product safety standards, based on third party testing. Third party testing costs are in addition to any costs of modifying the products to meet the standard. If a firm opted to change their marketing to eliminate any mention of sleep or target a different user group, as discussed above, there would be no third party testing costs associated with this rule.¹⁶

However, firms that continue to supply a product with a sleep surface incline of no more than 10 degrees (as well as firms that produce completely flat products that will also require testing to verify the maximum sleep surface angle) would incur third party testing costs associated with the maximum incline test in the draft supplemental proposed rule. Additionally, if firms are not

¹⁵ Staff found evidence that numerous products not marketed for sleep are actually used for sleep, so CPSC cannot ignore this possibility. In addition to the incident data available where children were sleeping in inclined products not marketed for sleep, the Durable Nursery Product Exposure Survey conducted by the CPSC in 2013 found that nationally approximately 208,803 children age three and under were most frequently put down in hand-held carriers for naps, approximately 327,036 children age three and under were most frequently put down in strollers for naps, approximately 847,767 children age three and under were most frequently put down in infant swings for naps, and approximately 127,712 children age three and under were most frequently put down in bouncers for naps (data run on 9/4/19). Note that only infant swings and bouncers were also used as the preferred product for overnight sleep but with much lower frequencies.

¹⁶ There could potentially be indirect third party testing costs resulting from remarketing a product as, for example, an infant bouncer (16 CFR 1229).

already testing their products to a sleep standard, such firms' products would be required to pass the bassinet standard and the firm would incur all of those third party testing costs as well.

Staff estimates that third party testing costs associated with the draft supplemental proposed rule to be between \$30 to \$100 per sample for the maximum incline test alone. Testing to the bassinet standard could add additional costs of up to \$1,000.¹⁷ All cost estimates are per sample tested. Therefore, the third party testing costs are expected to range between \$0 (for firms that choose to drop their product or change their marketing) and \$1,100 per sample tested (for firms that choose to include a sleep position in the 10 degrees or less range).¹⁸ As allowed by the component part testing rule (16 CFR 1109), importers may rely upon third party tests obtained by their suppliers, which could reduce the impact on importers.

We welcome comments regarding the impact that promulgating the draft supplemental proposed rule would have on the cost of testing and certifying products, particularly on small manufacturers and importers. Any information on the number of samples that must be tested would be especially helpful. Staff particularly requests comments on the third party testing costs of the maximum incline test in the draft supplemental proposed rule.

V. Other Federal or State Rules

CPSC staff has not identified any federal or state rule that either overlaps or conflicts with the draft supplemental proposed rule.

VI. Suppliers of Infant Sleep Products and the Impact on Small Businesses

The U.S. inclined sleep product market has changed substantially since the 2016 NPR was issued. Manufacturers and importers have removed most frame-style inclined sleep product models from the market, including some that were not subject to recalls, although one or two products remain. Additionally, a significant decline in the infant hammock market has occurred, both among larger-scale suppliers and home-based manufacturers. However, the focus of the rulemaking, and therefore the market research, is on products that are still being produced for sale and would be impacted by a change in regulations.¹⁹

As part of the current market evaluation, staff identified 18 firms still supplying sleep products to the U.S. market with sleep surface angles greater than 10 degrees, but less than or equal to 30 degrees. Staff identified an additional firm supplying a sleep product with an incline of 10 degrees or less that is not also being tested for compliance with either the bassinet standard or another sleep product standard. Of these 19 total firms, six appear to be very small, home-

¹⁷ See Jenkins, 2012.

¹⁸ As always, staff expects testing costs to be lower for those firms that conduct product testing overseas and for larger firms that may be able to get a price discount based on volume.

¹⁹ There may still be some frame-style inclined sleeper units available for sale even for products that are no longer being produced (this does *not* include recalled models).

based manufacturers of infant hammocks (two operating domestically and four overseas).²⁰ None has more than one infant hammock model in their product line, and the majority supply few, if any, other products. They generally have low sales volumes.²¹

Staff identified another 13 firms that supply products that would be subject to the draft supplemental proposed rule that are not home-based and are generally larger than the home-based manufacturers, 11 of which are domestic. These firms include both manufacturers and importers.²² Seven of those firms, although not as small as the home-based suppliers, still meet the definition of “small” domestic entities based on U.S. Small Business Administration (SBA) guidelines for their North American Industry Classification System (NAICS) codes. These firms also typically have only one inclined sleep product model in their product lines, but have much larger sales volumes than the home-based suppliers.

The remaining two firms are foreign manufacturers (along with the four home-based foreign manufacturers). Additionally, staff identified a few inclined sleep products entering the U.S. market via online retailers that operate marketplaces for smaller sellers and foreign retailers willing to supply foreign-manufactured inclined sleep products directly to U.S. consumers on their own behalf. This market has also changed drastically since February 2019, with many online retailers no longer willing to ship these products to the U.S. Foreign suppliers are not considered in the regulatory flexibility analysis because SBA guidelines and definitions pertain only to U.S.-based entities.

Table 1. Firms Supplying Products to the U.S. that would be Considered Infant Sleep Products under the Draft Supplemental Proposed Rule

CATEGORY	NUMBER OF FIRMS SUPPLYING INFANT SLEEP PRODUCTS
Total Firms	19
Total Domestic Firms	13
Very small home-based manufacturers	2*
Small	7
Manufacturers	4
Importers	3
Large	4
Total Foreign Firms	6*
Highlighted categories are the focus of this analysis. * Staff identified 6 home-based manufacturers (4 foreign and 2 domestic) selling infant hammocks marketed for sleep online, but there may be additional home-based manufacturers that staff was unable to identify (possibly including some without an online presence). Home-based manufacturers not located in the U.S. are captured along with the other foreign firms.	

²⁰ These suppliers were identified online and staff believes that there may be additional home-based manufacturers supplying infant hammocks on a very small scale (possibly including some without an on-line presence).

²¹ The two domestic home-based manufacturers identified by staff supply approximately 10-20 infant hammocks per year on average.

²² Determinations were made using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites.

A. Small Manufacturers

The two home-based manufacturers and four other small manufacturers are considered together because the impact on these firms will be similar.²³ As noted, these manufacturers might comply with the requirements of the draft supplemental proposed rule by changing their marketing to eliminate any reference to the product being intended for sleep purposes for children 5 months old or younger. If the manufacturer believes that the change in marketing would significantly impact demand, the manufacturer could opt to redesign the product so that the maximum angle intended for sleep is 10 degrees or less and meets the requirements of the bassinet standard. As discussed in Section IV, depending upon the changes required, the costs of redesign could be up to \$500,000. Potentially, manufacturers that redesign their products could also suffer a loss of sales if their customers prefer products with sleep angles greater than 10 degrees. Finally, some manufacturers may choose to drop their inclined sleep products if they believe that the cost of changing their marketing strategies or redesigning their products would adversely impact sales or be too costly.

Small manufacturers that opt to drop their inclined sleepers or stop marketing their products for sleep purposes (or market to older children) would not experience any third party testing costs as a direct result of the draft supplemental proposed rule. Small manufacturers that choose to redesign their products to have sleep positions with an incline of 10 degrees or less, could experience third party testing costs of up to \$1,100 per sample tested. This includes testing to the draft supplemental proposed rule's maximum incline test, as well as testing for compliance with the bassinet standard, as discussed in Section IV.B.

Third party testing costs are likely to be significant for the two very small home-based manufacturers of infant hammocks *if* they choose to redesign their products. These firms sell an average of 10 to 20 infant hammocks for approximately \$200 each, yielding annual revenue from these products of about \$2,000 to \$4,000. Testing two or three units per model would eliminate most, if not all, of the revenue these firms generate from their infant hammocks. Similarly, the testing costs for two of the small manufacturers could be significant if as few as four units per model are required to provide a "high degree of assurance" of compliance, as required by part 1107. Finally, no determination could be made for the final two small manufacturers, as no revenue data were available.

Staff requests comments on the cost of redesign, the time required for redesign, the likely response of manufacturers to the draft supplemental proposed rule's requirements (*i.e.*, redesign, remarket, or drop), the possible change in demand due to remarketing or changing the sleep surface's degree of incline, the cost of (and time required for) remarketing, and (for firms supplying comments) the relative significance of inclined sleepers to their total revenue. Staff also welcomes comments on testing costs, including the number of inclined sleeper units that typically need to be tested to provide a "high degree of assurance" of compliance.

²³ Whether the inclined sleepers supplied by these firms meet the current voluntary standard is irrelevant because products designed to be between >10 degrees and 30 degrees cannot pass a test that requires them to have sleep surfaces of 10 degrees or less.

B. Small Importers

Three small importers supply inclined sleepers to the U.S. market, one of which is a subsidiary of a larger foreign firm. All three importers have options that are similar to those available to manufacturers: (1) redesign their product (this would need to be done in conjunction with their supplier and its viability would be affected by the supplier's willingness and the degree of cost pass-through); (2) remarket their product (either removing sleep use or targeting an older age group);²⁴ (3) drop the inclined sleeper from their product line (possibly replacing it with a different type of product); or (4) replace with a different inclined sleep product from a different supplier (an option only available to importers).

As with manufacturers, the option chosen will depend upon the importer's perceived demand for their product and how the product's revenue affects their overall revenue. The option chosen may also depend upon how difficult and potentially costly it would be to redesign the product and, potentially, how difficult and time-consuming it is to find an alternative supplier. As already noted, firms may find it more difficult to redesign certain types of inclined sleep products. However, staff has insufficient information to determine which option a given importer might select.

As with manufacturers, importers will be subject to third party testing and certification requirements, and consequently, will be subject to costs similar to those for manufacturers if their supplying foreign firm(s) does not perform third party testing. Staff cannot make a determination as to whether the impact of the rule would be significant or affect a substantial number of small entities. As already discussed, to evaluate this criteria, we need information on the choice a given firm is likely to make (and the approximate cost of that choice) (*i.e.*, compliance effect), as well as the expected effect on demand for the product (if any) and the resulting change in revenue relative to overall revenue (*i.e.*, demand effect). Lacking this information, staff cannot rule out a significant impact on the three small importers.

Staff requests information on how importers may respond to the draft supplemental proposed rule (*i.e.*, which option(s) they are likely to select). Staff also requests information on the search costs (and timeframe) needed to identify replacement infant sleep products available from other suppliers. We would additionally like information on the willingness of suppliers to undertake redesign for their customers (the importers) and the degree to which costs may be passed-through to importers (for importers tied to their parent company and importers who are not tied to a particular supplier). Finally, information on how frequently suppliers third party test for their customers would be valuable.

C. Summary of Impacts

CPSC staff is aware of nine small domestic firms currently marketing products that would be impacted by the draft supplemental proposed rule in the United States. As described above, staff

²⁴ As noted in Section IV.A., a change in marketing could require product modifications to meet the requirements of the standard they are newly targeting. For example, depending upon the alternative use a firm decided to focus on, their inclined sleep product could become a floor seat (ASTM F3317), a rocker (ASTM F3084), a bouncer (16 CFR 1229), or some other product.

cannot definitively determine the impact of the draft supplemental proposed rule because the impact is dependent on several unknown factors including:

- How firms respond to the rule (*e.g.*, they would redesign, remarket, or drop);
- The costs associated with redesigning, remarketing, or replacing an inclined sleeper;
- The change, if any, on demand for that product.

However, staff found that third party costs are likely to be significant for the two very small home-based manufacturers of infant hammocks *if they choose to redesign*; and costs could be significant for an additional two small manufacturers, if they chose to redesign their products and testing as few as four units per model were required to provide a “high degree of assurance.”

VII. Alternatives

At least two alternatives are available that could minimize the economic impact on small entities while also meeting the statutory objectives:²⁵ (1) eliminate the requirement that products must meet the bassinet standard if they do not already fall into another sleep product standard; or (2) allow a later effective date.

If the Commission eliminates the requirement that products must meet the bassinet standard if they do not fall into another sleep product category, the cost of redesign for firms that selected that option would still likely be significant. Firms would still need to modify their products to meet the 10 degree maximum angle requirement (and test to that requirement), but they would not need to make any additional design changes to meet the bassinet standard’s requirements (or test to that standard). However, staff prepared the draft supplemental proposed rule with the intent to ensure that all sleep products meet a base set of safety requirements. This alternative would not accomplish this goal.

Second, the Commission could also reduce the draft supplemental proposed rule’s impact on small businesses by setting a later effective date than the one year currently recommended. A later effective date would reduce the economic impact on firms redesigning their existing products in two ways. Firms would be less likely to experience a lapse in production/importation, which could result if they are unable to bring their products into compliance and certify compliance based on third party tests within the required timeframe. Also, firms could spread the costs of developing compliant products over a longer time period, thereby reducing their annual costs, as well as the present value of their total costs (*i.e.*, they could time their spending to better accommodate their individual circumstances). Staff specifically requests comments on the 1-year effective date, which was set to help reduce the impact on affected firms, as well as feedback on how firms would likely respond to the draft supplemental proposed rule.

²⁵ Staff considered whether adopting the voluntary inclined sleeper standard with no modifications might also be an alternative, but ruled it out because it would not address the injuries and deaths that led to the recent inclined sleeper recalls.

VIII. Small Business Impacts of the Accreditation Requirements for Testing Laboratories

In accordance with section 14 of the CPSA, all children's products that are subject to a children's product safety rule must be tested by a CPSC-accepted third party conformity assessment body (i.e., testing laboratory) for compliance with applicable children's product safety rules. Testing laboratories that want to conduct this testing must meet the NOR pertaining to third party conformity testing. NORs have been codified for existing rules at 16 CFR part 1112. Consequently, staff recommends that the Commission propose an amendment to 16 CFR part 1112 that would establish the NOR for those testing laboratories that want to test for compliance with the infant sleep products final rule (in essence, test for maximum seat back angle). This section assesses the impact of the amendment on small laboratories.

A final regulatory flexibility analysis (FRFA) was conducted as part of the promulgation of the original 1112 rule (78 FR 15836, 15855-58), as required by the RFA. Briefly, the FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements were imposed on laboratories that did not intend to provide third party testing services. The only laboratories that were expected to provide such services were those that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

Based on similar reasoning, amending the rule to include the NOR for the infant sleep product standard will not have a significant adverse impact on small laboratories. Moreover, based upon the number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the infant sleep product standard. Most of these laboratories will have already been accredited to test for conformance to other juvenile product standards, and the only costs to them would be the cost of adding the infant sleep product standard to their scope of accreditation, a cost that test laboratories have indicated is extremely low when they are already accredited for other section 104 rules. Consequently, the Commission could certify that the NOR for the infant sleep product standard will not have a significant impact on a substantial number of small entities.

**TAB G: Infant Inclined Sleep Products: Summary of
Recalls – May 10, 2000 through August 20, 2019**

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

Memorandum

DATE: August 20, 2019

TO: Celestine Kish, Infant Inclined Sleep Products Project Manager,
Division of Human Factors, Directorate for Engineering Sciences

THROUGH: Robert Kaye, Director
Office of Compliance and Field Operations
Jennifer Timian, Director, Division of Regulatory Enforcement
Carolyn Manley, Assistant Division Director,
Division of Regulatory Enforcement

FROM: Michelle Guice, Compliance Officer, Division of Regulatory
Enforcement

SUBJECT: Infant Inclined Sleep Products: Summary of Recalls – May
10, 2000 through August 20, 2019

The Office of Compliance provides this summary in support of the draft supplemental notice of proposed rulemaking for infant inclined sleep products.

Summary of Recalls Involving Infant Inclined Sleep Products

Compliance staff reviewed recalls of infant inclined sleep products from May 10, 2000 to August 20, 2019. During that period, there were 13 consumer-level recalls involving infant inclined sleep products. The recalls were conducted in response to hazards involving strangulation, suffocation, fall, structural stability, entrapment, exposure to mold, and death. Six recalls involved infant hammocks, six recalls involved infant inclined sleep products, and one recall involved an infant inclined sleep accessory included with a play yard.

The six infant hammocks were recalled for hazards including: strangulation, suffocation, fall, structural stability, and entrapment. The recalls affected approximately 25,400 units of infant hammocks.

The six infant inclined sleep products and one infant inclined sleep accessory included with a play yard were recalled due to hazards including: entrapment, suffocation, fall, exposure to mold, and death after infants rolled from their back to their stomach or side while unrestrained

in the products. The recalls affected approximately 6.4 million units of infant inclined sleep products. One recall for exposure to mold affected 800,000 units, and 2 recalls for entrapment and suffocation affected 195,000 units.

In 2019, two recalls occurred due to reports of deaths while using infant inclined sleep products, after the infants rolled from their back to their stomach or side while unrestrained, or under other circumstances. In response to the reported deaths in those products, two additional recalls, one with an infant inclined sleep product, and one with an infant inclined sleep accessory included with a play yard, were conducted due to safety concerns with infant inclined sleep products. The recalls involving infant inclined sleepers affected approximately 5.4 million units and the recall involving the infant inclined sleeper accessory affected approximately 71,000 units.

Table I presents the 13 recalls conducted between May 10, 2000 and August 20, 2019, and notes the recall date, the firm involved, hazard(s), the approximate number of units affected, number of reported incidents/injuries, and the press release number.

TABLE I – Summary of Infant Inclined Sleep Products Recalls

Recall Date	Firm	Hazard	Number of Recalled Units	Number of Incidents Reported (Injuries Reported)	Press Release Number
May 10, 2000	Hangouts, of Boulder CO	Strangulation	350 Infant Hammocks	No Incidents/ Injuries Reported	00-107b ¹
September 18, 2000	Hamacas	Strangulation	53 Infant Hammocks	No Incidents/ Injuries Reported	01-500 ²
August 4, 2009	Nova Natural Toy & Crafts	Fall and Strangulation	265 Infant Hammocks	No Incidents/ Injuries Reported	09-760 ³
August 4, 2009	Kaplan Early Learning	Fall and Strangulation	200 Infant Hammocks	No Incidents/Injuries Reported	09-761 ⁴
December 8, 2009	Amby Baby Motion Beds/Hammocks	Structural Stability, Entrapment, and Suffocation	24,000 Infant Hammocks	Two Infant Suffocation Deaths in the Amby Baby Hammock	10-056 ⁵

¹ <https://www.cpsc.gov/Recalls/2000/cpsc-hangouts-recall-baby-hammocks>

² <https://www.cpsc.gov/Recalls/2000/cpsc-hamacas-recall-baby-hammocks>

³ <https://www.cpsc.gov/Recalls/2009/baby-hammocks-recalled-by-nova-natural-toys-crafts-due-to-fall-and-strangulation>

⁴ <https://www.cpsc.gov/Recalls/2009/baby-hammocks-recalled-by-kaplan-early-learning-due-to-fall-and-strangulation-hazards>

⁵ <https://www.cpsc.gov/Recalls/2009/infant-suffocation-deaths-prompt-recall-of-amby-baby-motion-bedshammocks>

Recall Date	Firm	Hazard	Number of Recalled Units	Number of Incidents Reported (Injuries Reported)	Press Release Number
July 26, 2010	Baby Matters LLC	Due to Entrapment, Suffocation and Fall Hazards; One Infant Death Reported	30,000 Inclined Sleep Products	One Infant Death Reported; One Infant became Entrapped; 22 Reports of Infants Hanging or Falling over the side of the Product; One Infant was Bruised as a Result of Hanging over the side of the Product	10-309 ⁶
August 24, 2010	MamaLittleHelper	Suffocation	500 Infant Hammocks	No Injuries Reported	10-324 ⁷
January 8, 2013	Fisher-Price	Exposure to Mold	800,000 Inclined Sleep Products	16 Reports of Infants treated for Respiratory Issues After Sleeping in the Product	13-087 ⁸
June 14, 2013	Baby Matters LLC	Deaths and Falling	165,000 Inclined Sleep Products	5 Infant Deaths; 92 Reports of Infants Hanging or Falling over the side of the Products	13-216 ⁹
April 12, 2019	Fisher-Price	Reports of Deaths	4.7 million Inclined Sleep Products	30 Infant Fatalities Have Occurred in Rock 'n Play Sleepers	19-105 ¹⁰
April 26, 2019	Kids II, Inc.	Reports of Deaths	694,000 Inclined Sleep Products	5 Infant Deaths	19-112 ¹¹

⁶ <https://www.cpsc.gov/Recalls/2010/baby-matters-recalls-nap-nanny-recliners-due-to-entrapment-suffocation-and-fall-hazards>

⁷ <https://www.cpsc.gov/Recalls/2010/baby-hammocks-recalled-by-mamalittlehelper-due-to-suffocation-hazard>

⁸ <https://www.cpsc.gov/Recalls/2013/fisher-price-recalls-to-inspect-rock-n-play-infant-sleepers-due-to-risk-of-exposure-to#>

⁹ <https://www.cpsc.gov/content/nap-nanny-and-chill-infant-recliners-recalled-by-baby-matters-llc-after-five-infant-deaths>

¹⁰ <https://www.cpsc.gov/Recalls/2019/fisher-price-recalls-rock-n-play-sleepers-due-to-reports-of-deaths>

¹¹ <https://www.cpsc.gov/Recalls/2019/kids-ii-recalls-all-rocking-sleepers-due-to-reports-of-deaths>

Recall Date	Firm	Hazard	Number of Recalled Units	Number of Incidents Reported (Injuries Reported)	Press Release Number
June 27, 2019	Fisher-Price	Safety Concerns About Inclined Sleep Products	71,000 Inclined Sleep Accessories Included with Play Yards	No Injuries Reported	19-151 ¹²
July 31, 2019	Dorel Juvenile Group USA	Safety Concerns About Inclined Sleep Products	24,000 Inclined Sleep Products	No Injuries Reported	19-177 ¹³
Total	13		6,509,368	131 Incidents/ 44 Injuries/11 Deaths	

¹² <https://www.cpsc.gov/Recalls/2019/fisher-price-recalls-inclined-sleeper-accessory-included-with-ultra-lite-day-night-play>

¹³ <https://www.cpsc.gov/Recalls/2019/dorel-juvenile-group-usa-recalls-inclined-sleepers-due-to-safety-concerns-about>