



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
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This document has been electronically
approved and signed.

DATE: September 30, 2015

BALLOT VOTE SHEET

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Patricia H. Adkins, Executive Director

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

SUBJECT: Draft Notice of Proposed Rulemaking for Infant Bouncer Seats

BALLOT VOTE DUE: October 6, 2015

The Office of the General Counsel is providing for Commission consideration the attached draft notice of proposed rulemaking for publication in the *Federal Register*. The proposed rule would establish a safety standard for infant bouncer seats under the Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008. Staff recommends that the Commission propose adoption of the voluntary standard with several modifications that staff believes will augment the effectiveness of the required warnings and instructions.

Please indicate your vote on the following options:

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

(Signature)

(Date)

CPSC Hotline: 1-800-638-CPSC(2772) ★ CPSC's Web Site: <http://www.cpsc.gov>

II. Approve publication of the attached document in the *Federal Register*, with changes. (Please specify.)

(Signature)

(Date)

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

(Signature)

(Date)

IV. Take other action. (Please specify.)

(Signature)

(Date)

Attachment: Draft *Federal Register* Notice: Proposed Rule to Establish a Safety Standard for Infant Bouncer Seats

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Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1229

[Docket No. CPSC-2015-XXXX]

Safety Standard for Infant Bouncer Seats

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (“CPSIA”), requires the United States Consumer Product Safety Commission (“Commission” or “CPSC”) to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standard, if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is proposing a safety standard for infant bouncer seats (“bouncer seats”) in response to the direction of section 104(b) of the CPSIA. In addition, the Commission is proposing an amendment to 16 CFR part 1112 to include 16 CFR part 1229 in the list of notice of requirements (“NORs”) issued by the Commission.

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 bouncer seats should be directed to the Office of Information and Regulatory Affairs, the Office

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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-2015-XXXX, 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. The Commission does not accept comments submitted by electronic mail (e-mail), except through www.regulations.gov. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, 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 confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted 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-2015-XXXX, into the “Search” box, and follow the prompts.

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FOR FURTHER INFORMATION CONTACT: Suad Wanna-Nakamura, Ph.D., Project Manager, Directorate for Health Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: 301-987-2550; e-mail: snakamura@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

The CPSIA was enacted on August 14, 2008. Section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, 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 and 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 determines that more stringent requirements would further reduce the risk of injury associated with the product.

The term “durable infant or toddler product” is defined in section 104(f)(1) of the CPSIA as “a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years,” and the statute specifies twelve categories of products that are included in the definition, including walkers, carriers and various types of children’s chairs. In issuing regulations governing product registration under section 104, the Commission determined that an “infant bouncer” falls within the definition of a “durable infant or toddler product.” 74 FR 68668 (Dec. 29, 2009); 16 CFR 1130.2(a)(15).

Pursuant to section 104(b)(1)(A) of the CPSIA, the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups,

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consultants, and members of the public in the development of this notice of proposed rulemaking (“NPR”), largely through the ASTM process. The NPR is based on the most recent voluntary standard developed by ASTM International (formerly the American Society for Testing and Materials), ASTM F2167-15, *Standard Consumer Safety Specification for Infant Bouncer Seats* (“ASTM F2167-15”), with specific modifications to improve and strengthen the requirements for on-product warnings and instructional materials provided with bouncer seats.

The testing and certification requirements of section 14(a) of the Consumer Product Safety Act (“CPSA”) apply to the standards promulgated under section 104 of the CPSIA. Section 14(a)(3) of the CPSA requires the Commission to publish an NOR for the accreditation of third party conformity assessment bodies (“test laboratories”) to assess conformity with a children’s product safety rule to which a children’s product is subject. The proposed rule for bouncer seats, if issued as a final rule, would be a children’s product safety rule that requires the issuance of an NOR. To meet the requirement that the Commission issue an NOR for the bouncer seat standard, this NPR also proposes to amend 16 CFR part 1112 to include 16 CFR part 1229, the CFR section where the bouncer seat standard will be codified, if the standard becomes final.

II. Product Description

A. Definition of “Bouncer Seats”

The scope section of ASTM F2167-15 defines an “infant bouncer seat” as: “a freestanding product intended to support an occupant in a reclined position to facilitate bouncing by the occupant, with the aid of a caregiver or by other means.” ASTM F2167-15 states that infant bouncer seats are intended for “infants who have not developed the ability to sit up unassisted (approximately 0 to 6 months of age).”

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Bouncer seats vary widely in style and complexity, but typically, bouncer seats consist of a cloth cover stretched over a wire or tubular frame. Wire frame bouncers have two designs. The forward bend design is constructed with the seating area supported from the front side of the product. The second wire frame design is a rear bend design. In the rear bend design, the seat is supported from the rear side of the product. Other bouncer designs are also currently available, including, but not limited to, products with individual wire legs, solid bases, and spring designs. These infant bouncer designs use different methods to support the seat and are intended for “bouncing,” as defined in ASTM F2167.

All bouncer seats support the child in an inclined position, and some brands have adjustable seat backs. Various bouncer seat models include a “soothing unit” that vibrates or bounces the chair, and may play music or other sounds. Most bouncer seats also feature an accessory bar with attached toys that are, or at some point will be, within the child’s reach. Most of the bouncer seat models examined by Commission staff provide a 3-point restraint system consisting of wide cloth crotch restraints, and short adjustable waist straps with plastic buckles. Only two models of bouncer seats reviewed by CPSC employed upper body restraints. Many bouncer seat brands also include an “infant insert,” intended for use to support smaller babies. See Tabs C and D, Staff Briefing Package: Infant Bouncer Seats Notice of Proposed Rulemaking, dated September 23, 2015 (“Staff NPR Briefing Package”), available at: [INSERT URL](#).

B. Market Description

Although additional suppliers may exist, CPSC staff identified 22 firms supplying infant bouncer seats to the U.S. market. The 22 identified firms primarily specialize in the manufacture and/or distribution of children’s products, including durable nursery products. The majority of

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the 22 known firms are domestic (including 8 manufacturers and 10 importers). The remaining four firms are foreign manufacturers.¹ In 2013, the CPSC conducted a Durable Nursery Product Exposure Survey (“DNPES”) of U.S. households with children under age 6. Data from the DNPES indicate that an estimated 6.75 million infant bouncers are in U.S. households (with 95% probability that the actual value is between 5.78 million and 7.72 million). Data collected also indicate that about 31 percent of the infant bouncers in U.S. households are currently in use (an estimated 2.09 million infant bouncers, with 95 percent probability that the actual value is between about 1.5 million and 2.68 million). Tab F, Staff NPR Briefing Package.

III. Incident Data

CPSC’s Directorate for Epidemiology, Division of Hazard Analysis is aware of 277 reported incidents involving bouncer seats, including 11 fatalities and 51 injuries, occurring between January 1, 2006 and February 2, 2015. The incidents are based on reports involving victims 12 months and younger in the Injury or Potential Injury Incident (“IPII”), In-Depth Investigation (“INDP”), and Death Certificates (“DTHS”) databases (collectively referred to as Consumer Product Safety Risk Management System data, or “CPSRMS” data). Additionally, CPSC staff found 672 bouncer-related incidents, including two fatalities, reported in the National Electronic Injury Surveillance System (“NEISS”) records retrieved for bouncer incidents from January 1, 2006 to December 31, 2013, involving children 12 months old and younger. A detailed review of the incident data and analysis associated with bouncer seats can be found in Tabs A, B, and D of the Staff NPR Briefing Package.

¹ Determinations were made using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites.

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A. Fatalities

For the reporting periods described in the preceding paragraph, CPSC staff found 11 reported fatalities in the CPSRMS data, and two reported fatalities in the NEISS data. A brief description of each incident follows:

- 120427HCC1640: A 6-month-old died of blunt force trauma to the head when the infant's father lifted him in the bouncer seat. The bouncer collapsed and the child fell out of the back onto carpeted floor. He suffered a linear skull fracture and died the following day.
- 121001HCC2002: A 3-month-old was fed and left to sleep in her bouncer seat. The child's father reported that he found her face down, unrestrained, in the seat. The seat was on the floor, and the child's mother and 2-year-old sister had been asleep on a couch nearby.² Cause of death was positional asphyxia.
- 070214CCC1300: A 2-month-old who suffered from reflux and a respiratory infection was placed, unrestrained, to sleep in a bouncer that was lined with a blanket; the bouncer was on the floor next to the couch where his mother slept for the night. The child turned over in the seat, and was found unresponsive, face down against seat back. Cause of death was positional asphyxia.
- 110726CAA3941: A 3-month-old was placed on an adult bed in an infant bouncer seat, unrestrained, for a nap. The mother reported that the child had fallen out of the seat and she found her face down on the bed. The child was diagnosed with an irreversible anoxic brain injury and died 19 days later.
- 726037034: A 3-month-old was left in a "bouncy (*sic*) seat on an adult bed." Cause of death was probable asphyxia due to suffocation. No further information is available.
- 1051041332: A 4-month-old "suffocated when face down in soft bedding on bouncy (*sic*) seat at home." No further information is available.
- 101012HCC3049: A 6-month-old (born several weeks premature) was placed in a bouncer on the floor (in front of a television) as he was falling asleep while his mother showered. She placed a pillow under the rear legs of the bouncer to raise it. She found the child unresponsive, turned with his face against the side of the bouncer, one leg out of the restraints. Cause of death was positional asphyxia.

² Both a car seat and an infant bouncer were present at the scene. CPSC Health Sciences staff found the information in the report insufficient to determine the hazard that contributed to the fatality in this incident.

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- 080917HBB3900: A 2-month-old in a bouncer was placed in a crib to sleep. She was found suspended, partially upside down, over the side of the bouncer with one leg entwined in the restraints. A depression in the mattress suggests that the child's face was against it. Cause of death was mechanical asphyxia.
- X1490229A: A 4-month-old was swaddled and placed for a nap, unrestrained, in a bouncer, which was then placed on the floor; the child reportedly just started to roll over, but had not done so completely on her own. Her parents found her unresponsive "with her face against the back of the infant seat and half way off the chair from the waist level down ..."; she could not be resuscitated. Cause of death was positional asphyxia.
- 140102HWE0001: A 6-month-old was sleeping, strapped into a bouncer and when she awoke, was moved in the bouncer to a bedroom and left briefly with two toddlers, and possibly a pet dog. When the caregiver returned, she found the chair overturned on the floor with the victim's neck lying over the chair's [toy bar]. The report is inconsistent regarding whether the bouncer was placed initially on the bed or on the floor. HS staff considers the injuries described in the ME's report to be consistent with a fall rather than a tip-over at floor level. The child died five days later. Cause of death was positional asphyxia.
- 140422CAA1573: A 3-month-old was placed to sleep for the evening, unrestrained, in a bouncer on the floor in a room with several other children. Her mother found her five hours later face down in front of the bouncer on the floor and not breathing.
- NEISS: 120328281: The parents of a 5-month-old found him unresponsive, flipped over in the bouncer seat with his leg still through one leg hole. The cause listed was cardiac arrest.³
- NEISS: 130645295: A 2-month-old child had been asleep in a "bouncy"; his father awoke to find the child unresponsive on the floor. The cause of death was cardiac arrest.⁴

Most of the infants' deaths involved the presence of excess bedding in or under the bouncer; placement of the bouncer on a soft surface such as an adult bed; placement of the bouncer in a crib; and carrying or placing the bouncer at an elevated height. Most of the bouncer seat deaths also involved the infant being placed in the bouncer to sleep unrestrained, which allowed the infant unsupervised time and movement within the hazardous environment which

³ CPSC staff found the information in this incident insufficient to determine the hazard that contributed to the fatality because the term "leg hole" was deemed inconsistent with the features of an infant bouncer and because of the lack of detail provided.

⁴ CPSC staff found the information in this incident insufficient to determine the hazard that contributed to the fatality.

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contributed to the death. Tab B, Staff NPR Briefing Package. In nine cases, the child was reported as napping or sleeping and without restraints in five of the nine incidents. In two cases, the child was partially out of the restraints when found; in the case when the bouncer was inside the crib, the child was partially suspended upside down over the side of the bouncer with one leg in the restraints. Moreover, in at least four cases, the child's emerging ability to turn over, resulted in the child's face resting against the conforming surface of the seat back, and this appears to have been a significant factor in causing the child's death. Tab D, Staff NPR Briefing Package.

B. Non-Fatalities

Of the 277 CPSRMS bouncer-related incidents involving children 12 months old and younger, 266 incidents were nonfatal. Fifty-one (51) of these nonfatal incidents reported injuries. Four of the 51 reported injuries involved serious head injuries related to falls from a bouncer placed on an elevated surface. Other reported injuries included skull fractures, leg fractures, head contusions, eye bruises, facial bruises and scratches, a split lip and torn upper frenulum, a finger bruise, leg cuts, leg bruises, heel lacerations, and a blood blister. Because reporting is ongoing, the number of injuries and fatalities associated with bouncer seats are subject to change. See Tab A, Staff NPR Briefing Package.

Incidents involving the infant occupant falling from the bouncer are of most concern to CPSC because falls have the greatest potential for a serious injury. According to Health Sciences staff's analysis, 77 of the 266 nonfatal incidents involved the infant occupant falling from the bouncer. In five of these incidents, the infant occupant fell from a bouncer placed at an elevated height, such as on a kitchen countertop or dining table, or the bouncer was being carried by the caregiver; in four (80%) of these elevated-height incidents, the infant fell from the

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bouncer and sustained a severe head injury. Severe head injuries, such as concussions and fractured skulls, could cause extensive brain damage and affect the infant's motor development, emotional development, speech, ability to think and learn, and overall quality of life, long after the incident has occurred. The majority of the remaining 189 nonfatal incidents that did not involve a fall resulted in no injuries or minor injuries. Only one incident resulted in a moderate injury; in that incident a 3-month-old infant shifted in the bouncer and sustained a fractured leg. See Tab B, Staff NPR Briefing Package.

C. Hazard Pattern Identification for CPSRMS Incidents

To identify hazard patterns associated with infant bouncer seats, CPSC staff considered all 277 reported incidents in CPSRMS involving product-related issues. Tab A, Staff NPR Briefing Package. Product-related issues associated with these incidents include:

Product Design - Seventy-five (75) incident reports describe issues related to bouncer product design. Design issues described in these incident reports consist of sharp plastic rods, uncushioned side metal bars, overhead attachments not clipping properly, sharp pieces of fabric, lack of padding in the footing area, bouncer frames that easily entrap arms/legs/fingers, easily movable feet cushion flaps, sharp plastic grooves from a musical component, sagging seat belts, and lopsided or low-riding bouncer frames. Sixteen of the 75 incidents resulted in injuries, all of which were minor.

Structural Integrity - Seventy (70) incident reports describe issues related to the structural integrity of bouncer components, such as bouncer seats collapsing when picked up, collapsing during use, and releasing fabric from the plastic frame, plus various other structural issues involving broken sides, recline adjustment pieces, wire bases, front tube retainers, and rubber feet. Twelve of the 70 incidents resulted in minor injuries.

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Toy Bar-Related - Thirty-six (36) incident reports involve problems with the toy bar or toys attached to the toy bar. These reports describe the following types of issues: toy bars that fail to snap into place, toy bars breaking after being used as a handle, toys breaking off the bar, toys on the bar swinging back to hit the victim, toys scratching and pinching fingers or toes, and children getting hands or feet caught on the toy attachments. Ten of the 36 incidents resulted in minor injuries.

Stability - Stability issues comprise thirty-three (33) tip-over incidents involving a bouncer seat placed on the floor. While 26 bouncer tip-over incidents resulted in no reported injuries, seven incident reports include injuries such as a split lip, head contusions, and facial bruises.

Chemical/Electric Hazards - Thirty (30) incident reports describe issues related to chemical or electrical hazards, including two reported injuries (a thigh welt and a rash). One incident involved a bouncer seat emanating a toxic smell; another incident involved a victim who developed a rash after directly touching the bouncer; and 28 incidents involved batteries or the vibration motors. Twenty-four of the battery/motor incidents included reports of leaking, cracking, or exploding batteries. Four of the battery/motor incident reports specifically described motor-related issues, which include overheating motors, motors making strange noises, and motors catching on fire, resulting in burning plastic and structural burn marks.

Restraints - Twenty (20) incidents, including two reported minor injuries, involve issues with bouncer restraints, including falling out of bouncer seats despite being strapped in, tearing/fraying straps, non-latching seat belts, and breaking seat buckles.

Hazardous Placement - Eleven (11) incidents involved a hazardous placement of the bouncer where victims in bouncer seats fell from elevated surfaces, fell face down onto soft

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bedding, or suffocated while attempting to slip out of a bouncer seat placed on an unstable surface. One incident included a reported skull fracture injury; another incident involved a fatality resulting from blunt force head trauma; and nine incidents involved fatalities due to asphyxia.

Unknown - Two (2) incidents involved an unknown hazard, including one that involved a reported injury, and one that resulted in a death from positional asphyxia.

D. NEISS Data Analysis

CPSC staff retrieved 672 NEISS records (estimated total of 17,200 injuries) describing infant bouncer seat incidents between January 1, 2006 and December 31, 2013. See Tab A, Staff NPR Briefing Package. Injury estimates are derived from NEISS data, where sampling weights are used to project the number of cases reported by NEISS hospitals to national estimates. A statistically significant upward trend exists in the estimated emergency department-treated injuries involving bouncer seats for victims under 1-year-old from 2006 to 2013.

An estimated 15,500 patients were treated and released for bouncer injuries, and an estimated 1,300 patients were treated and admitted, treated and transferred to another hospital, or held for observation. An estimated 15,100 (92%) bouncer injuries involved the head and face, while 1,300 estimated injuries involved an unknown area, or the rest of the body (appendages, torso, internal). Two cases involved a victim who died from cardiac arrest. One victim died after flipping over in an infant bouncer seat with his leg still through one leg opening, and the other victim was found on the floor unresponsive after being asleep in the bouncer. These two fatalities are in addition to the 11 fatalities reported in CPSRMS.

Of the 672 NEISS records describing bouncer injuries, 287 incidents took place on the floor or an unknown location. The remaining 385 incidents, or an estimated 9,200 injuries,

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involved hazardous placements: 342 of these incidents, or an estimated 8,100 injuries, resulted from falls. Hazardous placements included counters, tables, and other elevated surfaces (*e.g.*, beds, carried or lifted positions, chairs, couches, dressers, stairs, and appliances). An estimated 6,800 injuries, or 74 percent of all estimated bouncer injuries associated with a hazardous placement, involved the bouncer being placed on a counter or table. Health Sciences staff analysis determined that 50 of these hazardous placement incidents resulted in a severe head injury, such as a concussion or fractured skull. Twelve severe head injuries were the result of the caregiver carrying the infant in the bouncer. See Tab B, Staff's NPR Briefing Package. CPSC staff noted two other factors in the fall-related NEISS data. In 54 of the reports, the incident occurred when someone was carrying or picking up the child in the infant bouncer. In 33 of the cases, the child was reported to be unrestrained at the time of the incident; the number of cases of children falling while unrestrained is likely to be underreported.

Eighty-one percent of the incidents resulted in injuries (n=532; estimate=13,900). CPSC staff reviewed the NEISS cases and determined the severity of the reported injuries. Based on that analysis, 11 percent of the injuries were severe, such as skull fractures and intracranial hemorrhages; and 41 percent were moderate, such as less serious head injuries and fractures involving other body parts. CPSC staff concluded that infants were more likely to sustain a severe head injury when they fell from elevated heights, and that the potential for severe head injury increases if the child is being carried in the bouncer, and/or if they are unrestrained in the bouncer.

E. Product Recalls

Since January 1, 2006, Compliance staff conducted two bouncer seat recalls involving two different firms. The first recall, in April 2007, involved 1,400 units of Oeuf, LLC, infant

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bouncer seats.⁵ The bouncer seat was recalled after six reports of tubular steel frame breakage. The second recall of bouncer seats, in July of 2009, involved 6,500 units of BabySwede LLC BabyBjörn® Babysitter Balance and Babysitter Balance Air bouncer seats.⁶ Bouncer seats were recalled because small, sharp metal objects found in the padded area of the bouncer chair could protrude through the fabric, posing a laceration hazard to children. No injuries were associated with either product at the time of the recall. See Tab E, Staff NPR Briefing Package.

IV. International Standards for Bouncer Seats

CPSC staff found no other standard for infant bouncer seats. See Tab C, Staff NPR Briefing Package. However, CPSC staff identified two closely related international standards, BS EN 14036:2003, *Child Use and Care Articles — Baby Bouncers — Safety requirements* (“BS EN 14036”) and BS EN 12790:2002, *Test Methods and Child Care Articles -Reclined cradles* (“BS EN 12790”), which pertain to products with some characteristics similar to infant bouncer seats. The scope of BS EN 14036 does not include bouncers intended for inclined seating; rather, the standard involves products designed to suspend a child, from above, in an essentially vertical, semi-seated position. These products, sold as baby jumpers in the United States, enable the child's toes/balls of the feet to have contact with the floor to activate and maintain the bouncing action. General requirements in BS EN 14036 are similar to ASTM F2167, but are less stringent. Remaining requirements in BS EN 14036 are not applicable to infant bouncer seats.

BS EN 12790 specifies safety requirements and the corresponding test methods for fixed or folding reclined cradles intended for children up to 6 months and/or up to a weight of 9 kg.

⁵ CPSC link to recalled product: <http://www.cpsc.gov/en/Recalls/2007/Infant-Bouncer-Seats-Recalled-Due-to-Frame-Failure/>.

⁶ CPSC link to recalled product: <http://www.cpsc.gov/en/Recalls/2009/BabySwede-LLC-Recalls-Bouncer-Chairs-Due-to-Laceration-Hazard/>.

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Unlike infant bouncer seats, BS EN 12790 is intended to cover non-bouncing products designed to be a safe sleeping environment. BS EN 12790 contains the same general requirements as BS EN 14036. Additional testing in BS EN 12790 includes stability, static strength, dynamic strength, slip resistance, unintentional folding, and restraints. ASTM F2167 contains more stringent stability, static strength, and dynamic testing than BS EN 12790. Slip-resistance tests are substantially similar in both standards. BS EN 12790 contains an unintentional folding test that is not applicable to infant bouncer seats. Finally, although ASTM F2167 does not have a restraint slip test, the restraint strength test requires an additional pull test at 45lb (200 N) to the normal use direction. Accordingly, overall, ASTM F2167-15 is more stringent in most areas than BS EN 12790 and addresses the hazard patterns identified in CPSC's incident data.

V. Voluntary Standard—ASTM F2167

A. *History of ASTM F2167*

A voluntary standard for infant bouncer seats was first approved in December 2001 and published in January 2002, as ASTM F2167-01, *Standard Consumer Safety Specification for Infant Bouncer Seats*. Since then, ASTM has revised the standard nine times. Tab C of the Staff NPR Briefing Package includes a description of each revision. The current version, ASTM F2167-15, was approved on May 1, 2015, and published in June 2015. ASTM F2167-15 includes modified and new performance and labeling requirements developed by CPSC staff, in conjunction with stakeholders on the ASTM subcommittee task group, to address the hazards associated with bouncer seats. A description of the current voluntary standard for bouncer seats follows.

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B. Description of the Current Voluntary Standard—ASTM F2167-15

ASTM F2167-15 includes the following key provisions: scope, terminology, general requirements, performance requirements, test methods, marking and labeling, and instructional literature.

Scope. Section 1 of ASTM F2167-15 states the scope of the standard, detailing what constitutes an “infant bouncer seat.” As stated in section II.A of this preamble, the Scope section defines an “infant bouncer seat” as “a freestanding product intended to support an occupant in a reclined position to facilitate bouncing by the occupant, with the aid of a caregiver or by other means.” ASTM F2167-15 states that infant bouncer seats are intended for “infants who have not developed the ability to sit up unassisted (approximately 0 to 6 months of age).”

Terminology. Section 3 of ASTM F2167-15 provides definitions of terms specific to this standard. For example, section 3.1.1 of the ASTM standard defines “conspicuous” to mean a “label that is visible, when the infant bouncer seat is in a manufacturer’s recommended use position, to a person sitting near the infant bouncer seat at any one position around the infant bouncer seat but is not necessarily visible from all positions.”

General Requirements. Section 5 of ASTM F2167-15 addresses numerous hazards with several general requirements, most of which are also found in the other ASTM juvenile product standards. Several requirements reference an existing CPSC standard. The following general requirements apply to bouncer seats. Where the ASTM standard relies on a CPSC mandatory standard, the mandatory standard is cited in parentheses next to the requirement:

- Hazardous sharp points and edges (16 CFR 1500.48 and 1500.49);
- Small parts (16 CFR 1501);
- Lead in paint (16 CFR 1303);

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- Banned articles (16 CFR 1500.18(a)(6) and 1500.86(a)(4));
- Wood parts;
- Latching and locking mechanisms;
- Scissoring, shearing, and pinching;
- Openings;
- Exposed coil springs;
- Protective components;
- Permanency of labels and warnings; and
- Toys (ASTM F963).

Performance Requirements and Test Methods. Sections 6 and 7 of ASTM F2167-15 contain performance requirements specific to bouncer seats, as well as test methods that must be used to assess conformity with such requirements. Below is a discussion of each performance requirement and the related test method.

- **Restraints.** ASTM F2167-15 requires that restraints be provided with a bouncer seat that are capable of securing a child when the bouncer is placed in any use position recommended by the manufacturer. ASTM F 2167-15 requires both a waist and a crotch restraint, and the restraint must be designed in such a way that the crotch restraint must be used when the waist restraint is in use. The standard specifies that the restraint's anchorages shall not separate from the attachment points to the bouncer when tested. Testing to this requirement is performed by securing the bouncer seat and applying a 45lb (200N) force for a period of 10 seconds to a single attachment point of the restraint in the normal use direction. Although no provisions in the performance requirements address the actual use of the restraint, ASTM F2167-15 contains a warning label requirement regarding proper use of the restraint.

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- **Stability.** ASTM F2167-15 includes a test for bouncer stability in each direction, forward, sideward, and rearward. In the forward stability test, an infant CAMI dummy is placed in the infant bouncer and the restraints are adjusted to fit in accordance with the manufacturer's instructions. The dummy is then removed and the stability test fixture is placed in the seat. A vertical static force of 21lb (93N) or three times the manufacturer's recommended weight, whichever is greater, is applied for 60 seconds to the fixture at a distance of 6in (152.4mm) in front of the crotch post. To pass the test, the bouncer must not tip over or the front edge must not touch the test surface.

Repeatable stability testing in the sideward and rearward directions is more difficult to accomplish based on a bouncer's potential shifts in the center of gravity. Because of these potential shifts, sideward and rearward testing for bouncers is done differently than in the forward direction. The current sideward and rearward stability tests are performed with the infant CAMI dummy placed in the seat and the bouncer placed on a 20-degree incline in the most unstable orientation other than forward. To pass the test, the bouncer must not tip over in this position.

- **Slip Resistance.** The slip resistance test is designed to keep bouncers from traveling across a surface while being used by a child. Bouncers placed on smooth, hard surfaces, such as a kitchen counter, are less likely to creep along the surface while a child is in the seat, if the product is designed to meet the slip resistance requirement. The slip resistance requirement in ASTM F2167-15 includes both static and dynamic components. The static slip resistance test is performed on a smooth laminate surface with a matte finish and a 10-degree incline. A 7.5lb (3.4kg) CAMI dummy is placed in the bouncer with the front of the bouncer facing down the incline. The bouncer must not move down the incline more than 1/8 in. (3mm)

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in 1 minute. The test is repeated with the bouncer seat oriented with the left, right, and rear sides pointed down the incline.

In the dynamic slip resistance test, a test fixture is placed in the bouncer seat with a 7.5lb (93.4kg) weight, and the bouncer is placed on the 10-degree inclined surface. Additionally, if the bouncer has a feature, such as a vibration unit, the unit is to be turned on during the test. An additional 2.5lb (1.13kg) weight is dropped onto the test fixture from a height of 6 in. (152.4mm) a total of 10 times. To pass, the bouncer seat is not allowed to move more than 1/2in (13mm) during the test. This test is repeated with the bouncer in the remaining sideways and rear orientations.

- **Structural Integrity and Disassembly/Collapse.** ASTM F2167-15 requires that bouncer seats pass a series of three tests to evaluate structural integrity: (1) a static load test; (2) a dynamic load test; and (3) a disassembly/collapse test.

To pass the first two tests, at the conclusion of the tests, the bouncer seat shall have no failure of seams, breakage of materials, or changes of adjustments that could cause the product not to fully support the child or that creates a hazardous condition outlined in the general requirements of the standard. The static load test requires that a 6"x6"x3/4" (152.4x152.4x1.91 mm) wood block be placed in the bouncer seat and loaded with the greater of 60lb (27.3kg), or 3 times the manufacturer's recommended maximum weight, whichever is greater. The test is intended to ensure that the bouncer design is sufficient to hold the weight of any child that is likely to use the product.

The dynamic load test requires that a 6" (152.4mm) weld cap be dropped from a distance of 1" (25mm) with the convex surface face down onto the bouncer seat. Extra weight is added to the weld cap to provide a total weight of 33lb (15kg). The drop for the dynamic load test is

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repeated a total of 100 times. This test simulates the child being placed in the seat and removed, as well as the forces applied to the bouncer while the child is in the seat. This test provides a reasonable factor of safety to ensure that the bouncer seat does not fail when used in accordance with the manufacturer's recommendations.

The disassembly/collapse test simulates lifting the bouncer by the ends with a child seated in the product to see whether the bouncer collapses or folds up into a position that might result in injury. To conduct the test, a newborn CAMI dummy is placed in the bouncer seat and a 15lb (67N) force is applied to the bouncer at the location most likely to cause disassembly. In situations where multiple locations are present that could result in disassembly, the test is repeated for each location. If a hazardous condition results from the test, the bouncer fails the requirement. A hazardous condition is anything that would result in the bouncer not meeting the general requirements, or any visual indications of disassembly or collapse of the bouncer.

- **Drop Test.** The drop test is intended to evaluate the durability of bouncer seats in instances of misuse, and to assess compliance with the general safety requirements, such as small parts, sharp points, and sharp edges. The drop test applies dynamic forces to the bouncer in directions not associated with normal use by a child. The bouncer must be dropped from a height of 36" (914.4mm), once in each of six different planes (top, bottom, front, rear, left side, and right side). If the bouncer is of a folding design, the six drops must be done in both the folded and unfolded configurations (for a total of 12 drops). At the end of the test, the bouncer must meet the general requirements outlined in Section 5.0 of the standard.

- **Toy Bar Attachment Integrity.** ASTM F2167-15 includes general performance requirements to test toy bars on bouncer seats. A static test is performed with a 6"x6"x3/4" (152.4x152.4x1.91 mm) wood block placed in the bouncer seat and loaded with the greater of

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40lb (18.2kg) or two times the manufacturer's recommended maximum weight. The bouncer is then gradually lifted. In the dynamic test, an infant CAMI is placed in the seat and a cable is attached to the center grasping point of the handle. The bouncer is raised and allowed to drop 2" (5.1cm). The toy bar must completely release from the bouncer or move less than 2" (5.1cm) from the resting position if the bar has a single attachment point. Additionally, individual toys included with the bouncer are required to meet the general requirements in the standard.

- **Battery Compartments.** ASTM recently added battery and containment requirements to F2167. The new requirements include permanently marking the correct battery polarity adjacent to the battery compartment, providing a means to contain the electrolytic material in the event of battery leakage, protection against the possibility of charging non-rechargeable batteries, and defining a maximum surface temperature for any accessible component. The battery polarity requirement requires a visual inspection of the battery compartment. Surface temperature and charging protection are accomplished through the performance of an operational test. The bouncer is operated using new batteries of the type recommended by the manufacturer. Testing is performed by operating the bouncer at the highest setting for 60 minutes. Upon conclusion, no battery leakage, explosion, or fire can occur, and no accessible component shall exceed 160°F degrees (71°C). The performance requirement includes a provision for testing using a/c power; but staff is unaware of bouncers currently on the market that are a/c powered.

Marking and Labeling. Section 8 of ASTM F2167-15 requires products to be marked or labeled with manufacturing information and relevant product warnings.

- **Manufacturing Information.** Section 8.1 requires that each product and its retail packaging be marked or labeled, clearly, legibly, and permanently, to include the name and

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address of the manufacturer, distributor, or seller, and a code or other means to identify the date of manufacture. Section 8.2 states that a manufacturer should change the model number when the product undergoes a significant structural or design change that affects conformance to the standard.

- **Product Warnings.** CPSC staff and the ASTM task group and subcommittee worked to improve the warning label requirements for bouncer seats in section 8.3 of ASTM F2167 to address the hazard of falls from elevated surfaces. ASTM F2167-15 includes several changes to the warnings requirements intended to address this hazard, as well as suffocation. Bouncer seats must be labeled with two groups of warning statements, a fall hazard warning and a suffocation warning. ASTM F2167-15 includes new content on color in the warning labels, placement of the fall hazard warning on the front of the product, and changes to the suggested warning language for both falls and suffocation. As set forth in more detail in section VI of the preamble, CPSC is proposing to include additional changes to the warning label requirements to address the deaths and injuries associated with infants falling from bouncer seats, and associated with infants falling while remaining in the seat, that occur when caregivers place bouncer seats on an elevated surface.

Instructional Literature. Section 9 of ASTM F2167-15 requires that instructions be provided with bouncer seats and be easy to read and understand. Additionally, the section contains requirements relating to instructional literature contents, including warnings.

VI. Assessment of the Voluntary Standard ASTM F2167-15

CPSC staff examined the relationship between the performance requirements in ASTM F2167-15 and each of the hazard patterns identified in section III.C of this preamble. Tab C, Staff NPR Briefing Package. Based on staff's assessment, CPSC finds that the current voluntary

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standard, ASTM F2167-15, adequately addresses the mechanical hazard patterns identified in the incident data associated with bouncer seats. However, CPSC finds that the warning label requirements in ASTM F2167-15 can be improved to address infant falls from bouncers placed on an elevated surface. At this time, such falls cannot be addressed by a performance requirement for bouncer seats. Addressing incidents when infants fall from bouncer seats, as well as incidents when infants fall while remaining in the seat, will require a change in caregiver behavior. Accordingly, CPSC is proposing to strengthen the requirements for the warning label to increase compliance by caregivers and reduce the risk of injury to infants. Tab D, Staff NPR Briefing Package.

The following section discusses how each of the product-related hazard patterns identified in section III.C of this preamble is addressed by the current voluntary standard, ASTM F2167-15. Where CPSC is proposing additional requirements, the rationale for these changes is also explained.

A. *Product Design* – CPSC staff evaluated the current requirements in ASTM F2167 and tested bouncer samples to the tests for product design. The performance requirements to test for hazards related to product design are the same as those used to test for structural integrity. Additionally, the drop test and the general requirements in Section 5.0 are used to address this hazard pattern. CPSC staff found that each type of failure identified in the incidents is addressed in the standard with performance requirements and associated tests. CPSC staff opined that many of the incidents may be the result of manufacturing, shipping, or consumer assembly-related issues. Accordingly, at this time, the Commission does not believe that adding or strengthening requirements is likely to reduce the occurrence of these incidents, and the current performance requirements are adequate to address this hazard pattern.

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B. *Structural Integrity* – As reviewed in section V.B of this preamble, ASTM F2167-15 subjects infant bouncers to a series of three tests to evaluate structural integrity including: (1) a static load test; (2) a dynamic load test; and (3) a disassembly/collapse test. After reviewing the available incident information, CPSC staff concluded that it is likely that many of the incidents included in the structural integrity category are the result of product misassembly, and may not be the result of product design. CPSC staff opined that the three structural tests subject infant bouncers to the reasonable forces that could be applied during the normal life of the product and adequately test the structural strength of a bouncer. Based on staff’s assessment, the Commission is not proposing to add more stringent performance requirements at this time.

C. *Toy Bar-Related* – Based on staff’s assessment of the standard, the toy bar requirements in ASTM F 2167-15 are adequate to address the identified hazards. Staff evaluated many bouncers that included a bar designed with small toys attached that hang over the body of a child seated in the bouncer. Individual toys included with the bouncer are required to meet the general requirements in the standard, including ASTM F 963. Additionally, the toy bar is required to meet the toy bar integrity test requirement. The toy bar integrity requirement uses two different tests, a static integrity test and a dynamic integrity test, to address incidents in which the toy bars are used as handles. CPSC is unaware of any injuries involving toy bars releasing when being used as a handle that have occurred since 2012, when the toy bar integrity tests were added to ASTM F2167. Although many of the recent toy bar incident reports describe consumer complaints about the toy bar releasing or bending, CPSC does not consider these reports to be safety related, because the toy bars are specifically designed to perform in a manner that does not allow a consumer to use the toy bar as a handle, and no reported injuries resulted from these incidents.

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D. *Stability* – ASTM F2167-15 adequately addresses stability-related incidents.

CPSC staff worked with the ASTM subcommittee on bouncers to modify and enhance all the stability performance requirements. Beginning with ASTM F2167-14, the rear and side stability tests were strengthened by ASTM when the angle of incline was from 12 to 20 degrees. Additional changes in ASTM F2167-15 include a longer distance between the crotch post of the test fixture and the application of force for the forward stability test. Changes to the stability requirements will require the design of increasingly stable bouncer designs similar to ones currently available. CPSC believes that these additional requirements will reduce the likelihood of bouncer tip overs and associated injuries.

E. *Chemical/Electrical Hazards* – To address reported chemical and electrical incidents, ASTM recently added battery and containment requirements to the 2015 version of ASTM F2167. These additional requirements were developed with support from CPSC staff and based on the incidents reported to CPSC. New requirements include permanently marking the correct battery polarity adjacent to the battery compartment, providing a means to contain the electrolytic material in the event of battery leakage, protection against the possibility of charging non-rechargeable batteries, and defining a maximum surface temperature for any accessible component. Based on CPSC staff's assessment, CPSC believes that the new battery requirements adequately address reported electrical incidents by reducing the likelihood of overheating and battery leakage incidents.

F. *Restraints* – ASTM F2167-15 adequately addresses mechanical incidents involving restraints. ASTM F2167-15 requires that restraints be provided with a bouncer seat. Restraints must be capable of securing a child when the bouncer is placed in any use position recommended by the manufacturer. ASTM F 2167 requires both a waist and a crotch restraint,

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and the restraint must be designed in such a way that the crotch restraint must be used when the waist restraint is in use. Additionally, on-product warning information regarding use of restraints is required. See Tab D, Staff NPR Briefing Package. As described below in section VI.G.1, CPSC is proposing additional language for the product warning label to address incidents involving children who fell from bouncers when placed, unrestrained, to sleep.

G. *Hazardous Placement* – Hazardous placement of bouncer seats occurs when caregivers place bouncers in a hazardous environment, resulting in suffocation or head injuries. Factors that contribute most to these hazards include the presence of excess bedding in or under the bouncer; placement of the bouncer on a soft surface, such as an adult bed; placement of the bouncer in a crib; the infant being placed in the bouncer to sleep unrestrained, which allows the infant unsupervised time and movement within the hazardous environment; and carrying or placing the bouncer at an elevated height. ASTM F2167 addresses hazardous placement of bouncer seats with tests for stability and slip resistance, designed to keep bouncers from traveling across a surface while being used by a child. These performance requirements may help reduce the risk of injury in hazardous placement.

Although the standard includes performance testing for better stability and slip resistance, addressing hazardous placement incidents with performance requirements is difficult because the hazard scenario involves consumer behavior, a foreseeable misuse of the bouncer seat, which should be used only on the floor. Accordingly, CPSC is proposing modifications to the text, placement, and formatting of warnings requirements and instructional literature requirements of ASTM F2167-15 to help further reduce injuries related to this hazard pattern. A detailed description of staff's assessment, rationale, and citations to the relevant literature for the recommended changes appear in Tab D of the Staff's NPR Briefing Package.

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1. Modifications to the Warning Label Content

The Commission proposes to add two components to the warning statements for bouncer seats that are absent in ASTM F2167-15: (1) the phrase “even if baby is sleeping” to the warning to use restraints; and (2) developmental guidance on when to stop using the product to help avoid suffocation and fall risks. In general, guidelines for warning statements agree that warnings should identify the hazards, the consequences, and the means to avoid them (*e.g.*, Madden, 2006; Singer, Balliro, & Lerner, 2003, October). The content of the proposed modified warnings meets these requirements by calling attention to each of the behaviors that are related to the specific hazards identified, and advising caregivers how to avoid those hazards.

(a) Use of Restraints

“Always use restraints” is a part of the warnings and instructions in the current version of ASTM F2167, and has been so over many editions of the standard. Based on the incident data relating deaths to suffocation among unrestrained infants while they slept, and serious head injuries to unrestrained infants in falls from bouncer seats that are placed on elevated surfaces and falls from bouncer seats that are being carried, CPSC believes that the current requirement is inadequate to address the risk of injury to infants from falls out of bouncer seats, or the risk of suffocation among unrestrained infants who are sleeping.

The Commission’s proposed warning language includes the statement, “Adjust to fit snugly, *even if baby is sleeping.*” ASTM F2167-15 lacks the phrase that addresses sleeping. CPSC staff reports that while working with ASTM, some ASTM members expressed the opinion that “Always use restraints” is adequate because it allows for no exceptions to the use of restraints, and contended that the staff’s recommended language communicates that the product is intended for use as a place for the child to sleep, and may encourage such use. One member

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was concerned that including language regarding sleep may suggest that manufacturers should bring bouncers into compliance with requirements for products that are designed for sleep.

Although the Commission understands the marketing concerns of some manufacturers, the proposed rule addresses how caregivers use bouncer seats, the sleeping activity of infants that are intended to use the product, and the deaths and injuries reflected in the data when caregivers fail to use restraints. Accordingly, to address caregiver behavior, it is essential to include language that conveys the hazard associated with allowing a child to sleep in a bouncer seat while unrestrained. The Commission's concern is that young infants, such as those intended to use bouncer seats, spend more time asleep than awake.⁷ Infants that spend more than brief periods in a bouncer seat will fall asleep on occasion (and caregivers will place infants to sleep for the night in bouncer seats under some circumstances), just as infants fall asleep in strollers, swings, and car-seat carriers. It may be counterintuitive, and therefore unlikely to occur to consumers, that products made for infants' use, especially those that have features intended to sooth and comfort them, would be unsafe places for infants to sleep. In fact, despite claims that bouncer seats are not intended for children to sleep in, CPSC staff found that some manufacturers' marketing suggests that bouncers are intended for sleep as well as play.

Caregivers may remove or loosen restraints while a child is sleeping in a bouncer seat. Removing or loosening product restraints while a child naps or sleeps is a known hazard pattern across infant products that use restraints. It is foreseeable that some caregivers will perceive the restraints as uncomfortable and unnecessary (Lerner, Huey, & Kotwal; 2001), particularly for younger users, who may be seen as not yet mobile enough to be at risk of falling out of the bouncer, and even less at risk of falling if the infant is asleep. CPSC's proposed warning

⁷ For example, see the American Academy of Pediatrics website, <http://www.healthychildren.org/English/ages-stages/baby/sleep/Pages/default.aspx>.

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statement addresses the fact that a child *will* sleep in the bouncer, and addresses caregivers' known inclination to loosen or remove the restraints by specifying that they should do the opposite to avoid the risk of injury or death from the child falling from the bouncer seat or turning in the seat.

(b) Developmental Guidance

The second modification to ASTM F2167-15 in CPSC's proposed warning content is in the developmental guidance given in the suffocation warning and in the product instructions. The warning in the current ASTM standard includes the developmental statement: "never use for a child able to sit up unassisted," a milestone which, on average, a child will accomplish at about 6 months of age. Some packaging and instructions that CPSC staff reviewed also stated that the product is for use from birth *until* the child is able to sit up unassisted, and use a weight limit (25 lb) that reflects a 50th percentile 18-month-old. The Commission is concerned that this combination of guidance leads caregivers to use the product beyond the point that it is safe. Before infants can sit steadily by themselves, they lack upper body and torso control, but actively try to sit, turn, and reach for objects. Infants in bouncer seats are supported in an inclined position with their upper body unconstrained. The infant's actions may cause them to hang over the side or front, fall out or tip over the bouncer, or turn into the surface of the seat where the flexible, conforming design of the seat can compromise the external airways.

CPSC proposes that the bouncer seat warning label and product instructions advise caregivers to stop using the product when children start trying to sit up. On average, children reach this milestone at 4.8 months.⁸ CPSC staff recommended this milestone based on the data indicating that most witnessed instances in which the child's activities reportedly preceded tip-

⁸ Range, 3–8 months. Bayley, N. (1969). *Manual for the Bayley Scales of Infant Development*. New York, NY: The Psychological Corporation.

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overs or resulted in the child hanging out of the bouncer involved children 5 months of age or younger.

2. Modifications to Warning Label Placement

Language in ASTM F2167-15 requires the fall hazard warning to appear anywhere on the front surface of the product's seat back. To address hazards, warning labels must be conspicuous, formatted to help attract and maintain attention, and include appropriate instructional content. Accordingly, CPSC proposes that the fall hazard warning label be required to be on the front of the product near the infant's head to increase the likelihood that caregivers will notice it, and comply with its recommendations, at decision points affecting the child's safety. This location near the infant's head was adopted for warnings on hand-held infant carriers in 16 CFR part 1225, *Safety Standard for Hand-Held Infant Carriers* ("HHIC"; FR 78, No. 235; 73415, December 6, 2013) and the National Highway Transportation Administration's ("NHTSA") car seat standard, 49 CFR 571.213 Federal Motor Vehicle Safety Standard ("FMVSS") No. 213.

CPSC's research indicates that placement of the warning label near the child's face on the bouncer seat is essential in the effort to influence caregivers' behavior. Research indicates that the location of a warning label plays a vital role in its salience, a crucial factor in effectiveness (*cf.* topic reviews by Lesch, 2006; Silver & Braun, 1999). ASTM F2167-15 requires only that the label be *visible* on the front surface of the seat back with the Newborn CAMI manikin placed in the seat. The Commission is concerned that, because of its artificial and static nature, the test procedure in ASTM F2167-15 for visibility of the fall hazard warning label is unlikely to replicate visibility of the label under normal conditions of product use. In addition to allowing considerable variability in the conspicuity of the label location, a basic flaw in this method is the

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assumption that what is visible under static test conditions will be visible during routine use. A label below the shoulder level or along the torso down to the seat bight may be covered by parts of the child's body or clothing, and the area may be covered by a blanket, including an accessory cover that comes with at least one product.

Because a label must be seen to have an effect, visibility is a prerequisite to effectiveness. Visibility, in itself, however, is an insufficient requirement. Given the number, type, and severity of the incidents that prompted the revisions to the warnings, the appropriate criterion is that the label be likely to draw the caregiver's attention at any decision point that may affect safe use. As with the required labeling for hand-held infant carriers, the warning label should be near the child's face because that is where the caregiver's attention is most likely to be focused. This is the most conspicuous location on the product and offers the best opportunity to influence the caregiver's behavior.

During the ASTM process, when CPSC staff suggested locating the fall hazard warning next to the infants' head, ASTM subcommittee members expressed concerns that (1) common label materials present potential abrasion and cut hazards if adjacent to an infant's face; (2) the location is design-restrictive for smaller models because of the size of the label; and (3) due to space restrictions, the location is challenging for those firms that use labels in multiple languages.

Based on staff's review of bouncer seats and the identified issues, the Commission believes these issues can be resolved. As noted above, CPSC's proposed location for the fall hazard warning is the same as that recently adopted for warnings on infant car seats that are also hand-held carriers. NHTSA adopted this location for its air bag warning in these products in the late 1990's, based on its own research. CPSC staff examined car seats and found that both heat

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transfer and sewn-on labels, the latter of which was identified by industry as a concern, are used on car seats. CPSC's project manager for the hand-held carrier standard reported that neither injuries nor space requirements due to the need to produce labels in multiple languages were raised as concerns for hand-held carriers. Firms that produce infant car seat carriers have managed these issues successfully. CPSC staff contacted NHTSA staff responsible for routine data review, who confirmed that there have been no complaints of injury of any type resulting from car seat labels near a child's face. Finally, CPSC's proposed label is approximately 2.25 inches long and 2.0 inches wide. Review of hand-held infant carriers that are also infant car seats, which require a larger⁹ label for both the CPSC mandated strangulation warning and the NHTSA-mandated air bag warning, suggests that there is at least as much space, and perhaps more, on many infant bouncer models, as on car seat carriers.

Although no voluntary or mandatory requirement exists for multiple languages on products sold in the U.S., given the relatively small size of the proposed warning label, multiple options appear available to firms for placement of the fall hazard warning in multiples languages. For example, the warning label could appear in a different language on either side of the child's head, as suggested by the Canadian representative to the task group; different labels could be made for different markets; or the label length could be extended to accommodate additional languages, as some firms have done with infant car seat labels.

3. Modifications to Warning Label Format

ASTM F2167-15 (1) allows the text and the background of the warning label, except for the area behind the word "WARNING," to be any color as long as it is contrasting, and (2) provides no format guidance. Although example labels with CPSC's recommended format are

⁹ The message panel of the air bag warning alone must be no smaller than 30 cm² (11 in.²); the pictogram must be at least 30 mm in diameter (1.18 in.).

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presented in the voluntary standard, the standard includes the permissive statements that the figures “. . . are presented as EXAMPLES ONLY . . . [emphasis in original]” and that the format and “wording content,” as well as the use of highlighting, “are at the discretion of the manufacturer.”

The Commission proposes that the formatting requirements for bouncer seats reflect the format shown in the label in Figure 1. Good formatting helps attract and maintain attention, and aids reading and comprehension. Information is processed more quickly and easily when it is organized by content into brief chunks. CPSC is concerned that the quoted statements make it likely that some firms will continue to use poor quality labels that present warning information in a cluttered paragraph style that is difficult to read, rather than a label that is conspicuous, easy to read, and easy to comprehend, as is the recommended warning label.

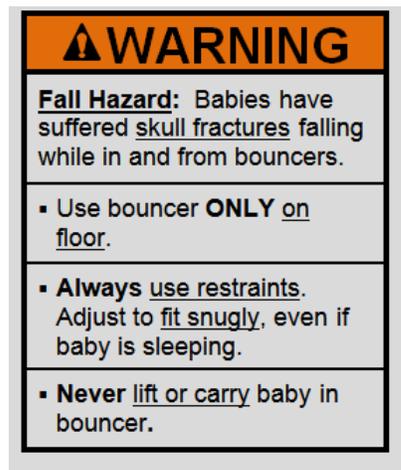


Figure 1

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VII. Proposed CPSC Standard for Bouncer Seats

The Commission concludes that ASTM F2167-15 adequately addresses most of the hazards associated with bouncer seats, but proposes to modify the warning label requirements to increase effectiveness aimed at changing caregiver behavior to further reduce the risk of injury to infants from falls. Thus, the Commission proposes to incorporate by reference ASTM F2167-15 with the following modifications to the warning label requirements:

- Revise the content of the warnings, markings, and instructions to:
 - add text to the warnings that states to use the restraints “... even if baby is sleeping ...”;
 - change the text in the warnings to read, “stop using when baby starts trying to sit up”; and
 - change the developmental guidance in the instructions, if stated, to read, “from birth (or “0”) until baby starts trying to sit up.”
- Require that the fall hazard label be located on the front surface of the bouncer adjacent to the area where the child’s head would rest, and modify the current visibility test to reflect this requirement.
- Specify a standard format (including black text on a white background, table design, bullet points, and black border) for the warnings on the product and in the instructions.

VIII. Amendment to 16 CFR part 1112 to Include NOR for Bouncer Seat Standard

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

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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 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 1229, *Safety Standard for Infant Bouncer Seats*, 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 infant bouncer seat standard, require an amendment to part 1112. To meet the requirement that the Commission issue an NOR for the proposed bouncer seat 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 bouncer seats 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 bouncer seats 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

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laboratory can apply to the CPSC to have 16 CFR part 1229, *Safety Standard for Infant Bouncer Seats*, 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.

IX. Incorporation by Reference

Section 1229.2(a) of the proposed rule would incorporate by reference ASTM F2167-15. The Office of the Federal Register ("OFR") has regulations concerning incorporation by reference. 1 CFR part 51. The regulations require that, for a proposed rule, agencies 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 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 V.B. of this preamble summarizes the provisions of ASTM F2167-15 that the Commission proposes to incorporate by reference. ASTM F2167-15 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 F2167-15 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.

X. 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). The Commission is

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proposing an effective date of 6 months after publication of the final rule in the *Federal Register*. Without evidence to the contrary, CPSC generally considers 6 months to be sufficient time for suppliers to come into compliance with a new standard, and a 6-month effective date is typical for other CPSIA section 104 rules. Six months is also the period that the Juvenile Products Manufacturers Association (“JPMA”) typically allows for products in the JPMA certification program to transition to a new standard once that standard is published. We also propose a 6-month effective date for the amendment to part 1112. We ask for comments on the proposed 6-month effective date.

XI. Regulatory Flexibility Act

A. Introduction

The Commission is issuing a proposed rule under the requirements of section 104 of the Consumer Product Safety Improvement Act (“CPSIA”) that would incorporate by reference the most recent ASTM standard for infant bouncer seats, ASTM F2167-15, with several modifications to the requirements for product warnings and instructional literature. In this section, we summarize staff’s evaluation of the potential economic impact of the proposed rule on infant bouncer seats on small entities, including small businesses, as required by the Regulatory Flexibility Act (“RFA”). 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 notice of proposed rulemaking (“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. The IRFA must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. See Tab F, Staff NPR Briefing Package.

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B. The Product

An infant bouncer seat is defined in ASTM F2167-15, *Standard Consumer Safety Specification for Infant Bouncer Seats*, as “a freestanding product intended to support an occupant in a reclined position to facilitate bouncing by the occupant, with the aid of a caregiver or by other means.” It is intended for “infants who have not developed the ability to sit up unassisted (approximately 0 to 6 months of age).” These products vary widely in price; they can be purchased for as little as \$20, but can also easily cost more than \$200.

C. The Market for Infant Bouncer Seats

Staff identified 22 firms (including large and small) supplying infant bouncer seats to the U.S. market, although there may be additional firms as well. These firms specialize primarily in the manufacture and/or distribution of children’s products, including durable nursery products. The majority of the 22 known firms are domestic (including 8 manufacturers and 10 importers). The remaining four firms are foreign manufacturers.¹⁰ Staff expects that the infant bouncer seats of 17 of these firms are already compliant with ASTM F2167 because the firms either: (1) have their bouncers certified by the Juvenile Products Manufacturers Association (“JPMA”) (six firms); (2) claim compliance with the voluntary standard (ten firms); or (3) have been tested to the ASTM standard by CPSC staff (one firm).¹¹

¹⁰ Determinations were made using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites.

¹¹ JPMA typically allows 6 months for products in their certification program to shift to a new standard once it is published. The version of the standard that firms are likely testing to currently is ASTM F2167-14. Two newer versions of the standard have been published since then, but neither will become effective for JPMA certification purposes before September 2015. Additionally, many infant bouncer seats are expected to be compliant with ASTM F2167-14a without modification, and firms compliant with earlier versions of the standard are likely to remain compliant as the standard evolves.

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D. Reason for Agency Action and Legal Basis for the Proposed Rule

Section 104 of the CPSIA requires the CPSC to promulgate a mandatory standard for infant bouncer seats that is substantially the same as, or more stringent than, the voluntary standard if the Commission determines that a more stringent standard would further reduce the risk of injury associated with such products.

CPSC staff worked closely with ASTM to develop the revised requirements, test procedures, and warning labels that have been incorporated into ASTM F2167 since the rulemaking process started in January 2013 in an effort to reduce this risk. However, not all of staff's warning label recommendations were adopted into the most recent version of the voluntary standard, ASTM F2167-15. Therefore, the Commission proposes to incorporate by reference ASTM F2167-15, with the remaining modifications staff recommended to ASTM.

E. Requirements of the Proposed Rule

The Commission proposes adopting the voluntary ASTM standard for infant bouncer seats (ASTM F2167-15) with additional changes to the warning labels (in particular, the location of the fall hazard warning label) and a test to ensure the visibility of those labels on the product. A description of the current voluntary standard appears in section V of this preamble, and a description of the proposed modifications to the warning requirements appears in section VII of this preamble.

All firms would need to modify the text of their warnings for both the product and the instruction manual. The fall hazard warning would need to be re-located next to the child's head¹² and be visible when accessories are in use (such as a toy bar or an infant insert used for supporting a smaller child's upper body).

¹² The warning was only recently moved to the front of the bouncer (ASTM F2167-15).

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Staff discussed these changes with several ASTM members and supplier representatives. The possible economic impact of these changes on small business is discussed in Tab F of Staff's NPR Briefing Package and in section XI.G of this preamble.

F. Other Federal or State Rules

No federal rules duplicate, overlap, or conflict with the proposed rule.

G. Impact on Small Businesses

CPSC is aware of approximately 22 firms (large and small) currently marketing infant bouncer seats in the United States, 18 of which are domestic. Under U.S. Small Business Administration ("SBA") guidelines, a manufacturer of infant bouncer seats is categorized as small if it has 500 or fewer employees, and importers and wholesalers are considered small if they have 100 or fewer employees. Our analysis is limited to domestic firms because SBA guidelines and definitions pertain to U.S.-based entities. Based on these guidelines, about 12 of the 22 firms are small—five domestic manufacturers and seven domestic importers. Additional unknown small domestic infant bouncer seats suppliers may be operating in the U.S. market.

1. Small Manufacturers

The economic impact of the proposed bouncer standard should be small for the five small domestic manufacturers, apart from third party testing costs. The bouncers of all of these firms already comply with the ASTM voluntary standard currently in effect for testing purposes (F2167-14). These firms are expected to remain compliant with the voluntary standard as it evolves, because they follow and, in at least three cases, actively participate in the standard development process. Therefore, compliance with the voluntary standard is part of an established business practice. ASTM F2167-15, the version the Commission proposes to

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incorporate, will be in effect by the time the mandatory standard becomes final and these firms are likely to be in compliance based on their history.

None of the small manufacturers typically includes more than four languages in their warnings (two firms use two languages; two firms use three languages; and one firm uses four languages). Based upon inspection of their products and the space available for the warnings, redesign should not be required for any of the bouncers supplied by the known small manufacturers. The firm using four languages might opt to redesign to give their product(s) a less cluttered appearance. However, discussions with a firm representative contacted by staff indicated that the firm was not concerned about the location of the warning labels.

Under section 14 of the CPSA, once the new infant bouncer seat requirements become effective, all manufacturers will be subject to the third party testing and certification requirements of the CPSA and the Commission's rule *Testing and Labeling Pertaining to Product Certification* at 16 CFR part 1107 ("the 1107 rule"). Third party testing will include any physical and mechanical test requirements specified in the final infant bouncer seats rule. Manufacturers and importers should already be conducting required lead testing for bouncers. Third party testing costs are in addition to the direct costs of meeting the infant bouncer seats standard.

All infant bouncer seats sold by U.S. manufacturers are currently tested to verify compliance with the ASTM standard, though not necessarily via third party. Thus, the impact to testing costs will be limited to the difference between the cost of third party tests and the cost of current testing regimes. As a frame of reference, suppliers have estimated that testing to the ASTM voluntary standard typically costs about \$560-\$800 per model sample. Based on an examination of firm revenues from recent Dun & Bradstreet or ReferenceUSAGov reports, the

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impact of third party testing to ASTM F2167-15 is unlikely to be economically significant for most small manufacturers (*i.e.*, testing costs will be less than 1 percent of gross revenue).

Although the Commission does not know how many samples will be needed to meet the “high degree of assurance” criterion required in the 1107 rule, over 24 units per model would be required to make testing costs to exceed one percent of gross revenue for the small manufacturer with the lowest gross revenue. One firm has a much larger number of infant bouncer models than the other small manufacturers, however, and its testing costs could exceed 1 percent of gross revenue if as few as seven units per model were required for testing. Note that this calculation assumes the rule would generate *additional* testing costs in the \$560-\$800 per model sample range. Given that all firms are conducting some testing already, this likely overestimates the impact of the rule with respect to testing costs. However, we do not know specifically how much the third party requirement adds to testing costs or precisely how many models are needed to meet the “high degree of assurance” criterion and cannot rule out a significant economic impact. We welcome comments regarding incremental costs due to third party testing (*i.e.*, how much does moving from a voluntary to a mandatory third party testing regime add to testing costs, in total and on a per test basis). In addition, we seek comments regarding the accuracy of assuming that a “high degree of assurance” can be achieved with fewer than seven samples.

2. Small Importers

a. Small Importers with Compliant Infant Bouncer Seats

Five small importers of infant bouncer seats are currently in compliance with the voluntary standard and, based on prior compliance with the voluntary standard, would likely continue compliance as new versions of the voluntary standard are published. The bouncers

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supplied by these firms would, for the most part, only require modifications to meet the warning label changes.

The placement of the new warnings could potentially require significant changes to existing models of imported bouncers. Imported bouncers tend to be produced to broadly meet the current requirements for several trading partners simultaneously, including the labeling requirements for multiple countries. Producers for international markets typically address labeling requirements for their various trading partners by simply providing a warning that covers all required safety issues in multiple languages. However, the proposed rule's specificity regarding warning label location could make simple replication of the warning label in multiple languages impractical due to space constraints on the front surface of the back of the bouncer. While only the English-language warning would be required for products sold in the United States, this could mean that foreign producers will need to design a product for the U.S. market. One solution could be as straightforward as reducing the number of languages used for warnings on U.S.-bound bouncer seats. Regardless, having a differing product for the U.S. market could create logistical problems or costs, which could be passed on to importers.

We have no information regarding the degree to which foreign producers tend to pass on increases in regulatory costs to importers and are seeking comment on this topic. Because we lack information on the costs to importers associated with complying with the proposed rule, we are unable to rule out a significant impact for three of the five importers of compliant bouncers. We begin our discussion of potential impacts by assuming, when possible, firms would prefer to develop a U.S.-specific product with fewer warning labels rather than exit the bouncer market or develop a bouncer with sufficient room to accommodate warnings in languages for both their U.S. and foreign markets. Developing such a bouncer would address the requirements in the

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proposed rule, while ensuring that the appearance of their bouncers remains comparable to their competition's products (for which one to three languages is typical). The Commission requests feedback from the public, particularly from small importers, on the portion of regulatory compliance costs typically borne by importers, as well as information on the costs of developing a compliant bouncer for the U.S. market.

CPSC staff believes that one importer would not likely experience a significant economic impact based on comparing redesign cost estimates provided by suppliers (around \$200,000 to \$300,000) to its annual revenue, even if its supplier passed on 100 percent of the costs of redesign.

The Commission requests feedback on the cost estimate for product redesign, as well as how that cost level might differ if the redesign focused exclusively on warning label changes and the logistical problems it might create. Based upon examination of this firm's revenues and the revenues associated with the sale of bouncers, this firm also could likely exit the market without experiencing a significant economic impact.

If product redesign costs \$200,000 and the supplying firm only passed on roughly 50 percent of the expected redesign costs, then two of the remaining four importers would not likely experience significant economic impact. The Commission requests input on whether it is reasonable to assume, in the absence of alternative information, foreign suppliers will share up to 50 percent of the costs of redesign, as well as information supporting any alternative estimates of the relative portions of cost sharing that is typical for an importer and its supplying firm. If the supplying firm were unwilling or unable to limit cost passed through, then one of these firms could probably exit the market without significant economic impact as sales of bouncers are likely to contribute less than one percent to its overall revenue.

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The fourth importer would likely only avoid significant economic impact if their supplier absorbed 100 percent of the cost of a redesign. Dropping bouncers from their product line could be an option. However, it is likely that the sales revenue generated by bouncer sales exceeds one percent of their overall revenue. This importer is an exclusive distributor for their supplier's products in the U.S., so an alternative supplier is not an option.

We request information on the relationship between exclusive distributors and their suppliers, particularly as it pertains to willingness to shoulder redevelopment costs to maintain a U.S. market presence.

Neither annual revenue nor bouncer sales revenue was available for the final small importer of compliant bouncers; therefore, no assessment of impact could be made.

b. Small Importers with Noncompliant Infant Bouncer Seats

Two firms import bouncers that do not comply with the voluntary standard. The bouncers for these firms will require changes to come into compliance with the voluntary standard as well as modifications to meet the proposed warning label requirements. Similar to the case of importers of compliant bouncers, the proposed location of the warning labels on the front of the bouncer adjacent to the head could present a problem, because one firm typically uses nine languages while the other uses six. These importers may need to tailor a product for the U.S, which could be logistically difficult or costly, especially for a small firm with low sales volume.

The size of the economic impact on the two firms with noncompliant infant bouncer seats will depend upon the cost of the changes required and the degree to which their supplying firms pass on any increases in production costs associated with changes in the product needed to meet the mandatory standard. Again, we do not have any information on the proportion of compliance

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costs passed on and are seeking public comment on this topic. It is possible that these two importers could discontinue the sale of infant bouncer seats altogether, as the product does not appear to represent a substantial portion of either firms' product lines. However, one of the two firms would likely only avoid a significant economic impact if its supplier absorbed 100 percent of the cost of a redesign and it seems likely that its bouncer sales might exceed 1 percent of its annual sales revenue as well. Again, we do not have specific information on bouncer sales revenues, and cannot rule out a significant economic impact for either firm.

Both of the small importers with noncompliant bouncers are directly tied to their foreign suppliers and finding an alternate supply source would not be a viable alternative for these firms. However, given this close relationship, the foreign suppliers likely would have an incentive to work with their U.S. subsidiaries to maintain an American market presence.

The Commission is interested in information regarding the relationship between foreign producers and their U.S. subsidiaries and whether such relationships decrease the likelihood that the subsidiary experiences a significant economic impact due to a rule.

3. Third Party Testing Costs for Small Importers

As with manufacturers, all 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. The majority of bouncer importers are already testing their products to verify compliance with the ASTM standard, and any costs would be limited to the incremental costs associated with third party testing over the current testing regime.

We were able to obtain revenue data for one of the small importers with noncompliant bouncers. For that importer, third party testing costs, considered alone and apart from any

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additional performance requirements due to the proposed rule, would not exceed one percent of gross revenue unless around 12 units per model required testing to provide a “high degree of assurance.” Although staff believes that it is unlikely that any importer would need to test more than 12 samples, we are seeking information regarding the validity of that assumption. We had no basis for examining the size of the impact for the remaining importer of noncompliant bouncers.

It is important to note that our analysis of the impact of the draft proposed rule have evaluated the impacts of complying with performance requirements and third party testing requirements independently. Firms will, in fact, experience the costs jointly. It is possible for testing costs, when evaluated independently, to not create significant economic impact (and vice versa).

The Commission seeks information on the extent to which performance requirements and testing costs evaluated jointly generate significant economic impact even when each component evaluated independently is not expected to lead to significant impact.

H. Alternatives

Three alternatives are available to the Commission that may minimize the economic impact on small entities: (1) adopt ASTM F2167-15 with no modifications;¹³ (2) adopt ASTM F2167-15 with the proposed modifications, except for the warning label location specificity; and (3) allow a later effective date.

Section 104 of the CPSIA requires that the Commission promulgate a standard that is either substantially the same as the voluntary standard or more stringent. Therefore, adopting

¹³ As discussed in the briefing memo, adopting the voluntary standard with no modifications is an option if the Commission determines that a more stringent standard would not further reduce the risk of injury associated with infant bouncers.

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ASTM F2167-15 with no modifications is the least stringent rule allowed by law. This alternative would reduce the impact on all of the known small businesses supplying infant bouncers to the U.S. market because this alternative would eliminate any economic impact related directly to complying with the proposed rule for all five of the known small domestic manufacturers and the five small importers with compliant infant bouncers, all of whom are expected to comply with ASTM F2167-15 by the time the final rule becomes effective. Firms with compliant products, however, would continue to be affected by third party testing requirements.

Alternatively, the Commission could adopt a more stringent alternative that is still less stringent than the proposed rule by adopting ASTM F2167-15 with the proposed modifications, except for the requirement that the warning labels on the product be located next to the occupant's head. With the exception of impacts due to third party testing, this would eliminate most of the impact on small manufacturers (all of which sell compliant bouncer seats), leaving them with only minor costs associated with changing the wording and format of their warning labels. The impact on the five small importers of compliant bouncers would be similarly reduced.

Finally, the Commission could reduce the proposed rule's impact on small businesses by setting a later effective date. A later effective date would reduce the economic impact on firms in two ways. One, firms would be less likely to experience a lapse in production/importation, which could result if they are unable to comply and third party test within the required timeframe. Two, firms could spread costs over a longer time period, thereby reducing their annual costs, as well as the present value of their total costs. We request comment on the 6-

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month effective date, as well as feedback on how firms (particularly small importers) would likely address the proposed rule.

I. 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 an amendment to 16 CFR part 1112 that would establish the NOR for those testing laboratories that want to test for compliance with the bouncers final rule. 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 bouncer seat standard will not have a significant adverse impact on small laboratories. Moreover, based upon the number of laboratories in the U.S. that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few

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laboratories will seek CPSC acceptance of their accreditation to test for conformance with the infant bouncer seat 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 bouncer seat 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. As a consequence, the Commission certifies that the NOR for the infant bouncer seat standard will not have a significant impact on a substantial number of small entities.

XII. 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, a rule that has "little or no potential for affecting the human environment," is categorically exempt from this requirement. 16 CFR 1021.5(c)(1). The proposed rule falls within the categorical exemption.

XIII. 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;
- a brief description of the need for the information and the proposed use of the information;

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- 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 Bouncer Seats

Description: The proposed rule would require each infant bouncer seat to comply with ASTM F2167-15, *Standard Consumer Safety Specification for Infant Bouncer Seats*. Sections 8 and 9 of ASTM F2167-15 contain requirements for marking, labeling, and instructional literature. These 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 bouncer seats.

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

Table 1 – Estimated Annual Reporting Burden

16 CFR Section	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours
1229.2(a)	22	4	88	1	88

Our estimate is based on the following:

Section 8.1.1 of ASTM F2167-15 requires that the name and the place of business (city, state, and mailing address, including zip code) or telephone number of the manufacturer, distributor, or seller be marked clearly and legibly on each product and its retail package. Section 8.1.2 of ASTM F2167-15 requires a code mark or other means that identifies the date (month and year, as a minimum) of manufacture.

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Twenty-two known entities supply bouncer seats to the U.S. market may need to make some modifications to their existing labels. We estimate that the time required to make these modifications is about 1 hour per model. Based on an evaluation of supplier product lines, each entity supplies an average of four models of bouncer seats;¹⁴ therefore, the estimated burden associated with labels is 1 hour per model x 22 entities x 4 models per entity = 88 hours. We estimate the hourly compensation for the time required to create and update labels is \$30.19 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” March 2015, Table 9, total compensation for all sales and office workers in goods-producing private industries: <http://www.bls.gov/ncs/>). Therefore, the estimated annual cost to industry associated with the labeling requirements is \$2,656.72 (\$30.19 per hour x 88 hours = \$2,656.72). No operating, maintenance, or capital costs are associated with the collection.

Section 9.1 of ASTM F2167-15 requires instructions to be supplied with the infant bouncer. Bouncer seats are complicated products that generally require use and assembly instructions. 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.” We are unaware of bouncer seats that generally require use instructions but lack such instructions. Therefore, we tentatively estimate that no burden hours are associated with section 9.1 of ASTM F2167-15, because any burden associated with supplying instructions with bouncer seats would

¹⁴ This number was derived during the market research phase of the initial regulatory flexibility analysis by dividing the total number of bouncer seats supplied by all bouncer seat suppliers by the total number of bouncer seat suppliers.

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be “usual and customary” and not within the definition of “burden” under the OMB’s regulations.

Based on this analysis, the proposed standard for bouncer seats would impose a burden to industry of 88 hours at a cost of \$2,656.72 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:

- 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; and
- the estimated burden hours associated with label modification, including any alternative estimates.

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XIV. 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 requirement 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.

XV. Request for Comments

This NPR begins a rulemaking proceeding under section 104(b) of the CPSIA to issue a consumer product safety standard for bouncer seats, and to amend part 1112 to add bouncer seats to the list of children’s product safety rules for which the CPSC has issued an NOR. We invite all interested persons to submit comments on any aspect of the proposed mandatory safety standard for bouncer seats and on the proposed amendment to part 1112. Specifically, the Commission requests comments on the costs of compliance with, and testing to, the proposed bouncer seats safety standard; the impact of the proposed rule on small businesses; the proposed 6-month effective date for the new mandatory bouncer seats safety standard; and the proposed amendment to part 1112. During the comment period, the ASTM F2167-15, Standard Consumer Safety Specification for Infant Bouncer Seats, is available as a read-only document at:

<http://www.astm.org/cpsc.htm>.

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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 1229

Bouncer seats, Chairs, Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, Seats, 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: Pub. L. 110-314, section 3, 122 Stat. 3016, 3017 (2008); 15 U.S.C. 2063.

- 2. Amend § 1112.15 by adding paragraph (b)(42) 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) * * *

(42) 16 CFR part 1229, Safety Standard for Infant Bouncer Seats.

* * * * *

- 3. Add part 1229 to read as follows:

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PART 1229-SAFETY STANDARD FOR INFANT BOUNCER SEATS

Sec.

1229.1 Scope.

1229.2 Requirements for infant bouncer seats.

Authority: Sec. 104, Public Law 110-314, 122 Stat. 3016.

§ 1229.1 Scope.

This part establishes a consumer product safety standard for infant bouncer seats.

§ 1229.2 Requirements for infant bouncer seats.

(a) Except as provided in paragraph (b) of this section, each infant bouncer seat must comply with all applicable provisions of ASTM F2167-15, Standard Consumer Safety Specification for Infant Bouncer Seats, approved on May 1, 2015. 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 Drive, P.O. Box 0700, West Conshohocken, PA 19428; <http://www.astm.org/epsc.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 F2167-15 with the following additions or exclusions:

(1) Instead of complying with sections 7.11.1 through 7.11.3.3 of ASTM F2167-15, comply with the following:

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(i) 7.11.1 *Visibility with Accessories Excluding Toy Bar.* Identify and install each accessory unrelated to the toy bar that could obscure the warning label during a caregiver's interaction with the occupant. Place the bouncer on the floor.

(ii) 7.11.1.1 Face the front of the bouncer from a distance of 1.0 ft (0.3 m and verify that all warning text is visible and not obscured by the accessory(ies).

(iii) 7.11.1.2 A label on the bouncer seat back surface that is obscured by an accessory such as an infant insert would meet the visibility requirement if the label is plainly visible and easily readable on the accessory.

(A) 7.11.2 *Visibility with Toy Bar and Related Accessories.* Identify and install the toy bar and related accessory(ies) that could obscure the warning label during a caregiver's interaction with the occupant. Place the bouncer on the floor.

(B) 7.11.2.1 Face the front of the bouncer from a distance of 1.0 ft (0.3 m and verify that all warning text is visible and not obscured by the toy bar and related accessory(ies).

(C) 7.11.2.2 A fall hazard label that is partly obscured by a toy bar or its related accessories, but is visible with a shift of the observer's head position would meet the visibility requirement.

(2) Instead of complying with sections 8.3.1 through 8.3.3.1 of ASTM F2167-15, comply with the following:

(i) 8.3.1 Warning Groups and Header—Each infant bouncer seat shall be labeled with two groups of warning statements: a fall hazard warning and a suffocation warning. Each warning statement group shall be preceded by a header consisting of the safety alert symbol “▲” and the signal word “WARNING.”

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(ii) 8.3.2 Warning Format—The background color for the safety alert symbol and the signal word shall be orange, red or yellow, whichever provides best contrast against the product material. The safety alert symbol and the signal word shall be in bold capital letters not less than 0.2 in. (5 mm) high. The remainder of the text shall be characters whose upper case shall be at least 0.1 in. (2.5 mm) high. All elements of these warnings shall be permanent, and in sans serif, non-condensed style font. Precautionary statements shall be indented from hazard statements and preceded with bullet points. The warning label and the panel containing the signal word “WARNING” shall be surrounded by a heavy black line. Message panels within the labels shall be delineated with solid lines between sections of differing content. The background color in the message panel shall be white and the text shall be black. If an outside border is used to surround the heavy black lines of the label, the border shall be white and the corners may be radiused.

(iii) 8.3.3 *Warning Locations:*

(A) 8.3.3.1 The fall hazard warnings label in 8.3.4.1 shall be on the front surface of the infant bouncer seat back adjacent to the area where a child’s head would rest, so that the label is plainly visible and easily readable. If one or more accessories are provided with the bouncer that could obscure the warning label during use, the visibility of the label shall be verified in accordance with 7.11.

(3) Instead of complying with sections 8.3.4.1 through 8.3.5 of ASTM F2167-15, comply with the following:

(i) 8.3.4.1 *Fall Hazard:*

Fall Hazard: Babies have suffered skull fractures falling while in and from bouncers.

- Use bouncer ONLY on floor.

DRAFT

- **Always** use restraints. Adjust to fit snugly, even if baby is sleeping.
- **Never** lift or carry baby in bouncer. [NOTE: Bouncer seats with a handle(s) intended for use to lift and carry a child are exempt from including this warning statement.]

(ii) 8.3.4.2 *Suffocation Hazard:*

Suffocation Hazard: Babies have suffocated when bouncers tipped over on soft surfaces.

- **Never** use on a bed, sofa, cushion, or other soft surface.
- **Never** leave baby unattended. To prevent falls and suffocation:
- **Always** use restraints. Adjust to fit snugly, even if baby is sleeping.
- **Stop** using bouncer when baby starts trying to sit up.

(iii) 8.3.5 Figs. 10-12 The safety alert symbol “▲” and the signal word “**WARNING**”

shall be as specified above, but with the option of background colors as described above. The warning statements’ wording content, as well as the use of any underlining, capital lettering, or bold typeface, or a combination thereof, are at the discretion of the manufacturer.

(4) In section 9 of ASTM F2167-15, replace Figure 10 with the following:



Figure 10

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(5) Instead of complying with section 9.1.1.5 of ASTM F2167-15, comply with the following:

(i) 9.1.1.5 Instructions must indicate the manufacturer’s recommended maximum weight, height, age, developmental level, consistent with the warning statement in 8.3.4.2, or combination thereof of the occupant for which the infant bouncer seat is intended. If the infant bouncer seat is not intended for use by a child for a specific reason (insert reason), the instructions shall so state this limitation.

(6) In section 10 of ASTM F2167-15, replace Figures 11 and 12 with the following:

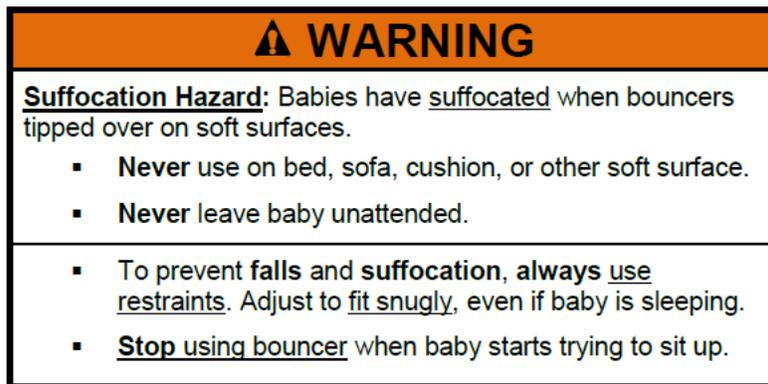


Figure 11

DRAFT

⚠ WARNING
<p>Fall Hazard: Babies have suffered <u>skull fractures</u> falling while in and from bouncers.</p> <ul style="list-style-type: none">▪ Use bouncer ONLY on floor. Baby's movements can shift or tip bouncers off counters, tables, and other surfaces.▪ Never lift or carry baby in bouncer.
<p>Suffocation Hazard: Babies have <u>suffocated</u> when bouncers tipped over on soft surfaces.</p> <ul style="list-style-type: none">▪ Never use on a bed, sofa, cushion, or other soft surface.▪ Never leave baby unattended.
<ul style="list-style-type: none">▪ To prevent falls and suffocation, always use restraints. Adjust to <u>fit snugly</u>, even if baby is sleeping.▪ Stop using bouncer when baby starts trying to sit up.

Figure 12

Dated: _____

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission



Staff Briefing Package
Infant Bouncer Seats
Notice of Proposed Rulemaking

September 30, 2015

CPSC Hotline: 1-800-638-CPSC(2772) CPSC's Web Site: <http://www.cpsc.gov>

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Briefing Memorandum: Notice of Proposed Rulemaking for Infant Bouncer Seats and Related Notice of Requirements



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

This document has been electronically
approved and signed.

Memorandum

September 30, 2015

TO: The Commission
Todd Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Patricia H. Adkins, Executive Director
Robert J. Howell, Deputy Executive Director for Safety Operations

FROM: George A. Borlase, Ph.D., P.E.
Assistant Executive Director
Office of Hazard Identification and Reduction

Suad C. Wanna-Nakamura, Ph.D.
Division of Pharmacology and Physiology Assessment
Directorate for Health Sciences

SUBJECT: Notice of Proposed Rulemaking for Infant Bouncer Seats and Related
Notice of Requirements

I. INTRODUCTION

On August 14, 2008, the Consumer Product Safety Improvement Act (“CPSIA”) of 2008, Pub. L. No. 110-314¹ was enacted. Section 104 of the CPSIA is the Danny Keysar Child Product Safety Notification Act, which requires the U.S. Consumer Product Safety Commission (“CPSC” or “Commission”) to: (1) examine and assess voluntary safety standards for certain 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.

¹ Section 104 Title I—Children’s Product Safety Standards and consumer registration of durable nursery products.
<http://cmsprod02/pagefiles/129663/cpsia.pdf> page 14/63

Section 104(f)(1) of the CPSIA defines “durable infant or toddler products” as “a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years,” and provides a non-inclusive list of product categories. Although infant bouncer seats are not listed, the Commission has specifically identified them as a category of “durable infant or toddler product” in the Commission’s product registration card rule under section 104(d).² Additionally, section 104 (b)(1)(A) of the CPSIA requires the Commission to consult with “representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts” in the development of this notice of proposed rulemaking (“NPR”). Staff began the consultation process through the standard development procedures of ASTM International³ (formerly the American Society for Testing and Materials) in January 2013.

The first edition of the voluntary standard for infant bouncer seats, ASTM F2167-01, *Standard Consumer Safety Specification for Infant Bouncer Seats*, was published in January 2002.⁴ The standard has gone through nine revisions. Three of these revisions were made since the consultation process started in January 2013. The standard was revised and approved in February 2014 (ASTM F2167-14)⁵ to improve the sideward and rearward stability tests. The next standard revision was made as a result of the mandatory rulemaking’s consultation process (ASTM F2167-14a)⁶ to include changes to the stability test to make the ASTM standard stricter, to address tip-over incidents, and to add requirements and test procedures to address incidents involving battery leakage, corrosion, and overheating.

In June 2015, ASTM published the current voluntary standard (ASTM F2167-15).⁷ The standard included substantial changes to the warnings, which included an added fall hazard label visibility test to address fall and suffocation hazards and other changes, including the following:

- (1) Moving the warnings from the back to the front surface of the bouncer (Sections 7.1.1 and 8.3.3.1);
- (2) Requiring a hazard color as the background for the safety alert icon and signal word (section 8.3.5 figures 10-12);
- (3) Strengthening and simplifying the suggested wording used in the content to be addressed (Section 8.3.5);
- (4) Providing example labels with the suggested wording and recommended format (Section 8.3.5); and

² 74 Fed. Reg. 68668 (December 29, 2009) <http://www.cpsc.gov/PageFiles/124299/durable.pdf> (16 C.F.R. § 1130.2(a)(16)).

³ ASTM International (formerly known as the American Society for Testing and Materials) website: www.astm.org.

⁴ First edition approved December 2001. Published December 2001.

⁵ Edition approved Feb. 1, 2014. Published March 2014.

⁶ Edition approved Sept. 1, 2014. Published December 2014.

⁷ Approved May 1, 2015. Published June 2015.

(5) Adding a test to ensure the fall hazard label is visible when manufacturer-provided accessories are used.⁸ The instructional literature section was also updated to reflect warning label changes.

This briefing package: (1) provides a review of the incident data; (2) assesses the effectiveness of the current voluntary standard for infant bouncer seats (ASTM F2176-15); (3) includes the staff's recommendations to the Commission, along with a discussion of the potential impact on small businesses; and (4) reviews recent recalls associated with infant bouncer seats.

II. BACKGROUND and DISCUSSION

A. Infant Bouncer Seat Product Description

An “infant bouncer seat” is defined in the scope section 1.2 of ASTM F2167-15, *Standard Consumer Safety Specification for Infant Bouncer Seats*, as “a freestanding product intended to support an occupant in a reclined position to facilitate bouncing by the occupant, with the aid of a caregiver or by other means” and “whose intended occupants are infants who have not developed the ability to sit up unassisted (approximately 0 to 6 months of age).”

Bouncer seats vary, from simple wire frame construction models with a fabric cover, a toy bar and three-point restraints, to more complex designs with additional features, such as battery-powered devices that vibrate and play melodies and nature sounds (Figure 1). These units are usually located in the front at the bottom edge of the seat. Most products are sold with a removable “head support insert,” used to support the head of newborns and small babies.



Figure 1- Examples of infant bouncer seats with wire frame designs, images copied from various retailer and manufacturer's websites.

While the most common infant bouncer seats have a wire frame construction, other designs are also available. Products with individual wire legs (Figure 2a), solid bases (Figure 2b), and three individual support components (Figure 2c) are some examples of a few models sold. These infant bouncer seats fall within the infant bouncer scope, as defined in ASTM F2167.

⁸ASTM 2167-15, Section 7.11.3.2 *Visibility with Accessories (Excluding Toy Bars)*—addresses accessories, but does not specifically use “infant head insert” or other products as examples.



Figure 2-Alternative bouncer designs: images were copied from various retailers and manufacturers websites.

B. Incident Data

The Directorate for Epidemiology’s Division of Hazard Analysis’s (“EPHA”) staff identified 277 incidents (11 fatalities and 266 nonfatal) involving infant bouncer seats between January 1, 2006 and February 2, 2015⁹ for children 12 months and younger (Tab A). Although the product is intended for infants up to 6 months old, children 7 to 12 months old were also believed to be within the scope of foreseeable use and were therefore included in the data search. EPHA staff searched the reported incidents in the Injury or Potential Injury Incident (“IPII”) file, In-Depth Investigation (“INDP”) file, Death Certificate file (“DTHS”), and CPSC Retailer Reporting System of manufacturer/retailer reports to the Office of Compliance. Staff also searched the NEISS database,¹⁰ which includes emergency department-treated injuries associated with consumer products and are collected from approximately 100 hospitals that have been selected according to a statistical design. Because reporting is ongoing, the number of reported injuries, fatalities, and non-injury incidents associated with infant bouncer seats may change in the future.

1. Fatalities

According to EPHA staff, 13 fatalities were associated with the use of infant bouncer seats from January 1, 2006 to February 2, 2015. Eleven were retrieved from the Consumer Product Safety Risk Management System (“CPSRMS”),¹¹ and two were extracted from the NEISS database. Nine of the infants were 2 to 4 month olds and all 13 were 6 months and under.

Health Sciences (“HS”) staff analyzed all the incidents, as detailed in Tab B (Marques, 2015) and believes that one death, reportedly a 5-month-old child who was found “flipped over in bouncy seat with leg still through the leg hole,” did not involve an infant bouncer seat because

⁹ NEISS records were retrieved from January 1, 2006 to December 31, 2013.

¹⁰ <http://www.cpsc.gov/en/research--statistics/neiss-injury-data/>.

¹¹ In response to the Consumer Product Safety Improvement Act, the Consumer Product Safety Risk Management System (CPSRMS) was developed and combines data from IPII, DTHS, and INDP into one searchable incident database.

the term “leg hole” is inconsistent with the features of these products and is a more likely reference to a jumper-type product.

With the exception of one death resulting from blunt head trauma after a child fell, when his father lifted the bouncer while the child was in it, all the deaths were unwitnessed and occurred while the child was sleeping or napping. Although the information provided in the records was limited, HS staff believes that hazardous placement of the bouncer seat is a major concern. The hazards that contributed to most of the deaths resulted from placing the bouncer inside cribs, on adult beds, and on other soft surfaces.

2. Injuries

Of the 266 nonfatal infant bouncer seat-related incidents retrieved from CPSRMS that occurred between January 1, 2006 and February 2, 2015, there were 51 reported injuries, four of which involved serious head injuries that resulted from falls from placing the product on elevated surfaces. Other reported injuries included leg fractures, head contusions, eye bruises, facial bruises and scratches, a split lip and torn upper frenulum, a finger bruise, leg cuts, leg bruises, heel lacerations, and a blood blister. HS staff determined that 77 of the 266 nonfatal incidents involved infants falling from bouncers placed on elevated surfaces.

3. National Injury Estimates

Between January 1, 2006 and December 31, 2013, an estimated 17,200 children age 0 to 1-year-old were treated in hospital emergency departments for injuries involving infant bouncer seats. Based on the annual estimates, a statistically significant upward trend was observed in this time period.

C. Hazard Patterns

1. CPSRMS Data

CPSC staff carefully reviewed all 277 available incident reports in CPSRMS involving product-related issues to identify hazard patterns associated with infant bouncer seat injuries. Staff grouped the hazard patterns in the following categories and listed them in order of frequency of the reports.¹² These hazard patterns are summarized in Table 1, Tab A.

Product Design

Seventy-five (75) incident reports described issues related to product design, resulting in 16 minor injuries. Design issue incidents included finger entrapments, contact with sharp edges, and quality issues related to performance, such as attachment components not clipping properly.

¹² The remaining two categories, non-product-related and unknown hazards, are not included in this list because they cannot be addressed by a mandatory safety standard.

Structural Integrity

Seventy (70) incident reports described issues related to the structural integrity of bouncer components, 12 resulting in minor injuries. Component-related issues included the product collapsing when the bouncer was picked up; the product collapsing during use; loosening of the hardware resulting in the fabric releasing from the frame, and broken sides.

Toy Bar-Related Incidents

Thirty-six (36) incident reports involved problems with the toy bar or toys attached to it, including reports describing toys breaking off the toy bar, swinging toys hitting a child occupant, sharp points, sharp edges, and children getting hands or feet caught on the toy attachments. Ten of the 36 incidents resulted in minor injuries.

Stability

Thirty-three (33) incident reports involved stability issues, such as tip-over incidents when a bouncer seat was placed on the floor. Seven cases resulted in moderate injuries, such as a cut lip, head contusions, and facial bruises.

Chemical/Electric Hazards

Thirty (30) cases were related to chemical or electrical hazards, including two reported injuries (a thigh welt and a rash) due to contact with the chemical. One incident reported a toxic smell emanating from the product, while the remaining reports involved batteries (leaking, cracking, or exploding) or the vibration motors (overheating or catching fire).

Restraints

Twenty (20) incidents, including two reported minor injuries, involved issues related to the bouncer restraint system, including falling out of bouncer seats despite being strapped in, tearing/fraying straps, and non-latched seat belts, or a break in the restraint buckles.

Hazardous Placement

Eleven (11) incidents involved placement of the product in a hazardous environment, resulting in infants in bouncer seats falling from elevated surfaces, falling face down onto soft bedding, or suffocating while attempting to get out of a bouncer seat that had been placed on an unstable surface. Incidents included a reported skull fracture injury, a fatality resulting from blunt force head trauma, and nine fatalities from asphyxia.

Unknown

Two (2) incidents involved an unknown hazard. One case resulted in a reported injury and the other a positional asphyxia death.

2. NEISS Data

According to NEISS records, 672 incidents resulted in emergency department visits (estimated total of 17,200 injuries) related to infant bouncer seats. Similar to the fatality incidents, the majority of the injuries resulted from falls from hazardous locations. Hazardous placement of bouncer seats occurred on kitchen counter tops, tables, and other elevated surfaces. Eighty five percent (85%) of the injuries involved infants between 0 to 6 months old, an age group that falls within the recommended age range for the product. The treated and released category accounted for 579 patients (estimated total of 15,500 injuries). Eighty-two (82) patients were admitted, held for observation, or transferred to another hospital (estimated total of 1,300 injuries), nine left without being seen, and two died (Tab A, Table 5).

The NEISS data include narrative descriptions captured by medical personnel that are useful in helping to describe features of a hazard or a pattern of injury. Human Factors (“HF”) staff reviewed the NEISS data with a focus on events where caregiver behavior or the occupant might have played a role in the incidents. HF staff identified certain hazard patterns associated with product use; the results of the analysis are detailed in the HF technical memorandum in Tab D (Sedney, 2015).

D. History of ASTM F2167 Standard to Present:

As detailed in staff’s mechanical engineering memorandum (Tab C), the voluntary standard for infant bouncer seats was first approved in December 2001 and published in January 2002 as ASTM F2167-01, *Standard Consumer Safety Specification for Infant Bouncer Seats*. The current version, ASTM F2167-15, was approved on May 1, 2015. This ASTM standard contains both general and performance requirements. The standard has been revised nine times. The following is a list in chronological order of substantial revisions made to the standard.

ASTM F2167-01 contained requirements to address the following issues:

- Sharp points and sharp edges
- Small parts
- Lead in paint
- Wood parts
- Locking or latching mechanisms
- Scissoring, shearing, pinching
- Openings
- Exposed coil springs
- Protective components
- Labeling and warnings
- Toy accessories
- Structural integrity
- Stability (forward, sideward, and rearward)
- Slip resistance (static and dynamic), and
- Disassembly and collapse.

ASTM F2167-05a (approved on May 1, 2005) revision:

- added ASTM reference documents
- modified definition of “openings” and added a figure
- modified marking and labeling requirements
- added keyword section that includes the term “bouncing motion” to remove the possibility of testing compromised samples for tests, such as stability after testing that can likely result in sample damage
- changed openings requirement, to improve definition of “hazardous openings,” and
- added figure to clarify hazardous opening and make testing consistent with other existing children’s products that have openings.

ASTM F2167-05b (approved on October 1, 2005) revision:

- modified forward stability test fixture to represent more closely the forces applied to a bouncer by a child using the product.

ASTM F2167-10 (approved on April 1, 2010) revision:

- clarified that English units are the standard, and metric values are calculated from the English unit standard, and
- modified definition of “conspicuous” to require that a warning label be visible to a person sitting down, instead of being visible to a person standing.

ASTM F2167-12 (approved on March 12, 2012) revision:

- added definition of “grasping point on toy” to clarify the toys location relative to the seated child
- added definition of “toy bar”
- added toy bar integrity requirement
- added static and dynamic toy bar integrity tests to address toy bars used as a handle to lift the bouncer and child, and
- added non-mandatory rationale section.

ASTM F2167-12a (approved on July 1, 2012) revision:

- added instructional literature on battery usage and storage.

ASTM F2167-14 (approved on February 1, 2014) revision:

- modified the sideward and rearward inclined testing surface from 12 degrees to 20 degrees to address tip-over incidents and falls from elevated surfaces.

ASTM F2167-14a (approved on August 1, 2014) revision:

- modified the forward stability test to make the test more severe by applying the test weight 1-inch further out from the crotch post and using the manufacturer’s recommended maximum weight if greater than the 21-pound minimum weight application per CPSC staff consultation process, and
- added requirements and a test procedure for battery compartment leakage and circuit overload at CPSC staff request.

ASTM F2167-15 (approved on May 1, 2015) version:

- added a fall hazard label visibility test to address fall and suffocation warning labels
- revised warning labels
- revised the instructional literature section to reflect warning label changes
- added rationale (non-binding) to provide supplemental information on latest revisions, and
- all four revisions were made through the CPSC consultation process.

E. Other Relevant Standards

EXHR staff found no standards for infant bouncer seats other than ASTM F2167, but was able to identify two closely related international standards, BS EN 14036:2003, *Child Use and Care Articles — Baby Bouncers — Safety requirements* and BS EN 12790:2002, *Test Methods and Child Care Articles -Reclined cradles*, that pertain to products with some characteristics similar to infant bouncer seats (See Tab C for details). Overall, EXHR staff determined that ASTM F2167 is more stringent in most areas than these two standards and addresses the hazard patterns observed in the CPSC incident data. One exception is the retention system test requirement in BS EN 12790, which includes an additional strap slip test (used to determine strap creep) lacking in ASTM F2167. However, CPSC staff is not recommending adding a strap creep test because incident data associated with restraints are minimal and no evidence of injuries from strap creep exists.

F. Adequacy of ASTM F2167-15 Requirements

Based on the engineering assessment (Tab C), the requirements contained in the current voluntary standard, ASTM F2167-15, adequately address the identified hazards associated with the use of infant bouncers, such as stability, slip resistance, structural integrity and disassembly/collapse, drop testing, batteries, and toy bar integrity (see discussion below). However, the standard does not fully address the hazard associated with the caregiver behavior and use of the product, as detailed in the HF technical memorandum in Tab D.

1. Structural Integrity

The most common scenarios related to structural integrity of bouncer seats, collapse during use and fabric detaching from the frame, are addressed through a series of three tests that evaluate structural integrity. Tests include: (1) a static load test, (2) a dynamic load test, and (3) a disassembly/collapse test, as described in Tab C.

2. Product Design

Product design incidents include reports of product failures related to the general requirements, including: sharp plastic rods, overhead attachments not clipping properly, sharp pieces of fabric, lack of padding in the footing area, bouncer frames that easily entrap arms/legs/fingers, easily movable feet cushion flaps, sharp plastic grooves from a musical component, sagging seat belts, and lopsided or low-riding bouncer frames.

The performance requirements to test for hazards related to product design are the same as those used to test for structural integrity. The current standard also has provisions to address sharp edges (section 5.1), and by reference, 16 C.F.R. §1500.49.¹³ Based on evaluation and testing, staff concludes that the current performance requirements are adequate to address this hazard pattern. Staff notes that incidents in this category may be the result of manufacturing, shipping, and consumer assembly-related issues.

3. Toy Bars

Staff identified incidents of toy bar failure, when the caregiver was using the toy bar as a handle. Some cases involved entrapment or pinching of a child's fingers, toes, arms, or legs in the toys or toy bar. Other reports describe small parts from broken components of a toy bar or toy, with the remainder describing toys that struck the child.

In most of the incidents, minor injuries resulted when the child initiated motion of the toy by pushing it with a hand or foot and the toy struck the child on the return swing. Staff believes that a combination of a short tether between the toy and toy bar and the light weight of the toy on the end are unlikely to result in a substantial injury. In incidents that involved the toy bar used as a handle, it is unclear if the handle was designed to break free (some handle bars are expected to completely release before the entire bouncer is lifted off the ground), failed, or broke.

Individual toys included with the bouncer are required to meet the general requirements in the standard, including the mandatory standard for toys, ASTM F963; however, the toy bar is also required to meet the toy bar integrity test requirement. This requirement uses two different tests, a static integrity test and a dynamic integrity test, to address incidents in which the toy bars are used as handles.

Performance requirements for the toy bar integrity tests, as described in ASTM Section 6.7.1, address the risk of injuries when the toy bar is used as a handle. These tests address a previously identified hazard pattern, where consumers' attempts to lift the seat by the toy bar caused the toy bar to bend or break, resulting in the occupant falling out of the infant bouncer seat. Bouncer seats that meet the toy bar integrity requirement must be designed to function as a handle (Section 6.7.1.2), break free (Section 6.7.1.1), or substantially deform before lifting. CPSC is unaware of any injuries involving toy bars releasing when being used as a handle that have occurred since 2012, when the toy bar integrity tests were added to ASTM F2167. However, many of the recent incidents describe consumer complaints about the toy bar releasing or bending. These incident reports are not considered safety related, because the infant bouncer seats are specifically designed to behave this way for safety purposes, and no reported injuries have occurred from these incidents.

Toy bar requirements are consistent with other ASTM children product standards that have been incorporated as CPSC children's product regulations. Staff believes that these requirements adequately address these hazards.

¹³ 16 C.F.R. § 1500.49 Technical Requirements for Determining a Sharp Metal or Glass Edge in Toys or Other Articles Intended for Use by Children Under Eight Years of Age.

4. Stability

Stability issues related to bouncers include incidents where an occupied bouncer tipped in a forward, sideways, or rearward direction.

ASTM F2167-15 addresses bouncer stability requirements in forward, sideways, and rearward directions. Stability tests are intended to prevent bouncers from tipping while in use. To pass the tests, the bouncer must not tip over and the front edge must not touch the test surface. For the forward stability test, an infant CAMI dummy is placed in the infant bouncer and the restraints are adjusted to fit in accordance with the manufacturer's instructions. The dummy is then removed and the stability test fixture is placed in the seat. A vertical static force is applied for 60 seconds at a distance of 6 inches (152.4mm) in front of the crotch post. The magnitude of this force is at least three times the manufacturer's recommended weight, as defined in the standard.

Because of a bouncer's potential shifts in center of gravity, repeatable stability testing in the sideward and rearward directions is more difficult than in forward directions, and is therefore conducted differently. The current sideward and rearward stability tests are performed with the infant CAMI dummy placed in the seat and the bouncer placed on a 20-degree incline in the most unstable orientation other than forward. To pass the test, the bouncer must not tip over in this position. These changes were made by ASTM in addition to the CPSC staff voluntary standard review and consultation process. The modifications were published in the *F2167-14 edition*.

To address incidents related to stability, CPSC staff worked with the ASTM subcommittee on bouncers to modify all the stability performance requirements. In F2167-14, ASTM changed the angle of incline for the rear and side stability tests from 12 to 20 degrees. This strengthened the tests. The changes in ASTM F2167-15 include a longer distance between the crotch post of the test fixture and the application of force for the forward stability test. In F2167-15, the force is applied at a distance of 6 inches (152.4mm) in front of the crotch post instead of the previous distance of 5 inches (127mm).

Staff's assessment is that recent changes to the stability requirements will lead to increasingly stable bouncer designs, reducing the likelihood of bouncer tip overs and associated injuries.

5. Chemical/Electrical

Staff reviewed cases related to battery issues, including the battery-operated vibration unit leaking battery, smoking, or catching fire. The primary electrical hazards associated with bouncers are related to battery overheating and the potential leakage or fire.

ASTM recently added battery and containment requirements to the standard. These additions were part of the voluntary standard review and consultation process, and the additions were developed with support from CPSC staff and were based on the incidents reported to CPSC. The new requirements include permanently marking the correct battery polarity adjacent to the battery compartment, providing a means to contain the electrolytic material in the event of

battery leakage, protection against the possibility of charging non-rechargeable batteries, and defining a maximum surface temperature for any accessible component (ASTM F2167-15 Sections 7.1 and 7.1.1). The performance requirement includes a provision for testing using a/c power.

Staff concludes that the new ASTM battery requirements (ASTM F2167-15 Sections 7.1 and 7.1.1) adequately address the electrical incidents. The additional requirements to address battery compartments and electrical circuitry will require bouncers to have electrical designs similar to other juvenile products, which staff believes will reduce the likelihood of overheating and battery leakage incidents.

6. Restraints

Following review of incidents involving restraints, including restrained children falling out of the bouncer, tearing/fraying of straps, non-latching seat belts, and buckle failure, staff does not recommend any changes to the current testing of restraints.

ASTM F2167-15 requires that restraints be provided with a bouncer seat. Restraints must be capable of securing a child when the bouncer is placed in any use position recommended by the manufacturer. ASTM F 2167-15 requires both a waist and a crotch restraint, and the waist restraint must be designed to be used when the crotch restraint is in use. The standard specifies that the restraint's anchorages shall not separate from the attachment points to the bouncer. Although no provisions in the performance requirement address actual use of the restraint, the standard has a warning label requirement on how to use the restraint properly. Because restraint use is linked to caregiver behavior, strengthening restraint use is best addressed by enhanced warnings and instructions. Staff worked with the infant bouncer task group on revisions to warnings labels and instructions that improve visibility and comprehension and that provide specific guidance to caregivers regarding fall-related injuries and proper use of the restraint. However, based on fatalities involving sleeping, unrestrained infants, staff recommends (Tab D) additional warning language for restraints that is not in ASTM F2167-15: "Always use restraints. Adjust to fit snugly, *even if baby is sleeping.*"

7. Hazardous Placement

Hazardous environment incidents result from product placement on elevated surfaces, and on uneven surfaces in cribs and other hazardous locations. Hazardous environment incidents are addressed by ASTM F2167-15 with multiple tests, including slip resistance and stability requirements. However, performance requirements do not address cases where caregivers place bouncers on elevated surfaces and other hazardous locations. Hazard scenarios involving consumer behavior and foreseeable misuse of the product must be addressed through enhanced warning labels and instructions; therefore staff recommends the modifications to the warnings and instructions discussed below in section 8.

8. Warnings

As part of the consultation process, staff worked with ASTM to improve the warning labels and instructions. In June 2015, ASTM published the current voluntary standard (ASTM F2167-15).¹⁴ Substantial changes were made to the warnings in this edition of the standard that include the following:

- (1) moving the warnings from the back to the front surface of the bouncer (Sections 7.1.1 and 8.3.3.1);
- (2) A fall hazard label visibility test was added to address falls
- (3) requiring a hazard color as the background for the safety alert icon and signal word (section 8.3.5 figures 10-12);
- (4) strengthening and simplifying the wording used in the content to be addressed (Section 8.3.5);
- (5) providing example labels with the suggested wording and recommended format (Section 8.3.5); and
- (6) adding a test to ensure the fall hazard label is visible, including when manufacturer-provided accessories are used (Section 7.11.3.2¹⁵). HF staff believes these changes are important but insufficient in the current standard, as detailed in Tab D.

HF staff analyzed the incident data and reviewed research on warning label design and characteristics that could increase the likelihood of consumer compliance with a warning. HF staff determined that these warnings should capture the consumer's attention and be easy to comprehend. The warning should be well-designed, convey the severity of potential injury, and be relevant to the consumer to increase the motivation to comply. The goal of these warnings is to guide new consumers and existing consumers to use the product safely. The changes incorporated into ASTM F2167-15 go a long way in addressing the fall hazard. However, staff believes that more can be done. Thus, staff recommends that the Commission issue a proposed rule with the following changes to ASTM F2167-15:

1. Add a requirement that the fall hazard label be located on the front surface of the bouncer, adjacent to the area where the child's head would rest, and modify the current visibility test to reflect this requirement;
2. Add text to the warnings recommending that consumers use the restraints: ". . . even if baby is sleeping . . .";
3. Change the text in the warnings advising consumers to: "stop using when baby starts trying to sit up";
4. Specify a standard format (including black text on a white background, table design, bullet points, and black border) for the warnings on the product and in the instructions.

¹⁴Approved on May 1, 2015. Published June 2015.

¹⁵ 7.11.1- through 7.11.2.2. Appendix A, Tab D

Following is an explanation of each recommendation¹⁶:

1. Add a requirement that the fall hazard label be located in the area adjacent to the area where the child's head would rest.

HF Staff's Rationale: Prominent placement of the label is crucial so that the consumer can notice the label when and where the hazard is likely to occur. The position adjacent to the child's head in the seat (as with strangulation warnings for handheld infant carriers that are also car seats, ASTM F2050- 13a) is the most conspicuous location for a warning label, and the recommendation is based, in part, on experimental and focus group research conducted by the National Highway Transportation Safety Administration ("NHTSA"¹⁷). The focus of a caregiver's visual attention while interacting with a child in the bouncer is likely to be on the child's face.

Placing the label near the child's face ensures that the warning is visible when behavior may be influenced (*e.g.*, the caregiver may consider the surface height while putting the child in the bouncer). More importantly, research findings (Tab. D) indicate that attention and perception are influenced by emotion. Because of the emotional attachment between caregiver and child, the label is more likely to be perceived if it is near the child's face than at other locations on the product. The presentation of the hazards and the potential consequence, a skull fracture, while a caregiver is looking at his or her child, may increase the perception of the risk and the severity of related injuries, factors associated with warning compliance. Although balloted, ASTM did not accept CPSC staff's recommendations; subcommittee members expressed concern that locating the label by the child's head could be design restrictive for some small products and might be challenging for firms that use labels in multiple languages. Staff believes that the primary issues surrounding bouncer seat injuries are related to caregiver behavior, especially placing bouncers in hazardous locations and failing to use restraints. Thus, safety would be increased with more prominent placement of the labels, staff believes.

2. Add the words, "*even while child is sleeping,*" in the warning that addresses the restraints.

HF Staff's Rationale: In nine of the 13 bouncer-related fatalities, children reportedly were placed in the bouncer to sleep or nap. In five of these cases, the children were unrestrained, and in two, they were found partially out of their restraints. The recommended warning statement addresses the fact that the child will sleep in the bouncer and addresses caregivers' known inclination to loosen or remove the restraints by stating expressly that caregivers should do the opposite.

3. Revise the developmental guidance in the warnings that advises caregivers about when to stop using the bouncer. The current guidance is "NEVER use for a child able to sit up unassisted." The new guidance would state: "stop using the bouncer when the child starts trying to sit up".

¹⁶ Sedney 2015, Tab D.

¹⁷ Federal Register. 61,(152), 40784-40809.

HF Staff's Rationale: Manufacturers recommend using bouncers until a child can sit upright, but never when a child is able to sit upright. Children are at-risk of injury in infant bouncer seats at earlier stages of development because infants lack upper body control, and the upper body is unrestrained and at an incline in a bouncer, as they attempt to sit up, lean, turn, and reach for objects. It is likely that these actions contribute to incidents resulting in injury or death. Staff recommends advising caregivers to stop using the product when the child begins trying to sit up. On average, children reach this milestone at 4.8 months.¹⁸ The subcommittee voted to table this issue for future consideration.

4. Specify a format that includes black text on a white background: brief, bulleted statements organized in a table format according to hazard and topic, and surrounded by a black border to ensure that the warning content is conspicuous and easy to read and comprehend quickly. Example warnings including the recommended format already in the standard (Section 8.3.5, Figures 10-12), but there is no requirement that specifies the format to be used.

HF Staff's Rationale: Section 8.3.5 of the ASTM 2167-15 states that the labels shown are “EXAMPLES ONLY,” and that the “warning statements’ wording content, as well as format such as the use of any underlining, capital lettering, or bold typeface, or a combination thereof, are at the discretion of the manufacturer.” With the exception of the panel that contains the word “WARNING” and the safety alert symbol, the text and background can be any colors, provided they are contrasting; and the messages can be presented in any style (*e.g.*, as a paragraph in all upper case letters). The hazard scenarios resulting in infant bouncer-related injuries and deaths are not straightforward and the scenarios involve a combination of factors. Consequently, the warnings must be longer than is ideal; and yet, the warnings must gain and hold attention long enough to be read. Good formatting helps attract and maintain attention, as well as aid reading and comprehension. Staff’s recommended format for the warnings establishes minimum requirements for presentation of the hazard information that are consistent with best practices; including the requirements in the standard ensures that the warnings and the requirements are uniform across products.

G. Compliance Recalls

Compliance staff provided a summary of infant bouncer seat recalls from January 1, 2006 to July 9, 2015 (Tab E). During that time, there were two consumer-level recalls involving infant bouncer seats. One recall in 2007 involved approximately 1,400 units,¹⁹ and another in July 2009, involved approximately 6,500 units.²⁰ There were no injuries associated with the two recalls.

¹⁸ Range, 3–8 months. Bayley, N. (1969). *Manual for the Bayley Scales of Infant Development*. New York, NY: The Psychological Corporation.

¹⁹ CPSC link to recalled product: <http://www.cpsc.gov/en/Recalls/2007/Infant-Bouncer-Seats-Recalled-Due-to-Frame-Failure/>.

²⁰ CPSC link to recalled product: <http://www.cpsc.gov/en/Recalls/2009/BabySwede-LLC-Recalls-Bouncer-Chairs-Due-to-Laceration-Hazard/>.

H. Potential Small Business Impact

Staff identified 22 firms supplying infant bouncer seats to the U.S. market. These firms primarily specialize in the manufacture and/or distribution of children's products. Based on U.S. Small Business Administration guidelines, 12 of the 22 firms are small businesses, including five domestic manufacturers and seven domestic importers.

As described in Tab F, staff cannot rule out a significant impact on six of the 12 known small suppliers (50 percent) of bouncers to the U.S. market. Accordingly, we have prepared an initial regulatory flexibility analysis ("IRFA").

The impact on small manufacturers is expected to be limited. They all produce compliant bouncers; therefore, small manufacturers would only be affected by the warning label recommendations. There is sufficient room on each firm's bouncers to accommodate warnings in every language the firm uses. Changes needed to comply with the staff-recommended proposed rule would be limited to wording and format. Thus, costs should be small. However, staff could not conclude that third party testing costs would be insignificant for one small manufacturer.

The staff-recommended proposed standard could affect one or more of the seven small importers more significantly because they operate in several international markets and need to supply warnings in multiple languages. Additionally, the two importers of noncompliant bouncers may face additional costs to come into compliance with the staff-recommended proposed rule. The economic impact will depend upon how much of the cost increase each firm bears relative to their foreign supplier. A significant impact could not be ruled out for five of these small importers (two with noncompliant bouncers and three with compliant bouncers).

The economic impact on small domestic suppliers could be reduced in three ways. One, adopting ASTM F2167-15 with no modifications would reduce the impact on all of the known small businesses supplying infant bouncers to the U.S. market. Two, adopting ASTM F2167-15 with the staff-recommended modifications, except for the requirement that the warning labels on the product be located next to the occupant's head, would reduce the impact on suppliers of compliant bouncers (and some of the impact on importers of noncompliant bouncers), leaving only minor costs associated with changing the wording and format of their warning labels. Third, a later effective date could be set, allowing firms to spread costs over a longer time period and reduce the possibility of a lapse in production/importation.

III 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 children's product safety rules. 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 proposed rule for infant bouncer seats, 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*. 16 C.F.R. 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 infant bouncer seat standard, 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 bouncer seats in the list of children's product safety rules for which the CPSC has issued NORs.

V STAFF RECOMMENDATIONS

Staff recommends that the Commission issue a proposed rule for infant bouncer seats that incorporates by reference ASTM F2167 – 15, *Standard Consumer Safety Specification for Infant Bouncer Seats* with the four modifications listed below to improve and strengthen the requirements stated in the current voluntary standard:

- a requirement that the fall hazard label be located in the area adjacent to the area where the child's head would rest,
- addition of text in each warning that addresses use of the restraints if the child is sleeping;
- a requirement for developmental guidance that advises caregivers to stop using the bouncer when the child starts trying to sit up, in the warnings to replace the current guidance; and
- a specified format to ensure that the warning content is conspicuous and easy to read and comprehend quickly.

Staff is recommending that the Commission propose an effective date of six months following publication of the rule to allow infant bouncer seat manufacturers' time to bring their products into compliance after a final rule is issued. A six-month effective date is consistent with the amount of time that has been given to a number of other section 104 rules. Although staff is proposing incorporation of the voluntary standard with changes, manufacturers who already comply with the voluntary standard will be in compliance with the regulation. A six month effective date will also allow time for manufacturers and importers to arrange for third party testing. However, if product redesign is necessary, then more time may be needed. Staff requests public comments on the appropriate effective date for the staff-recommended infant bouncer rule.

TAB A: Infant Bouncer Seats-Related Deaths, Injuries, and Potential Injuries January 1, 2006 – February 2, 2015

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

Memorandum

Date: May 18, 2015

TO : Suad C. Wanna-Nakamura, Ph.D.
Infant Bouncer Seats Project Manager
Division of Pharmacology and Physiology Assessment
Directorate for Health Sciences

THROUGH: Kathleen Stralka
Associate Executive Director
Directorate for Epidemiology

Stephen Hanway
Division Director, Division of Hazard Analysis
Directorate for Epidemiology

FROM : Ted Yang
Division of Hazard Analysis
Directorate for Epidemiology

SUBJECT : Infant Bouncer Seats-Related Deaths, Injuries, and Potential Injuries; January 1, 2006 – February 2, 2015²¹

I. Introduction

This memorandum characterizes the number and types of incidents for victims 12 months and younger involving infant bouncer seats over a period of at least 8 years starting in 2006. CPSC staff based hazard pattern characterizations on reports found in CPSC's incident databases. Staff reviewed incident reports involving bouncers from January 1, 2006 to February 2, 2015. Staff's characterizations of the severity of injury are based on National Electronic Injury Surveillance System ("NEISS") records retrieved for bouncer incidents from January 1, 2006 to December 31, 2013. CPSC staff has not included incidents earlier than 2006, because they add no additional relevant information relating to hazard patterns.

An infant bouncer seat is defined in ASTM F2167-15 as "a freestanding product intended to support an occupant in a reclined position to facilitate bouncing by the occupant, with the aid of a caregiver or by other means. The intended occupants are infants who have not developed the ability to sit up unassisted (approximately 0 to 6 months of age)." Due to the age approximation

²¹ 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.

included in the relevant population for this product, incidents involving victims 7-12 months old were also considered to be within the scope of foreseeable use.

II. Incident Data

a. CPSRMS Incident Data²²

For victims 12 months and younger, CPSC staff is aware of a total of 277 incidents, including eleven fatalities and 51 reported injuries, involving infant bouncer seats occurring between January 1, 2006 and February 2, 2015 based on reports in the Injury or Potential Injury Incident (“IPII”), In-Depth Investigation (“INDP”), and Death Certificates (“DTHS”) databases received by CPSC no later than February 2, 2015 and from manufacturer/retailer reports to the Office Compliance and retrieved from the Consumer Product Safety Risk Management System (CPSRMS) which combines the data from IPII, DTHS, and INDP into one searchable incident database.

Fatalities

There were thirteen (13) individual bouncer seat incidents involving fatalities between January 1, 2006 and February 2, 2015. Of the thirteen incidents, two were captured in NEISS and an additional 11 incidents were reported in CPSRMS. The eleven (11) fatalities associated with CPSRMS reported incidents in the period outlined above included:

1. 070214CCC1300: A 2-month-old who suffered from reflux and a respiratory infection was placed, unrestrained, to sleep in a bouncer that was lined with a blanket; the bouncer was on the floor next to the couch where his mother slept for the night. The child turned over in the seat, and was found unresponsive, face down against seat back. Cause of death was positional asphyxia.
2. 0726037034: A 3-month-old was left in a “bouncy (sic) seat on an adult bed.” Cause of death was probable asphyxia due to suffocation. There was no further information.
3. 080917HBB3900: A 2-month-old in a bouncer was placed in a crib to sleep. She was found suspended, partially upside down, over the side of the bouncer with one leg entwined in the restraints. A depression in the mattress suggests that the child’s face was against it. Cause of death was mechanical asphyxia.
4. 101012HCC3049: A 6-month-old (born several weeks premature) was placed in a bouncer on the floor (in front of a television) as he was falling asleep while his mother

²² CPSC staff searched the following databases: INDP file, IPII file, and the DTHS file. Reported deaths and incidents do not provide a complete count of all that occurred during this time period. However, reported deaths and incidents do provide a minimum number of deaths and incidents occurring during this period and illustrate the circumstances involved in the incidents related to bouncers.

CPSC staff extracted reported incident data on 2/2/15. Incident reports involving bouncers do not always clearly specify the product involved as a bouncer. As such, staff extracted all data coded under product codes 1327/1508/1520/1543/1558/4074, yielding a large initial data pool. Upon careful joint review with CPSC’s Directorates for Engineering Sciences, Economic Analysis, and Health Sciences staff, staff considered many incidents out-of-scope for the purposes of this memorandum. With the exception of incidents occurring on U.S. military bases, all incidents that occurred outside of the U.S. have been excluded. To prevent any double-counting, when staff identified multiple reports of the same incident, the incidents were consolidated and counted as one.

showered. She placed a pillow under the rear legs of the bouncer to raise it. She found the child unresponsive, turned with his face against the side of the bouncer, one leg out of the restraints. Cause of death was positional asphyxia.

5. 1051041332: A 4-month-old “suffocated when face down in soft bedding on bouncey (sic) seat at home.” There was no further information.
6. 110726CAA3941: A 3-month-old was placed on an adult bed in an infant bouncer seat, unrestrained, for a nap. The mother reported that the child had fallen out of the seat and she found her face down on the bed. The child was diagnosed with an irreversible anoxic brain injury and died 19 days later.
7. 120427HCC1640: A 6-month-old died of blunt force trauma to the head when the infant’s father lifted him in the bouncer seat. The bouncer collapsed and the child fell out of the back onto carpeted floor. He suffered a linear skull fracture and died the following day.
8. 121001HCC2002: A 3-month-old was fed and left to sleep in her bouncer seat. The child’s father reported that he found her face down, unrestrained, in the seat. The seat was on the floor, and the child’s mother and 2-year-old sister had been asleep on a couch nearby. Cause of death was positional asphyxia.
9. X1490229A: A 4-month-old was swaddled and placed for a nap, unrestrained, in a bouncer, which was then placed on the floor; the child was reportedly just starting to roll over, but had not done so completely on her own. Her parents found her unresponsive “with her face against the back of the infant seat and half way of the chair from the waist level down ...”; she could not be resuscitated. Cause of death was positional asphyxia.
10. 140102HWE0001: A 6-month-old was sleeping, strapped into a bouncer and when she awoke, was moved in the bouncer to a bedroom and left briefly with two toddlers, and possibly a pet dog. When the caregiver returned, she found the chair overturned on the floor with the victim’s neck lying over the chair’s [toy bar]. The report is inconsistent regarding whether the bouncer was placed initially on the bed or on the floor. The child died five days later. Cause of death was positional asphyxia.
11. 140422CAA1573: A 3-month-old was placed to sleep for the evening, unrestrained, in a bouncer on the floor in a room with several other children. Her mother found her five hours later face down in front of the bouncer on the floor and not breathing. The official cause of death is not known, because the coroner’s report is not provided in the investigation report.

The two (2) fatalities associated with NEISS reported incidents included:

1. 120328281: The parents of a 5-month-old found him unresponsive, flipped over in the bouncer seat with his leg still through one leg hole.

2. 130645295: A 2-month-old child had been asleep in a “bouncy”; his father awoke to find the child unresponsive on the floor.

Injuries

Fifty-one (51) reported injuries were associated with incidents retrieved from CPSRMS in the period outlined above, four of which were serious head injuries related to falls from elevated surfaces. Other reported injuries included skull fractures, leg fractures, head contusions, eye bruises, facial bruises and scratches, a split lip and torn upper frenulum, a finger bruise, leg cuts, leg bruises, heel lacerations, and a blood blister.

Because reporting is ongoing, the number of injuries and fatalities associated with infant bouncer seats are subject to change in the future.

b. CPSRMS Hazard Pattern Analysis

CPSC staff considered all 277 reported incidents based on reports in CPSRMS involving product-related issues to identify hazard patterns associated with infant bouncer seats. Product-related issues associated with these incidents include:

Product Design

Seventy-five (75) incident reports describe issues related to bouncer product design. Design issues described in these incident reports consisted of sharp plastic rods, uncushioned side metal bars, overhead attachments not clipping properly, sharp pieces of fabric, lack of padding in the footing area, bouncer frames that easily entrap arms/legs/fingers, easily movable feet cushion flaps, sharp plastic grooves from a musical component, sagging seat belts, and lopsided or low-riding bouncer frames. Sixteen of the 75 incidents resulted in injuries, all of which were minor.

Structural Integrity

Seventy (70) incident reports describe issues related to the structural integrity of bouncer components, such as bouncer seats collapsing upon being picked up, collapsing during use, and releasing fabric from the plastic frame, plus various other structural issues involving broken sides, recline adjustment pieces, wire bases, front tube retainers, and rubber feet. Twelve of the 70 incidents resulted in minor injuries.

Toy Bar-Related

Thirty-six (36) incident reports involve problems with the toy bar or toys attached to the toy bar. These reports describe the following types of issues: toy bars that fail to snap into place, toy bars breaking after being used as a handle, toys breaking off the bar, toys on the bar swinging back to hit the victim, toys scratching and pinching fingers or toes, and children getting hands or feet caught on the toy attachments. Ten of the 36 incidents resulted in minor injuries.

Stability

Stability issues comprised thirty-three (33) tip-over incidents involving a bouncer seat placed on the floor. While 26 bouncer tip-over incidents resulted in no reported injuries, 7 incident reports included minor injuries such as a split lip, head contusions, and facial bruises.

Chemical/Electric Hazards

Thirty (30) incident reports describe issues related to chemical or electrical hazards, including two reported injuries (a thigh welt and a rash). One incident involved a bouncer seat emanating a toxic smell, another incident involved a victim who developed a rash after directly touching the bouncer, and twenty-eight incidents involved batteries or the vibration motors. Twenty-four of the battery/motor incidents include reports of leaking, cracking, or exploding batteries. Four of the battery/motor incident reports specifically describe motor-related issues, which included overheating motors, motors making strange noises, and motors catching on fire, resulting in burning plastic and structural burn marks.

Restraints

Twenty (20) incidents, including two reported minor injuries, involve issues with bouncer restraints, including falling out of bouncer seats despite being strapped in, tearing/fraying straps, non-latching seat belts, and breaking seat buckles.

Hazardous Placement

Eleven (11) incidents involved a hazardous placement where victims in bouncer seats fell from elevated surfaces, fell face down onto soft bedding, or suffocated while attempting to slip out of a bouncer seat placed on an unstable surface. One incident included a reported skull fracture injury; another incident involved a fatality resulting from blunt force head trauma, while nine incidents involved fatalities due to asphyxia.

Unknown

Two (2) incidents involved an unknown hazard, including one which involved a reported injury and one which resulted in a positional asphyxia death.

The distribution of the 277 reported incidents involving product-related issues, hazardous environment, and non-product-related issues are summarized in Table 1.

Table 1
Bouncer Hazard Patterns in CPSRMS²³: 1/1/2006 – 2/2/2015 (age 0 - 1)

Product Issue	Incident Count	Fatalities
Product Design	75	0
Structural Integrity	70	0
Toy Bar-Related	36	0
Stability	33	0
Chemical/Electric Hazards	30	0
Restraints	20	0
Hazardous Placement	11	10
Unknown	2	1
Total	277	11

²³ In response to the Consumer Product Safety Improvement Act, the Consumer Product Safety Risk Management System (CPSRMS) was developed which combines the data from IPII, DTHS, and INDP into one searchable incident database.

c. NEISS Incident Data²⁴

CPSC staff retrieved 672 NEISS records describing infant bouncer seat incidents between 1/1/2006 and 12/31/2013. Injury estimates are derived from NEISS data, where sampling weights are used to project the number of cases reported by NEISS hospitals to national estimates. Table 2 provides a summary of estimated bouncer seat injuries based on the records retained. All estimates provided in the following tables are rounded to the nearest hundred.

Table 2
Estimated NEISS Bouncer Injuries, 2006 - 2013 (age 0 - 1)

Year	Cases	Estimated Injuries
2006	67	1,400
2007	66	1,700
2008	74	1,600
2009	86	2,200
2010	94	2,300
2011	121	3,400
2012	90	2,500
2013	74	2,100
2006 – 2013	672	17,200

Based on the annual estimates provided by Table 2, a statistically significant upward trend exists in the estimated emergency department-treated injuries involving bouncers for victims under 1 year old from 2006 - 2013.

d. NEISS Severity of Injury Summary

Hazardous Placement:

Of the 672 NEISS records describing bouncer injuries, 287 incidents took place on the floor or an unknown location. The remaining 385 incidents, or an estimated 9,200 injuries, involved hazardous placements: 342 of these incidents, or an estimated 8,100 injuries, resulted from falls. Hazardous placements included counters, tables, and other elevated surfaces (*i.e.*, beds, carried or lifted positions, chairs, couches, dressers, stairs, appliances, etc.). An estimated 6,800 injuries, or 74% of all estimated bouncer injuries associated with a hazardous placement, involved the bouncer being placed on a counter or table. Table 3 provides a breakdown of estimated bouncer injuries by hazardous placement.

²⁴ CPSC staff extracted incident data on 2/2/15. Incident reports involving bouncers do not always clearly specify the product involved as a bouncer. As such, all data coded under product codes 1327/1508/1520/1543/1558/4074 were extracted, yielding a very large initial data pool. Upon careful joint review with CPSC's Directorates for Engineering Sciences, Economic Analysis, and Health Sciences staff, many cases were considered out-of-scope for the purposes of this memorandum. With the exception of incidents occurring in U.S. military bases, all incidents that occurred outside of the U.S. have been excluded.

Table 3
Estimated NEISS Bouncer Injuries by Hazardous Placement, 2006 - 2013 (age 0 - 1)

Location	Cases	Estimated Injuries
Counter or table	268	6,800
Other elevated surfaces [†]	117	2,400
Total	385	9,200

[†] Includes beds, carried/lifted positions, chairs, couches, dressers, stairs, appliances, etc.

Injury Types by Body Part:

An estimated 15,100 (92%) bouncer injuries involved the head and face. Conversely, only 1,300 estimated injuries involve an unknown area or the rest of the body (appendages, torso, internal). Table 4 provides a breakdown of bouncer injuries by body part.

Table 4
Estimated NEISS Bouncer Injuries by Body Part, 2006 - 2013 (age 0 - 1)

Body Part	Cases	Estimated Injuries
Head	525	13,000
Face	71	2,100
Unknown/other (appendages, torso, internal)	51	1,300
Total *	647	16,400

* Of the 672 total infant bouncer seat incidents, 25 cases involved no apparent injuries.

Disposition:

An estimated 15,500 patients were treated and released for bouncer injuries. Conversely, an estimated 1,300 patients were treated and admitted, treated and transferred to another hospital, or held for observation. Nine (9) specific cases described incidents involving victims who left without being seen. Two cases involved a victim who died from cardiac arrest; one victim died after flipping over in an infant bouncer seat with his leg still through one leg opening, while another victim was found on the floor unresponsive after being asleep in the bouncer. Both cases were confirmed to be unique incidents from the 11 incidents reported in CPSRMS involving fatalities. Table 5 provides a breakdown of bouncer injuries by disposition.

Table 5
Estimated NEISS Bouncer Injuries by Disposition, 2006 - 2013 (age 0 - 1)

Disposition	Cases	Estimated Injuries
Treated and released	579	15,500
Hospitalized/transferred/held for observation	82	1,300
Left without being seen	9	*
Death	2	*
Total	672	17,200

* Estimate is smaller than 1,200. 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% or smaller.

Age Groups:

An estimated 14,600 (85%) bouncer injuries involved victims between 0-6 months old. The birth to 6 month old age range reflects the intended approximate age range for bouncer occupants

discussed in ASTM F2167-15. An estimated 2,700 bouncer injuries involved victims 7-12 months old. Table 6 provides a breakdown of bouncer injuries by age group.

Table 6
Estimated NEISS Bouncer Injuries by Age Group, 2006 - 2013 (age 0 - 1)

Age Group	Cases	Estimated Injuries[†]
0-2 months	219	5,400
3-4 months	175	4,800
5-6 months	170	4,400
7-12 months	108	2,700
Total	672	17,200

[†]Estimates may not add up to 17,200 due to rounding.

TAB B: Health Science Analysis of Infant Bouncer Seat-Related Deaths and Injuries

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

Memorandum

Date: July 23, 2015

TO : Suad C. Wanna-Nakamura, Ph.D.
Infant Bouncer Seats Project Manager
Division of Pharmacology and Physiology
Directorate for Health 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 : Stefanie Marques, Ph.D., Physiologist
Division of Pharmacology and Physiology
Directorate for Health Sciences

SUBJECT : Health Science Analysis of Infant Bouncer Seat-Related Deaths and Injuries

Introduction

Section 104 of the Consumer Product Safety Improvement Act of 2008 (“CPSIA”) requires the U.S. Consumer Product Safety Commission (“CPSC” or “Commission”) to assess the effectiveness of voluntary consumer product safety standards for durable infant and toddler products and to 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. A bouncer is defined in the ASTM voluntary standard F2167-15 as “a freestanding product intended to support an occupant in a reclined position to facilitate bouncing by the occupant, with the aid of a caregiver or by other means.”

This memorandum provides Health Sciences (“HS”) staff’s analysis on deaths and injuries associated with the use of bouncers from January 1, 2006 to February 2, 2015.

CPSC Hotline: 1-800-638-CPSC(2772) CPSC’s Web Site: <http://www.cpsc.gov>

Health Sciences Analysis of Bouncer-Related Deaths:

Thirteen deaths related to bouncers occurred from January 1, 2006 to February 2, 2015. In the following three incidents (2 incidents from the National Electronic Injury Surveillance System (“NEISS”)) it is HS staff’s opinion that the information is insufficient to determine the hazard that contributed to the fatality.

1) An incident reported via NEISS states:

“2 MOM CHILD HAD BEEN ASLEEP IN BOUNCY, DAD AWOKE TO FIND BABY IN FLOOR UNRESPONSIVE DX: CARDIAC ARREST”

The limited NEISS narrative does not state whether the bouncer tipped over or indicate how the baby landed on the floor, therefore HS staff cannot determine how the bouncer seat was involved in this incident.

2) A second NEISS fatality incident states:

“5MOM PARENTS FOUND PT UNRESPONSIVE & FLIPPED OVER IN BOUNCY SEAT W/LEGSTILL THRU 1 LEG HOLE,STIFF,PALE,LIPS PURPLE,AT HOME;CARDIAC ARREST”

It is HS staff’s opinion that the term “leg hole” is inconsistent with the features of a bouncer and more consistent with features associated with other products that consumers also refer to as “bouncy seats,” such as a jumper type product. Also, insufficient information is provided in this report to determine how the infant was found and how the product was involved in the death.

3) The third incident, which occurred in March 2012, involves a 3-month-old infant who fell asleep unrestrained in a product (121001HCC2002). In this incident the mother stated that they had been out shopping with the infant when they came home around 10 in the evening. The mother carried the infant in her car seat into the house and placed the infant in the car seat down next to a loveseat, where she fed the infant. Then, the mother states that the infant fell asleep, and the mother went to sleep next to the infant on the loveseat. A couple hours later the father came home and found the infant with her face pressed up against the side of the product unresponsive. Police investigation photos show the car seat on the floor next to a bouncer. At the time of the incident, one police detective on the scene and the medical examiner referred to the car seat as the product in which the infant was found. However, in a report by a second police detective over 2 months later, it stated that the father confirmed in an interview with a sergeant at the hospital that it was the bouncy seat and not the car seat in which the infant was found unresponsive. It is HS staff’s opinion, that in the absence of any other information from the mother as to when and why she transferred the infant from the car seat to the bouncer during the time line of events described above, it is not clear whether the infant was in the car seat or the bouncer at the time of death.

It is HS staff's believes that hazardous placement of the bouncer may have contributed to the deaths. They are as follows in chronological order:

4) In May 2006, a 2-month-old infant was sleeping unrestrained in a bouncer on the floor (070214CCC1300); photos of the scene show that at least one baby blanket was placed in the bouncer. The following morning, his mother, who was sleeping next to the victim on the couch, noticed that he had turned over in the bouncer and was lying face down in the bouncer unresponsive. The medical examiner ruled the cause of death as positional asphyxia. It is HS staff's opinion that because the infant was unrestrained, this allowed him to turn over in the bouncer; being able to move, in combination with the presence of extra bedding, created the hazardous environment in this incident.

5) In April 2007, a 3-month-old infant was left unattended in a bouncer on an adult bed (0726037034). The medical examiner ruled the cause of death as probable asphyxia due to suffocation. Since this only a death certificate report, the information for this incident is limited. However, the cause of death suggests that the infant fell out of the bouncer onto the adult bed, so it is HS staff's opinion that the placement of the bouncer on a soft surface (the adult bed) created the hazardous environment in this incident.

6) In September 2008, a 2-month-old infant was put to sleep and secured in a bouncer, which was placed in a crib (080917HBB3900). The infant's mother fed the infant at 12 a.m., and then approximately 4 hours later checked on the infant again and found the infant hanging out of the bouncer with her head and upper torso down toward the crib mattress while her left leg was still intertwined in the restraints. The medical examiner ruled the cause of death as mechanical asphyxia. It is HS staff's opinion that the placement of the bouncer in the crib created the hazardous environment in this incident.

7) In July 2009, a 6-month-old infant was placed in a bouncer on the floor and secured with the restraint system (101012HCC3049). The infant's mother elevated the head of the bouncer approximately 20 degrees by placing a pillow underneath the bouncer legs. The infant's mother believed the infant was falling asleep, so she left the room to take a shower. After finishing her shower, which lasted approximately 10 minutes, and getting dressed, the infant's mother went to check on the infant and found that the infant was on his right side and unresponsive with blood and vomit on his face. The medical examiner stated the infant "was found with his face turned into the side of the cushioning, with the legs in a slightly contorted position" and ruled the cause of death as positional asphyxia. The medical examiner also noted that even though the infant was born premature at 32 weeks and had spent 4 weeks in the hospital for respiratory distress syndrome that the infant was "fairly healthy." It is HS staff's opinion that placing the pillow underneath the bouncer, which made the angle of the bouncer steeper, created the hazardous environment in this incident.

8) In September 2010, a 4-month-old infant was found in a bouncer, face down, in soft bedding (1051041332). The medical examiner ruled the cause of death as suffocation by bedding. It is HS staff's opinion that the presence of extra bedding created the hazardous environment in this incident.

9) In June 2011, a 3-month-old infant was put down for a nap unrestrained in a bouncer, which had been placed on top of a queen-sized bed in the parents' room (110726CAA3941); the parents were in the living room smoking marijuana and, according to the mother, checked on the infant every seven to ten minutes. Upon checking on the infant, the mother found that the infant had fallen out of the bouncer and was face down on the bed not breathing. The infant was transported from her local hospital to a larger city hospital where she was diagnosed with irreversible anoxic brain injury, then placed on comfort care and died 19 days later. The coroner's report is not provided in the investigation report, and therefore, the cause of death is not known.

10) In February 2012, a 6-month-old infant was in a bouncer seat when his father picked up and lifted the bouncer to move it closer to the television in the living room (120427HCC1640). Upon lifting the bouncer, it collapsed and the infant slipped out head first onto the carpeted floor. It is not known whether the infant was secured in the bouncer seat. The infant died the next day and the medical examiner ruled the cause of death as blunt force trauma of the head due to a short fall from a "bouncy seat" to the floor. It is HS staff's opinion that carrying the bouncer at an elevated height contributed to the fall

11) In May 2013, a 4-month-old infant was swaddled and placed in a bouncer unrestrained for a nap (X1490229A). The infant was found approximately 3 hours later half way out of the bouncer with her face against the back of the bouncer; she was blue and unresponsive. The parents stated the infant had just started to roll over but had not done it completely on her own. The medical examiner ruled the cause of death as positional asphyxiation. It is HS staff's opinion that, because the infant was unrestrained, this allowed her to turn over in the bouncer; being able to move, in combination with being swaddled with extra bedding, created the hazardous environment in this incident.

12) In December 2013, a 5-month-old infant was placed in a bouncer restrained for a nap (140102HWE0001). Initially the bouncer was in the living room, but once the infant had fallen asleep in the bouncer, the infant and the bouncer were moved to a quieter bedroom down the hall. Sometime later, when the caregiver heard that the infant was alert, the infant and the bouncer were moved again to the upstairs master bedroom where there were several other toddler children and possibly a dog. The caregiver of the infant, a family friend, stated that she placed the bouncer on the floor next to bed and checked on the infant several times. At one point she left the room to wash her hands for about 2 minutes and when she returned to check on the infant she found the infant still strapped in, tipped forward in the bouncer, with her neck pressed against the bouncer toy bar, unresponsive. The caregiver performed CPR until emergency personnel arrived. The infant arrived at the hospital brain dead and was taken off life support 5 days later. Although the caregiver stated to police that she had placed the bouncer on the floor, per the CPSC investigator's narrative, when questioned further by the medical examiner during their visit to the scene, she admitted to placing the bouncer on the bed; however, in the medical examiner's report it states that the bouncer was placed on the floor and that "the marks on her face and neck were consistent with pressure from the carrying handle causing a positional asphyxia." The medical examiner's report notes that the infant had abrasions and bruising on her cheek, forehead, scalp, lower abdomen, anterior right groin, left knee, right thigh, and right calf; in HS staff's opinion this extensive bruising seems more consistent with the infant and the bouncer falling from the

height of the bed onto the floor, rather than the infant and the bouncer tipping forward while already on the floor. In HS staff's opinion placing the bouncer on a bed in room with several other children and a pet unsupervised created the hazardous environment in this incident.

13) In April 2014, a 3-month-old infant was placed in a bouncer on top of a buckled seat belt to sleep (140422CAA1573); the mother stated that she did not use the restraints because the infant was too big. Over 5 hours later, the mother of the infant woke up and found the infant face down on the floor at the end of the bouncer, unresponsive, with the infant's feet wrapped up in a large quilted blanket that was with the infant when she was placed in the bouncer. The infant's mother performed CPR on the infant until emergency medical services ("EMS") arrived. The infant was transported to her local hospital where she died. There was no medical examiner's report included in the incident investigation, therefore the official cause of death is not known. Although initially the infant was described as having her feet wrapped in a large quilted blanket that was placed in the bouncer with the infant, the police detective's recreation of the scene shows the infant face down on a large comforter type blanket on the floor near the bouncer with the bouncer still upright. The mother stated that infant was able to scoot to the bottom of the bouncer without assistance. It is HS staff's opinion that combination of the infant being unrestrained, her being able to move out of the bouncer, and the presence of the large blanket either in or around the bouncer created the hazardous environment in this incident.

Health Sciences Analysis of Bouncer-Related Injuries:

CPSRMS²⁵ data

Epidemiology staff's search of the CPSC database resulted in 277 bouncer-related incidents involving children 12 months old and younger that occurred between January 1, 2006 and February 2, 2015. Eleven incidents involved an infant's death and 51 incidents resulted in an injury.

It is HS staff's opinion that incidents involving the infant occupant falling from the bouncer are of most concern because they have the greatest potential for a serious injury. According to HS staff's analysis, 77 of the 266 non-fatal incidents involved the infant occupant falling from the bouncer. In five of these incidents, the infant occupant fell from the bouncer that was placed at an elevated height, such as on a kitchen countertop or dining table, or was being carried by the caregiver; in four (80%) of these elevated height incidents, the infant fell from the bouncer and sustained a severe head injury. In 39 fall incidents, the bouncer was placed on the floor; in 13 (33%) of these incidents the infant occupant sustained a minor injury such as a bruise, bump, or abrasion. In the remaining 33 fall incidents, the location of the bouncer could not be determined; in 5 (15%) of these incidents the infant occupant sustained minor injuries.

The majority of the remaining 189 non-fatal incidents that did not involve a fall resulted in no or minor injuries. Only one incident resulted in a moderate injury; in this incident a 3-month-old infant shifted in the bouncer and sustained a fractured leg.

²⁵ In response to the Consumer Product Safety Improvement Act, the Consumer Product Safety Risk Management System (CPSRMS) was developed which combines the data from IPII, DTHS, and INDP into one searchable incident database.

NEISS data

Epidemiology staff's search of the NEISS resulted in 672 bouncer-related incidents involving children 12 months old and younger that occurred between January 1, 2006 and December 31, 2013. Epidemiology staff determined that 385 incidents involved bouncers placed in hazardous locations such as kitchen countertops, tables and other elevated surfaces. HS staff analysis determined that 50 of these hazardous location incidents resulted in a severe head injury such as a concussion or fractured skull, 12 of these severe head injuries were the result of the caregiver carrying the infant in the bouncer.

Conclusion:

It is HS staff's opinion that the biggest concern regarding bouncer-related deaths was placement of the bouncer in a hazardous environment. The hazardous environments that contributed to most of the infants' deaths were created either by the presence of excess bedding in or under the bouncer; placement of the bouncer on a soft surface such as an adult bed; placement of the bouncer in a crib; and carrying or placing the bouncer at an elevated height. It is HS staff's opinion that the fact that most of the deaths also involved the infant being placed in the bouncer to sleep unrestrained allowed the infant unsupervised time and movement within the hazardous environment which contributed to their death.

The one fatality that resulted from the bouncer being carried at an elevated height, combined with the CPSRMS and NEISS injury data, strongly suggest that the biggest issue regarding bouncer-related incidents is infants falling while in the bouncer or from the bouncer at an elevated height. According to HS staff's analysis, infants were more likely to sustain a severe head injury when they fell from bouncers placed at elevated heights, and the likelihood of severe head injury increases if the child is being carried in the bouncer and/or they are unrestrained in the bouncer.

Severe head injuries such as concussions and fractured skulls could cause extensive brain damage and affect the infant's motor development, emotional development, speech, ability to think and learn and overall quality of life long after the incident has occurred.

**TAB C: Staff’s Review and Evaluation of ASTM F2167-15,
*Standard Consumer Safety Specification for Infant Bouncer
Seats*, for Incorporation by Reference into Staff’s Draft
Proposed Rule**

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UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
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Memorandum

June 26, 2015

TO: Suad C. Wanna-Nakamura, Ph.D.
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THROUGH: George A. Borlase, Ph.D., P.E.
Assistant Executive Director
Office of Hazard Identification and Reduction

Andrew G. Stadnik, P.E.
Assistant Executive Director
Directorate for Laboratory Sciences

FROM: Richard McCallion
Mechanical Engineer
Office of Hazard Identification and Reduction

SUBJECT: Staff's Review and Evaluation of ASTM F2167-15, *Standard Consumer Safety Specification for Infant Bouncer Seats*, for Incorporation by Reference into Staff's Draft Proposed Rule

I. INTRODUCTION

In accordance with section 104 of the CPSIA, this memorandum assesses the effectiveness of ASTM F2167, *Standard Consumer Safety Specification for Infant Bouncer Seats* ("ASTM F2167"), and outlines staff's recommendation to incorporate by reference the most recent version of that standard (ASTM F2167-15²⁶) into the proposed mandatory rule for infant bouncers.

II. PRODUCT DESCRIPTION

An infant bouncer seat is defined in ASTM F2167-15, Section 1.2 as "a freestanding product intended to support an occupant in a reclined position to facilitate bouncing by the occupant,

²⁶ Current edition approved May 1, 2015. Published June 2015. Originally approved in 2001. Last previous edition approved in 2014 as F2167 – 14a.

with the aid of a caregiver or by other means. Intended occupants are infants who have not developed the ability to sit up unassisted (approximately 0 to 6 months of age).”

Many different styles of infant bouncer seats are available, but the most common type is a wire frame construction with a fabric cover. The wire frame bouncers have two designs. The forward bend design is constructed with the seating area supported from the front side of the product (figure 1a). The second wire frame design is a rear bend design. In this design the seat is supported from the rear side of the seat (figure 1b).



(a) Infant Bouncer – Forward Bend (b) Infant Bouncer –Rear Bend

Figure 1 - Wire Frame Designs

Other bouncer designs are also currently available including, but not limited to, products with individual wire legs, solid bases, and spring designs. These infant bouncer designs (figure 2) use different methods to support the seat and are intended for bouncing as defined in ASTM F2167. The first bouncer shown below, figure 2(a), is supported by 4 wire legs, and the seat is attached to the base centrally on either side of the seat. The second design, figure 2(b), has a solid base with the seat supported by an arm that allows the seat to move forward to back. In the final design, figure 2(c), the seat is supported by 3 legs with a spring-loaded connection at the bottom of the seat. Wheels are installed on the 2 front legs to allow the front legs to roll forward as the seat deflects down during use.

A majority of the bouncer designs include a toy bar and vibration feature. The toy bars are typically flexible bars that extend over the seating area of the bouncer seat with toys or other components attached that are intended to be played with by the child in the seat. The vibration units are battery powered and are typically attached to the bouncer frame at the bottom edge of the seat.



(a) 4 Legs



(b) Solid Base



(c) Spring Design

Figure 2 - Alternative Bouncer Designs

III. HISTORY OF ASTM F2167 STANDARD

A voluntary standard for infant bouncer seats was first approved in December 2001 and originally published in January 2002, as ASTM F2167-01, *Standard Consumer Safety Specification for Infant Bouncer Seats*. The current version, ASTM F2167-15, was approved on May 1, 2015. The standard has been revised 9 times. Substantial revisions are described below and highlight changes to the standard over time. Other versions of ASTM F2167 that primarily included editorial or minor updates are not listed below.

ASTM F2167-01 contained requirements to address the following issues:

- Sharp points and sharp edges
- Small parts
- Lead in paint
- Wood parts
- Locking or latching mechanisms
- Scissoring, shearing, pinching
- Openings
- Exposed coil springs
- Protective components
- Labeling and warnings
- Toy accessories
- Structural integrity
- Stability (forward, sideward, and rearward)
- Slip resistance (static and dynamic)
- Disassembly and collapse

ASTM F2167-05a (approved on May 1, 2005) revision:

- Added ASTM reference documents
- Modified definition of openings and added a figure
- Reorganized requirements and test methods sections
- Modified marking and labeling requirements

- Added keyword section that includes the term “bouncing motion” to remove the possibility of testing compromised samples for tests such as stability after testing that can likely result in sample damage
- Changed openings requirement, which better defined hazardous openings as openings that extend completely through rigid materials of certain depths and diameters
- Added figure to further clarify the hazardous opening that required testing and to make F2067 consistent with other existing children’s product standards

ASTM F2167-05b (approved on October 1, 2005) revision:

- Modified forward stability test fixture to more closely represent the forces applied to a bouncer by a child using the product

ASTM F2167-10 (approved on April 1, 2010) revision:

- Clarified that English units are the standard and metric values are calculated from the English unit standard
- Modified definition of “conspicuous” to require that a warning label be visible to a person sitting down instead of being visible to a person standing
- Editorial changes

ASTM F2167-12 (approved on March 12, 2012) revision:

- Added definition of “grasping point on toy” to clarify the toys location relative to the seated child.
- Added definition of “toy bar”
- Added toy bar integrity requirement
- Added static and dynamic toy bar integrity tests to address toy bars used as a handle to lift the bouncer and child
- Added non-mandatory rationale section

ASTM F2167-12a (approved on July 1, 2012) revision:

- Added instructional literature on battery usage and storage

ASTM F2167-14 (approved on February1, 2014) revision:

- Modified the sideward and rearward inclined testing surface from 12 degrees to 20 degrees to address tip over incidents and falls from elevated surfaces
- Editorial changes

ASTM F2167-14a (approved on August 1, 2014) revision

- Modified the forward stability test was made more severe by applying the test weight 1 inch further out from the crotch post and using the manufacturer’s recommended maximum weight if greater than the 21-pound minimum weight application at CPSC staff request

- Added requirements and a test procedure for battery compartment leakage and circuit overload at CPSC staff request

ASTM F2167-15 (approved on May 1, 2015) version:

- Added a fall hazard label visibility test to address fall and suffocation warning labels
- Updated warning labels
- Updated the instructional literature section to reflect warning label changes
- Added rationale (non-binding) to provide supplemental information on latest revisions

IV. ADEQUACY OF ASTM F2167-15 TO ADDRESS IDENTIFIED HAZARD PATTERNS

CPSC staff examined the relationship between the performance requirements in ASTM F2167-15 and each of the hazard patterns identified in Tab A of the memorandum from the Directorate for Epidemiology. Additionally, staff tested 10 samples of infant bouncers, using currently available infant bouncers of the types shown in the introduction of this memo. Staff also tested an old exemplar sample that is no longer in production to compare with currently available designs. Each of the samples tested was subjected to all of the performance requirements of ASTM F2167-15.

Based on staff's assessment, the performance requirements contained in the current voluntary standard, ASTM F2167-15, sufficiently address the identified hazards associated with the use of infant bouncers. Performance requirements in ASTM F2167-15 cover: the restraint system, stability, slip resistance, structural integrity, and disassembly/collapse, drop testing, batteries, and toy bar integrity. These requirements are in addition to the general requirements that are typically included with most juvenile product standards. Discussed below is each of the 7 hazard patterns identified in Tab A, and staff's assessment of the adequacy of ASTM F2167-15, as it relates to each hazard pattern.

A. Structural Integrity

The most common scenario was collapse during use and fabric detaching from the frame. Other incidents resulted from broken sides, recline adjustment problems, wire frame issues and rubber feet. Bouncer misassembly incidents, where components were not properly connected and came apart are also included in the structural integrity hazard pattern.

ASTM F2167 subjects infant bouncers to a series of three tests to evaluate structural integrity including: (1) a static load test; (2) a dynamic load test; and (3) a disassembly/collapse test.

In the static load test, a 6"x6"x3/4" (152.4x152.4x1.91 mm) wood block is placed in the bouncer seat and loaded with the greater of 60lb (27.3kg) or 3 times the manufacturer's recommended

maximum weight, whichever is greater. This is to ensure that the bouncer design is sufficient to hold the weight of any child that is likely to use the product.

In the dynamic load test, a 6" (152.4mm) weld cap is dropped from a distance of 1" (25mm) with the convex surface face down onto the bouncer seat. Extra weight is added to the weld cap to provide a total weight of 33lb (15kg). The drop for the dynamic load test is repeated a total of 100 times. This test simulates the child being placed in the seat and removed, as well as the forces applied to the bouncer while the child is in the seat. This test provides a reasonable factor of safety to ensure that the bouncer seat does not fail when used in accordance with the manufacturer's recommendations.

Upon completion of both the static load and dynamic load tests, the bouncer must meet the general requirements outlined in Section 5.0 of the standard.

The disassembly/collapse test simulates lifting the bouncer by the ends with a child seated in the product to see if the bouncer collapses or folds up into a position that might result in injury. To conduct the test, a newborn CAMI dummy is placed in the bouncer seat and a 15lb (67N) force is applied to the bouncer at the location most likely to cause disassembly. In situations where there are multiple locations that could result in disassembly, the test is repeated for each location. If a hazardous condition results from the test, the bouncer fails the requirement. A hazardous condition is anything that would result in the bouncer not meeting the general requirements, or any visual indications of disassembly or collapse of the bouncer.

After reviewing the information available on the structure failure type incidents it is likely many of the incidents are the result of misassembly and not the result of product design. The three structural tests subject infant bouncers to the reasonable forces that could be applied during the normal life of the product and adequately test the structural strength of a bouncer. Therefore, staff does not believe that additional or more stringent performance requirements would reduce the risk of structural integrity-related incidents at this time.

B. Product Design

Product design incidents include reports of product failures related to the general requirements including: sharp plastic rods, uncushioned side metal bars, overhead attachments not clipping properly, sharp pieces of fabric, lack of padding in the footing area, bouncer frames that easily entrap arms/legs/fingers, easily movable feet cushion flaps, sharp plastic grooves from a musical component, sagging seat belts, and lopsided or low-riding bouncer frames. This hazard pattern also includes incidents of unintended shifting or leaning of the bouncer due to a structural change considered abnormal by the consumer.

Staff evaluated the current requirements in ASTM F2167 and tested bouncer samples to the tests for product design. Each type of failure identified in the incidents is addressed in the standard with performance requirements and associated tests. Adding or strengthening requirements is not likely to reduce the occurrence of these incidents. Staff believes many of these incidents are the result of manufacturing, shipping, and consumer assembly related issues. Based on this

evaluation and testing, staff concludes that the current performance requirements are adequate to address this hazard pattern.

The performance requirements to test for hazards related to product design are the same as those used to test for structural integrity. In addition, the drop test and the general requirements in Section 5.0 are used to address this hazard pattern. The drop test is included to evaluate the durability of the product in instances of misuse, and to assess compliance with the general safety requirements, such as small parts, sharp points, and sharp edges. This test applies dynamic forces to the bouncer in directions not associated with normal use by a child. In the drop test, the bouncer is dropped from a height of 36" (914.4mm) once in each of six different planes (top, bottom, front, rear, left side, and right side). If the bouncer is of a folding design, the 6 drops are done in both the folded and unfolded configurations (for a total of 12 drops). At the end of the test, the bouncer must meet the general requirements outlined in Section 5.0 of the standard.

C. Toy Bars

Staff identified incidents where the toy bar failed as the caregiver was using it as a handle. Some incidents involved entrapment or pinching of a child's fingers, toes, arms, or legs in the toys or toy bar. Other reports describe small parts coming from broken components of a toy bar or toy. The remainder of the incidents reported includes toys that struck the child.

In the majority of the incidents reviewed, the child had initiated the motion of the toy by pushing it with a hand or foot and the toy struck the child on the return swing. Minor injuries were reported. Due to the low weight of the toys and short tether between the toy and toy bar, staff believes that not enough energy could be developed in this scenario to result in a substantial injury to a child. In incidents that involved the toy bar used as a handle it is unclear if the handle was designed to break free, failed, or broke.

ASTM F2167-15 includes general performance requirements applicable for testing related to this type of incident. A static test is performed with a 6"x6"x3/4" (152.4x152.4x1.91 mm) wood block placed in the bouncer seat and loaded with the greater of 40lb (18.2kg) or 2 times the manufacturer's recommended maximum weight. The bouncer is then gradually lifted. In the dynamic test, an infant CAMI is placed in the seat and a cable is attached to the center grasping point of the handle. The bouncer is raised and allowed to drop 2" (5.1cm). The toy bar must completely release from the bouncer or move less than 2" (5.1cm) from the resting position if the bar has a single attachment point.

Staff evaluated many bouncers that included a bar designed with small toys attached that hang over the body of a child seated in the bouncer. Individual toys included with the bouncer are required to meet the general requirements in the standard; however, the toy bar is also required to meet the toy bar integrity test requirement. This requirement uses two different tests, a static integrity test and a dynamic integrity test, to address incidents in which the toy bars are used as handles.

The toy bar integrity tests as described above are intended to address the risk of injuries when the toy bar is used as a handle to carry the bouncer seat and child. These tests address a previously

identified hazard pattern, where consumers would lift the seat by the toy bar, the toy bar would bend or break and the bouncer seat would uncontrollably shift or fall, resulting in injuries to the child. Bouncer seats that meet the toy bar integrity requirement must be designed to function as a handle, break free, or substantially deform prior to lifting. The incidents from toy bars breaking, when used as a handle, have decreased since 2012, when the toy bar integrity tests were added to ASTM F2167. However, many of the recent incidents describe consumer complaints about the toy bar releasing or bending. These incident reports are not considered safety related, because the bouncers are specifically designed that way for safety purposes and no reported injuries have occurred from these incidents.

These requirements for toy bars are consistent with other ASTM juvenile product standards, incorporated as CPSC juvenile product regulations, and staff believes that they adequately address these hazards.

D. Stability

Stability issues related to bouncers include incidents where an occupied bouncer tipped over in the forward, sideways or rearward directions.

ASTM F2167-15 addresses bouncer stability in each direction with a forward, sideways, and rearward test requirement. In the forward stability test, an infant CAMI dummy is placed in the infant bouncer and the restraints are adjusted to fit in accordance with the manufacturer's instructions. The dummy is then removed and the stability test fixture is placed in the seat. A vertical static force of 21lb (93N) or three times the manufacturer's recommended weight, whichever is greater, is applied for 60 seconds to the fixture at a distance of 6in (152.4mm) in front of the crotch post. To pass the test, the bouncer must not tip over or the front edge must not touch the test surface.

Repeatable stability testing in the sideward and rearward directions is more difficult to accomplish based on a bouncer's potential shifts in the center of gravity. Because of these potential shifts, sideward and rearward testing for bouncers is done differently than in the forward direction. The current sideward and rearward stability tests are performed with the infant CAMI dummy placed in the seat and the bouncer placed on a 20 degree incline in the most unstable orientation other than forward. To pass the test, the bouncer must not tip over in this position.

In order to address incidents relating to stability, CPSC staff worked with the ASTM subcommittee on bouncers to modify all the stability performance requirements.

In F2167-14, the rear and side stability tests were strengthened by ASTM when the angle of incline was from 12 to 20 degrees. The changes in ASTM F2167-15 include a longer distance between the crotch post of the test fixture and the application of force for the forward stability test. In F2167-15, the force is applied at a distance of 6in (152.4mm) in front of the crotch post instead of the previous distance of 5in (127mm).

Sample testing by CPSC staff determined that most current models would comply with the updated standard. However, two samples did not meet the new requirement. One failing sample was an infant bouncer that is no longer in production, and the second was a wire frame bouncer with a forward bend design. CPSC staff determined that wire frame bouncers with a forward bend and individual wire leg designs (figures 1a and 2a) are the most likely to fail the forward stability test. In these designs, the bouncer becomes less stable when the force is applied farther out. However, forward stability is not affected by the new test in wire frame, rear bend design bouncers.

Overall, these recent changes to the stability requirements will require the design of increasingly stable bouncer designs similar to ones currently available. CPSC staff believes these new requirements will reduce the likelihood of bouncer tip overs and associated injuries.

E. Chemical/Electrical

Staff reviewed incidents related to battery issues, including the battery-operated vibration unit leaking battery, smoking, or catching fire. The main electrical hazards associated with bouncers are related to battery overheating and the potential leakage or fire.

ASTM recently added battery and containment requirements to the standard. These additions were developed with support from CPSC staff and based on the incidents reported to CPSC. The new requirements include permanently marking the correct battery polarity adjacent to the battery compartment, providing a means to contain the electrolytic material in the event of battery leakage, protection against the possibility of charging non-rechargeable batteries, and defining a maximum surface temperature for any accessible component. The battery polarity requirement requires a visual inspection of the battery compartment. Surface temperature and charging protection is accomplished through the performance of an operational test. The bouncer is operated using new batteries of the type recommended by the manufacturer. Testing is performed by operating the bouncer at the highest setting for 60 minutes. Upon conclusion, there shall be no battery leakage, explosion, fire, and no accessible component shall exceed 160°F degrees (71°C). The performance requirement includes a provision for testing using a/c power, but staff is unaware of bouncers currently on the market that are a/c powered.

Staff believes the new ASTM battery requirements adequately address the electrical incidents. The addition of requirements to address battery compartments and electrical circuitry will require bouncers to have electrical designs similar to other juvenile products. CPSC staff believes these new requirements will reduce the likelihood of overheating and battery leakage incidents.

F. Restraints

Staff reviewed the incidents involving restraints. The issues involved restrained children falling out of the bouncer, tearing/fraying of straps, non-latching seat belts and buckle failure. The remaining incidents described scenarios where the restraint functioned as designed. Staff does not recommend any changes to the current testing of restraints.

ASTM F2167 requires that restraints be provided with a bouncer seat. Restraints must be capable of securing a child when the bouncer is placed in any use position recommended by the manufacturer. ASTM F 2167 requires both a waist and a crotch restraint, and the restraint must be designed in such a way that the crotch restraint must be used when the waist restraint is in use. Testing to this requirement is performed by securing the bouncer seat and applying a 45lb (200N) force for a period of 10 seconds to a single attachment point of the restraint in the normal use direction. The standard specifies that the restraint's anchorages shall not separate from the attachment points to the bouncer. While no provisions in the performance requirements address the actual use of the restraint, ASTM F2167 contains a warning label requirement regarding proper use of the restraint. See the Human Factors memorandum for more information regarding labeling requirements.

Staff does not recommend any changes to the current testing of restraints.

G. Hazardous Placement

Hazardous environment incidents are the result of the bouncer falling face down on soft surfaces, falling from elevated surfaces, or suffocation after attempting to slip out of seat that is located on an unstable surface.

ASTM F2167 addresses this type of hazard with multiple tests. The slip resistance test is designed to keep bouncers from traveling across a surface while being used by a child. Bouncers placed on smooth, hard surfaces, such as a kitchen counter, are less likely to creep along the surface while a child is in the seat if the product is designed to meet the slip resistance requirement. The slip resistance requirement in ASTM F2167 includes both static and dynamic components. The static slip resistance test is performed on a smooth laminate surface with a matte finish and a 10-degree incline. A 7.5lb (3.4kg) CAMI dummy is placed in the bouncer with the front of the bouncer facing down the incline. The bouncer must not move down the incline more than 1/8 in. (3mm) in 1 minute. The test is repeated with the bouncer seat oriented with the left, right, and rear sides pointed down the incline. In the dynamic slip resistance test, a test fixture is placed in the bouncer seat with a 7.5lb (93.4kg) weight, and the bouncer is placed on the 10-degree inclined surface. Additionally, if the bouncer has a feature such as a vibration unit, the unit is to be turned on during the test. An additional 2.5lb (1.13kg) weight is dropped onto the test fixture from a height of 6 in. (152.4mm) a total of 10 times. The bouncer seat is not allowed to move more than 1/2in (13mm) during the test. This test is repeated with the bouncer in the remaining sideways and rear orientations.

CPSC staff finds that addressing these incidents with performance requirements is difficult because the hazard scenario involves consumer behavior, a foreseeable misuse of the bouncer product, which should only be used on the floor. However, CPSC staff believes that some performance requirements may help reduce the risk of injury in hazardous placement scenarios. ASTM has added the recommendation by CPSC staff to increase the stability requirements, which should reduce these types of injuries by increasing the stability of the bouncer. Staff is recommending modifications the warnings, labeling and instructional literature requirements of F2167-15 to help further reduce injuries relating to this hazard pattern (Tab D).

While, both the slip resistance and stability requirements are intended to increase stability when product is properly used. Attempts to reduce the likelihood of incidents occurring when bouncers are misused by placing them on elevated surfaces cannot be completely eliminated with performance requirements. How to address the hazardous placement of infant bouncers is further discussed in Tab D.

VI. OTHER STANDARDS

Other than ASTM F2167, CPSC staff found no other standards for infant bouncer seats. CPSC staff identified two closely related international standards, BS EN 14036:2003, *Child Use and Care Articles — Baby Bouncers — Safety requirements* and BS EN 12790:2002, *Test Methods and Child Care Articles -Reclined cradles*, that pertain to products with some characteristics similar to infant bouncer seats.

The scope of BS EN 14036:2003, *Child Use and Care Articles — Baby Bouncers — Safety requirements* is products designed to suspend a child, from above, in an essentially vertical, semi-seated position. These products enable the child's toes/balls of the feet to have contact with the floor to activate and maintain the bouncing action and are sold as baby jumpers in the United States (figure 3). The scope of this standard does not include bouncers intended for children in an inclined position. General requirements in BS EN 14036 are similar to ASTM F2167, and BS EN 14036 has structural test requirements and a drop test. Although these tests are similar to the ASTM standard, they are less stringent. The remaining requirements are not applicable to infant bouncer seats.



Figure 3 – Example of Baby Jumper

BS EN 12790:2002, *Test Methods and Child Care Articles -Reclined cradles* specifies safety requirements and the corresponding test methods for fixed or folding reclined cradles intended for children up to 6 months and/or up to a weight of 9 kg. This standard covers non-bouncing products designed to be a safe sleeping environment. It contains the same general requirements as BS EN 14036. Additional testing includes stability, static strength, dynamic strength, slip

resistance, unintentional folding, and restraints. The stability requirement uses a 13.5 degree-test angle for sideways and rearward stability, which is less than the ASTM F2167 test angle of 20 degrees. BS EN 12790 contains no forward stability test equivalent to F2167. The static strength test uses a smaller test weight than ASTM F2167, 20 kg, and the dynamic strength test is intended to test the strength of the handle as opposed to the seat. Slip tests are substantially similar in both standards. BS EN 12790 contains an unintentional folding test that is not applicable to infant bouncer seats. ASTM F2167 has a different provision that addresses potential infant bouncer seat folding issues. Finally, BS EN 112790 contains two tests for the restraints. A slip test is used to determine strap creep. The second test is a strength test similar to ASTM F2167 restraint requirement. ASTM F2167 does not contain a slip test, but the strength test requires an additional pull test at 45lb (200 N) to the normal use direction.

CPSC staff believes that ASTM F2167-15 is more stringent in most areas and addresses the hazard patterns seen in CPSC's incident data. The exception is the test requirement for the retention system. BS EN 12790 contains an additional strap slip test lacking in ASTM F2167. However, because incident data regarding restraints is minimal and staff has no evidence of injuries related to strap creep, CPSC staff is not recommending adding a strap creep test at this time.

VII. RECOMMENDATIONS

Staff recommends that the Commission publish the draft proposed rule that incorporates by reference the requirements contained in ASTM F2167-15 as the mandatory safety standard for infant bouncer seats. ASTM F2167-15 which includes recent updated requirements that ASTM has incorporated with CPSC staff input and participation. Staff believes these updates will better address incidents and reduce the number of injuries from infant bouncers. The staff recommended modifications to ASTM F2167-15 as detailed in Tab D.

TAB D: Human Factors Assessment of Hazard Patterns and Mitigation Strategies in Infant Bouncer Seats

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D**



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

Memorandum

Date: August 4, 2015

To: Suad C. Wanna-Nakamura, Ph.D.
Infant Bouncer Seats Project Manager
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Through: Joel Recht, Ph.D., Associate Executive Director
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Bonnie Novak, Director
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From: Catherine A. Sedney, Senior Engineering Psychologist
Division of Human Factors

Subject: Human Factors Assessment of Hazard Patterns and Mitigation Strategies in
Infant Bouncer Seats

I. Introduction

This memorandum summarizes the Human Factors (“HF”) assessment of the hazard patterns associated with infant bouncer seats, and the adequacy of the existing voluntary standard to mitigate those hazards, in support of rulemaking mandated by Section 104 of the Consumer Product Safety Improvement Act of 2008 (“CPSIA”).

The applicable voluntary standard, ASTM F2167, *Standard Consumer Safety Specification for Infant Bouncer Seats* (“ASTM F2167”) establishes “requirements, test methods, and marking requirements to promote safe use of an infant bouncer seat by an occupant and a caregiver.” As defined in section 1.2 of the voluntary standard, “...an infant bouncer seat is a freestanding product intended to support an occupant in a reclined position to facilitate bouncing by the occupant, with the aid of a caregiver or by other means. Intended occupants are infants who have not developed the ability to sit up unassisted (approximately 0 to 6 months of age).”

The ASTM Subcommittee for Infant Bouncers balloted changes to sections 8 and 9 of the voluntary standard, which describe requirements for warnings on the product and in the instructional literature provided with the product; certain changes were incorporated in the current version of the standard. Staff believes these changes are important but insufficient, and recommends that the Commission issue a proposed rule for infant bouncer seats that incorporates

by reference ASTM F2167 – 15, with specific modifications to improve and strengthen the current voluntary standard’s requirements.

This memorandum, prepared by staff of the CPSC Division of Human Factors (“HF”), presents (a) an assessment of factors affecting adult and intended child user interaction with the product; (b) an assessment of the adequacy of the requirements for warnings on the product and in the instructional literature in the current voluntary standard; and (c) recommendations regarding the warnings and instructions for normal use and foreseeable misuse and abuse.

II. Products

Bouncer seats vary widely in style and complexity, but typically consist of a cloth cover stretched over a wire or tubular frame. All support the child in an inclined position, and some brands have adjustable seat backs. Various products include a “soothing unit” that vibrates or bounces the chair, and that may play music or other sounds. The vibrating unit and its controls are generally located at the front of the seat. Most products also feature an accessory bar with attached toys that are, or at some point will be, within the child’s reach. Of the models examined or seen on websites, most have three-point restraints consisting of wide cloth crotch restraints, and short adjustable waist straps with plastic buckles. Restraints consisting solely of web straps were atypical, and staff saw only two models that employed upper body restraints. Many brands also include an “infant insert” used to support smaller babies. Figure 1 displays images of exemplar products shown on manufacturer and retail websites. ASTM F2167 – 15 specifies the product’s sole use as a reclined support that facilitates bouncing. Manufacturers promote the interactive nature of their products for play and learning, as well as for their soothing qualities for resting. Based on consumer reviews on retail websites, as well as incident reports, staff surmises that caregivers use the products as a place to contain the baby, while they do chores, shower, feeding and naptime and as an inclined sleep aid for infants with reflux.

III. Incident Data

Staff from the Directorate for Epidemiology’s Division of Hazard Analysis (“EPHA”) provided national estimates for infant bouncer-related emergency department visits from CPSC’s National Electronic Injury Surveillance System (“NEISS”), and searched the Commission’s Consumer Product Safety Risk Management System (CPSRMS) which combines the data from IPII, DTHS, and INDP into one searchable incident database (see footnote) for incidents involving infant bouncer seats (Yang, 2015) and children 12 months and younger.²⁷ EPHA staff reported 277 incidents retrieved from CPSRMS sources between 1/1/2006 and 2/2/2015, and 672 reports received from NEISS. Based on the NEISS reports, EPHA staff estimated that there were 17,200 emergency room visits for infant bouncer-related incidents from 2006 to 2013.

²⁷ NEISS is the National Electronic Incident Surveillance System. NEISS data refers to cases that resulted in visits to a representative sample of U.S. hospital emergency rooms. CPSRMS combines data reported the In-Depth Investigation file (“INDP”), the Injury or Potential Injury file (“IPII”), and the Death Certificate (“DTHS”) file.



Figure 1. Photos of infant bouncer seats copied from various websites.

HF staff reviewed incident data provided by EPHA staff (Yang, 2015), and focused on reports that were suggestive of child or caregiver behavior as a factor in the incidents. Incidents involving other issues (*e.g.*, battery leakage, structural failures such as screws separating and joints breaking) are addressed in the Engineering memo in Tab C (McCallion, 2015).

A. Fatalities

According to EPHA's analysis, there were 13 bouncer-related fatalities during the period reviewed; 11 were reported in the CPSRMS incident database, and two were reported in NEISS. Of the 13 fatalities, one resulted from a fall; nine occurred while children were reported to be napping or sleeping.²⁸ Beyond that, the fatalities are difficult to categorize because some of the reports lack detail or are otherwise unclear, and the reports do not present a consistent hazard pattern. For example, children placed on adult beds and in cribs while in certain infant products, such as car seat carriers, are generally considered to be at risk of tipping over and suffocating in the underlying bedding. This was assumed to be a significant risk for infants in bouncer seats as well, primarily because of the on-product warning, which states that bouncers can tip over and suffocate a child if placed on soft surfaces. Although three incidents were reported to have

²⁸ In the remaining incidents, children may have been placed in the bouncer to sleep or nap; however, it was not specified in the report.

occurred on a bed, none of the documents describing these three fatalities reported a confirmed product tip-over in the expected scenario. One incident that was described in the medical examiner's ("ME") report as a tip-over that occurred on the floor seems likely instead to have been due to the bouncer falling from a bed to the floor (see (9) in the list below).

Behavioral details other than placement of the product are, however, notable in the deaths. In nine cases, the child was reported as napping or sleeping, and was not wearing restraints in five of the nine. In two cases, the child was partially out of the restraints when found; in the case when the bouncer was inside the crib, the child was partially suspended upside down over the side of the bouncer with one leg in the restraints. In at least four cases, the child's emerging ability to turn over, which resulted in the face resting against the conforming surface of the seat back, appears to have been a significant factor. Below are summaries of the reports; cause of death is drawn from the analysis of staff from the Directorate of Health Sciences ("HS") (Marques, 2015).

1. CPSRMS (Reported) Incidents

(1) 120427HCC1640: A 6-month-old died of blunt force trauma to the head when the infant's father lifted him in the bouncer seat. The bouncer collapsed and the child fell out of the back onto carpeted floor. He suffered a linear skull fracture and died the following day.

(2) 121001HCC2002: A 3-month-old was fed and left to sleep in her bouncer seat. The child's father reported that he found her face down, unrestrained, in the seat. The seat was on the floor, and the child's mother and 2-year-old sister had been asleep on a couch nearby.²⁹ Cause of death was positional asphyxia.

(3) 070214CCC1300: A 2-month-old who suffered from reflux and a respiratory infection was placed, unrestrained, to sleep in a bouncer that was lined with a blanket; the bouncer was on the floor next to the couch where his mother slept for the night. The child turned over in the seat, and was found unresponsive, face down against seat back. Cause of death was positional asphyxia.

²⁹ Both a car seat and an infant bouncer were present at the scene, and the Medical Examiner's Report of Investigation (Page 2 of 15, Exhibit 3; dated 3/29/12) states that after arriving home with the victim and the victim's 2-year-old sibling, the child's mother gave her a bottle of juice in her car seat. The child's father arrived later and initially reported that he found the victim unresponsive with her face against an inside corner of the car seat. The Emergency Medical Services ("EMS") report (Exhibit 1, Page 1 of 2; dated 3/29/12) states, in part, that the father found the child "lying face down in bouncing seat carrier." The Police Department Report of Investigation (Page 4-5 of 5, Exhibit 2; dated 7/09/12) prepared by a detective who arrived while Crime Scene Unit ("CSU") detectives were processing the scene and taking photographs. His report, presumably based on contemporaneous notes, includes that he spoke via cell phone to the police sergeant who went to the hospital to talk with the parents and that the sergeant "stated [that the victim's father] clarified that it was not a car seat [the victim] was sleeping inside of, but a "bouncy" chair." HS staff found the information insufficient to determine the hazard that contributed to the fatality in this incident because there is no statement from the child's mother as to why she moved the child from the car seat to the bouncer, and the detective's report is dated two months after the incident.

(4) 110726CAA3941: A 3-month-old was placed on an adult bed in an infant bouncer seat, unrestrained, for a nap. The mother reported that the child had fallen out of the seat and she found her face down on the bed. The child was diagnosed with an irreversible anoxic brain injury and died 19 days later.

(5) X1490229A: A 4-month-old was swaddled and placed for a nap, unrestrained, in a bouncer, which was then placed on the floor; the child was reportedly just started to roll over, but had not done so completely on her own. Her parents found her unresponsive “with her face against the back of the infant seat and half way of the chair from the waist level down ...”; she could not be resuscitated. Cause of death was positional asphyxia.

(6) 140422CAA1573: A 3-month-old was placed to sleep for the evening, unrestrained,³⁰ in a bouncer on the floor in a room with several other children. Her mother found her five hours later face down in front of the bouncer on the floor and not breathing.

(7) 101012HCC3049: A 6-month-old (born several weeks premature) was placed in a bouncer on the floor (in front of a television) as he was falling asleep while his mother showered. She placed a pillow under the rear legs of the bouncer to raise it approximately 20 degrees. She found the child unresponsive, turned with his face against the side of the bouncer, one leg out of the restraints. Cause of death was positional asphyxia.

(8) 080917HBB3900: A 2-month-old in a bouncer was placed in a crib to sleep. She was found suspended, partially upside down, over the side of the bouncer with one leg entwined in the restraints. A depression in the mattress suggests that the child’s face was against it. Cause of death was mechanical asphyxia.

(9) 140102HWE0001: A 6-month-old was sleeping, strapped into a bouncer, and when she awoke, was moved in the bouncer to a bedroom, and left briefly with two toddlers, and possibly a pet dog. When the caregiver returned, she found the chair overturned on the floor with the victim’s neck lying over the chair’s [toy bar]. The report is inconsistent regarding whether the bouncer was placed initially on the bed or on the floor³¹; HS staff considers the injuries described in the ME’s report to be consistent with a fall rather than a tip-over at floor level. The child died five days later. Cause of death was positional asphyxia.

(10) 726037034: A 3-month-old was left in a “bouncy [*sic*] seat on an adult bed.” Cause of death was probable asphyxia due to suffocation. There was no further information.

(11) 1051041332: A 4-month-old “suffocated when face down in soft bedding on bouncy [*sic*] seat at home.” There was no further information.

³⁰ According to the report, the child was said to be too large for the restraint; the ME’s report was not included in the file, and the child’s height and weight were not released.

³¹ The ME’s report states that the child was placed on the floor next to the bed. The CPSC investigator reports that the ME stated that the caregiver stated that she placed the bouncer on the bed.

2. NEISS Incidents

(1) 120328281: The parents of a 5-month-old found him unresponsive, flipped over in the bouncer seat with his leg still through one leg hole. The cause listed was cardiac arrest.³²

(2) 130645295: A 2-month-old child had been asleep in a “bouncy”; his father awoke to find the child unresponsive on the floor. The cause of death was cardiac arrest.³³

B. Non-fatal Incidents & Complaints

1. CPSRMS (Reported) Incidents

Severe injuries, all skull fractures, occurred in four incidents.

(1) I0710174A: A 4-month-old child slid out the back of the seat when her caregiver lifted the bouncer by “the arch that goes over the top of the seat,” presumably the toy bar, and it broke off.

(2) 121019CCC3038: A 7-month-old was strapped in a bouncer seat that was on a table for feeding. It collapsed as the child’s mother was moving the seat, and the seat and child fell to the wooden floor.

(3) I1070704A: A 1-month-old was reportedly sleeping in an upright position in a bouncer that was on a kitchen table. He fell out and onto the floor.

(4) 060515CCC1528: A 4-month-old was in a bouncer on a kitchen counter when the buckle of the seat belt released and she slid out of the seat and onto a tile floor.

Complaints regarding tip-overs and restraint issues were reported primarily in incidents that resulted in minor or no injuries. Of the 33 tip-over incidents reported in the EPI analysis, HF staff identified 30 incidents, and one near tip-over, involving children 3 to 8 months of age that occurred while they were wearing restraints. Of these, caregivers witnessed 21 incidents, and reported that the child did something, such as leaning over, reaching for something, starting to sit up, or pushing with their feet, that precipitated the tip-over. Seventeen of the 20 children were 3 to 5 months of age. The injuries were minor, or no injury occurred. Reports included bumps to the head, and in one case, a child was hanging by his legs upside down in the bouncer after tipping it over.

Eight non-tip-over incidents involved children aged 2 to 5 months who were reported to be hanging out of the bouncer, forward, sideways, or backwards (*e.g.*, by the legs, at the waist, over the edge, with the back against the frame) despite being restrained. Three incidents were

³² HS staff found the information in this incident insufficient to determine the hazard that contributed to the fatality because the term “leg hole” was deemed inconsistent with the features of an infant bouncer and because of the lack of detail provided.

³³ HS staff found the information in this incident insufficient to determine the hazard that contributed to the fatality.

observed to occur after children leaned or tried to sit up. Caregivers were present and the reports cite no injuries.

2. NEISS Incidents

Although details in the NEISS data are typically sparse, because they are abstracted from emergency department medical records, in this assessment staff attempted to focus on incidents in which the role of occupant or caregiver behavior rather than, for example, component failures, may have played a role. Of the 672 NEISS cases identified by EPI staff, the subset consists of 658 incidents. The ages reported in the narratives ranged from younger than 1 month to 12 months. Eight-four percent of the children (n=555; estimate=14,500) were reported to be 6 months old or younger, the manufacturer-recommended age range for the product.

As shown in the table below, fall incidents predominate, but the data include a small number of reports characterized as tip-overs,³⁴ and a few as impact³⁵ unrelated specifically to either of the preceding categories. Note that EPI staff attributes 385 incidents to hazardous environments, 342 of which were falls; these are reports that describe a fall from a specific location, such as a counter, bed, couch, or a person lifting the bouncer or carrying the child in the bouncer. The total number is higher in the HF assessment because it includes all incidents described as falls.

Table 1. Incidents by type

Type	N	Estimate	%
Fall	621	16,100	95
Tip	21	*	*
Impact	16	*	*
Total	658	17,000	100

Source: NEISS Database, February 2015
 Column totals may not sum to due to rounding.
 *Estimates and percentages are not provided when n<20, estimates are < 1,200 or CV > 0.33

As EPI reported, the most commonly cited locations were counters, often detailed as kitchen counters, and tables, specifically kitchen or dining room tables. Based on the standard height of kitchen counters and tables used for dining, at least 245 of the reports that involved falls were from surfaces estimated to be 29 to 36 inches above floor level (38%; estimate=6,200).³⁶ Other high surfaces included appliances, such as washers, dryers, and stoves. In combination, 272 incident reports included descriptions of specific surfaces characterized as high (44%; estimate=7,000). Lower surfaces cited in falls included beds, sofas, and coffee tables.

³⁴ “Tip-overs” included cases with narrative descriptions that reported a bouncer that tipped over, fell over, or flipped over were counted as tip-overs.

³⁵ “Impact” included, for example, a case in which a child’s head struck the door jamb as she was being carried, unrestrained, in the bouncer; or a less informative description, a child “struck head on side of seat.”

³⁶ Excludes lower tables specified, such as end tables and coffee tables.

Based on previous work, staff's concept of the fall hazard was that of bouncers falling from elevated surfaces. This does occur frequently; however, an unexpected finding was that in over half of the incidents, children reportedly fell out of the bouncer (n=339; 53% of estimate=8,600). Counted in this category were incidents in which the narratives included a descriptor such as those shown below (emphasis added in all).

- 1 [month-old-male] *fell out of* bouncer seat
- 1-[month-old-female] sitting in bouncy seat on kitchen table, *fell forward out of seat onto* [sic] tile floor
- [patient] *fell off of* bouncy seat which was on counter
- fx skull *fell* [sic] *from* baby bouncy seat to floor
- 4 [month-old-male] was in a bouncy seat, on the table, at home, & fell face first, when [sic] *she* [sic] *bounced out of it.* dx; chi

These were distinguished from narratives (n=129; 22% of estimate=3,600), that more clearly described a child who was in a seat that fell, as in the following examples.

- 3 [month-old male] in bouncy seat on kitchen table, chair fell to carpeted floor; head injury
- A 3 [month-]old male was in bouncy seat on a desk and seat fell onto floor hand [sic] infant hit his head dx skull fx
- 1 [month-old male] fell from table *in a bouncy seat*, cried [sic] immediately, hit [sic] head; subarachnoid [sic] hemorrhage

The descriptions for many incidents, examples of which are given below, were more vague, and it could be determined only that the child, the seat, or both, fell.

- 47 day old [sic] female was in a bouncy seat, on the kitchen table...she fell & landed on head, on wood floor
- 22 days old [sic] f[emale] was in a bounce seat up on the counter when she fell off off [sic] hitting head on cement floor
- 2 [month-old] male in bouncy seat and fell to the floor. dx concussion

Table 2. Falls by type

Mode	N	Estimate	%
Child fell out	339	8,600	53
Fell (unclear)	153	4,000	25
Seat fell	129	3,600	22
Total	621	16,100	100

Source: NEISS Database, February 2015
Column totals may not sum to due to rounding.

In addition to, and sometimes overlapping these three categories, were incidents in which two other factors were important. In 54 of the 658 cases, the incident occurred when someone was carrying or picking up the child in the infant bouncer. In most of those instances, the children fell

out of the bouncer (n=39). The only incidents resulting in injuries in which the child did not fall were three cases that resulted when the child's head struck a surface, such as door jamb, as they were carried in the bouncer. In some cases, the incidents resulted when the adult carrying the bouncer tripped or fell, including down stairs. In a few cases, it was reported that the bouncer collapsed, and in one, that the "handle," which most likely was a toy bar, broke as the bouncer was picked up.

The second factor was reported failure to use the restraints. The child was reported to be unrestrained at the time of the incident in 33 cases, including some cases involving high surfaces and cases in which children were carried or lifted in an infant bouncer. In two-thirds of these cases, the child was 3 months of age or younger.

Eighty-two percent of the incidents resulted in injuries (n=532; estimate=13,900). HS staff reviewed the NEISS cases and determined the severity of the reported injuries (Marques, 2015). Based on that analysis, 11 percent of the injuries were severe, such as skull fractures and intracranial hemorrhages, and 41 percent were moderate, such as less serious head injuries and fractures involving other body parts.

Table 3. Injury frequency by severity

Severity	n	Estimate	%
Severe	72	*	*
Moderate	268	6,900	41
Minor	192	5,800	34
Subtotal: Injuries	532	13,900	82
Unknown	101	2,400	14
None	25	*	*
Total	658	17,000	100

Source: NEISS Database, February 2015
 Column totals may not sum to due to rounding.
 *Estimates and percentages are not provided when n<20, estimates are <1,200 or CV > 0.33

Of the severe injuries, 44 involved infants 3 months of age and younger, and 59 involved infants 5 months of age and younger.

Table 4. Severe injuries* among younger users

Age	n
≤1 – 3 mos.	44
≤1 – 5 mos.	59

*Total for all age groups = 72
 Source: NEISS Database, February 2015
 Estimates and percentages are not provided when n<20, estimates are <1,200 or CV > 0.33

HS staff concluded that infants were more likely to sustain a severe head injury when they fell from elevated heights, and concluded further that the potential for severe head injury increases if the child is being carried in the bouncer, and/or they are unrestrained in the bouncer. The table

below presents the number of incidents in these three categories from the HF assessment (*i.e.*, the child in a bouncer on a surface characterized as high, lifted or carried in a bouncer, or unrestrained in the bouncer) with the number of severe injuries that resulted.

Table 5. Severe Injuries by Incident Characteristic

Category	N	# Severe Injuries (N=72)
high surface	272	36
lift/carry	54	12
unrestrained	33	9

Source: NEISS Database, February 2015
 Estimates and percentages are not provided when n<20, estimates are <1,200 or CV > 0.33

The subset also included a number of cases in which the narrative describes the action that preceded the incident (*e.g.*, leaning forward, “pushing herself out”). These reports are consistent with the anecdotal reports in the CPSRMS database in which children’s actions resulted in them hanging out or partially out of the seat, or in tipping over the seat. The pattern of children falling out of seats reflects the developmental capabilities of the age group, when the movement of the upper torso is unconstrained, as is discussed in the following section. The pattern also suggests that failure to use the existing three-point restraints is underreported. People tend to present themselves in a positive light when providing information for interviews and surveys, which is a common problem in research that relies on such data³⁷ (Fowler, 1995). Although caregivers may believe it is safe to use an infant bouncer without the restraints before an incident occurs (*e.g.*, Lerner, Huey, & Kotwal; 2001), the risk of doing so would be obvious in hindsight. Following an incident resulting in injury, caregivers are likely to be reluctant to report that they failed to use the restraints because this admission may make them appear negligent or foolish; they also may fail to report this information out of concern that admitting that they did not use the restraints may trigger an investigation by local authorities. Incidents due to carrying children in infant bouncers, or placing them on high surfaces, may be underreported as well, given that no product failure (*e.g.*, collapse) was reported in most cases.

C. Product Design and Infant User Issues Affecting Risk of Injury & Death

Several factors converge to put infants in bouncer seats at risk of falling out of the seat, falling while restrained in the seat, hanging partially out of the seat, and turning over in the seat. Infant bouncer seats are marketed for children from birth *until* children are “able to sit up unassisted.” However, bouncers display warnings, without explanation, stating that consumers should never use bouncers for a child who is *able* to sit up unassisted. The marketing and labeling for infant bouncer seats, thus, suggest that the child’s use of the seat is safe until that point. In combination with this information, the typical 25-lb weight limit (Figure 2), which is roughly the weight of a

³⁷ This is also known as self-report bias. Depending on the demand characteristics of the research setting, people tend to answer questions and otherwise behave in ways they believe to be socially acceptable.

50th percentile 18-month-old or a 95th percentile 9-month-old,³⁸ suggests a longer period of product use than may be safe for many children.

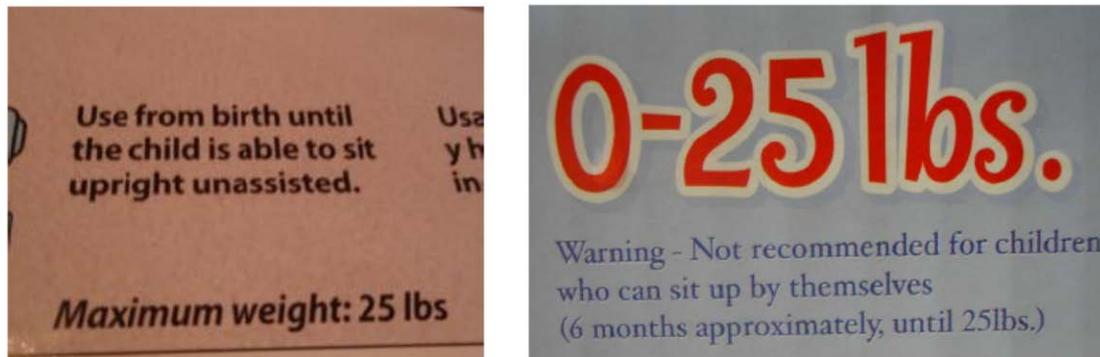


Figure 2. Partial labels, photocopied, respectively, from IDIs 081126HCC3160 (left) and 061121HCC1106 (right).

The scope of the voluntary standard defines the user age group for bouncers as “approximately 0 to 6 months of age,” based presumably on the rationale that children reach the milestone of sitting up without help, on average, at 6 months (*e.g.*, Bayley Scales of Infant Development [“BSID”]; Bayley, 1969).³⁹ Motor ability, however, is a continuum, and 6 months is merely the mean measured for one operational definition of “sitting unassisted.” Depending on the definition and source, normal children may be reported as sitting up as early as 4 months and as late as 9 months (Bayley, 1969; Davis, Moon, Sachs, & Ottolini, 1998).

More important in terms of the types of incidents reported, throughout the weeks and months before they can sit steadily by themselves, infants are actively attempting not only to sit up, but also are trying to turn over and to reach for objects. Table 1 presents the age range and mean age at which children accomplish some of these early milestones. Trained observers test these behaviors while children are on a flat surface. In an infant bouncer, children are in a partially upright position that gives them the support to extend their range of movement. With the upper body unconstrained, it is easier for infants to try to sit, lean, turn over, and reach for things than it would be if lying flat, even though their attempts will be unsophisticated and awkward. Because children at this age do not have control of their torso muscles, infants’ activities may cause them

³⁸ Based on data from the National Health and Nutrition Survey (“NHANES”) results for 2000; http://www.cdc.gov/growthcharts/percentile_data_files.htm.

³⁹ The BSID (also commonly called “the Bayley Scales”) are a standardized test of motor and cognitive development for children from birth through 30 months of age. The 1969 manual reports normative data on milestone achievements for a large, representative sample of healthy U.S. children; that is, the samples did not include disabled, premature or other at-risk children. Haywood and Getchell (2009) compared the results for major milestones, such as sitting, creeping, and standing, reported in early developmental studies, including Bayley’s detailed 1969 work, to the results obtained in the World Health Organization’s 2006 Multicentre Growth Reference Study Group. Haywood and Getchell concluded that infants are “currently attaining motor milestones at about the same age as infants did more than 80 years ago . . .” The 1969 Bayley Scales continue to be used because of the detail they provide.

to hang over the side or front of the bouncer, fall out or tip over the bouncer, or turn into the surface of the seat back, where the flexible, conforming material can compromise the external airways. At these early stages of development, children typically lack the strength and motor control to reverse their actions.

Table 6. Range and mean age of selected developmental milestones (Bayley, 1969)

Range (mos.)	Mean (mos.)	Milestone	Description
2-6	3.8	Sits with slight support	Child sits with a slight prop, such as a pillow at lower back (p. 85).
2-7	4.4	Turns from back to side	With child on back on a flat surface, child turns from back to side (p. 85).
2-6	4.1	Reaches for cube	Child reaches for cube, even if without hand-eye coordination and without actually touching it (p. 51).
3-8	4.8	Effort to sit	Child lifts head and shoulders while lying on his back (p. 85).

The age at which infants attain these milestones, or even attempt them, is highly variable, as can be seen in Table 6. This can make it difficult for parents and other caregivers to anticipate these behaviors and appreciate that their own actions, such as putting the child in an infant bouncer on a counter, or in the seat without buckling the restraints, places the infant at significant risk.

Performance requirements incorporated into the current version of ASTM F2167 improve the stability of infant bouncer seats (McCallion, 2015). The extent to which these requirements will reduce incidents in which infant bouncers tip over or fall is unknown. However, stability requirements are unlikely to affect children’s actions that result in them hanging from part of the bouncer, turning in the seat, or falling out of the seat, despite use of the three-point restraints. Stability performance requirements also will not prevent falls that result from someone carrying or lifting a child in the product. Although restraining the upper torso could prevent children from turning in the seat or falling out of the seat, upper body restraints for infant products appear limited to the traditional harness style associated with the potential for strangulation.⁴⁰ Because the timeframe for the development and testing of alternative restraint designs can be several years, staff did not address upper torso restraint and retention at this time. Staff will work with ASTM to explore performance requirements for restraints that adequately limit movement of the upper body without introducing new hazards, including the risk of strangulation. Given that design changes that would reduce the risk of falls and other restraint-related incidents are not yet available, warnings and use guidance based on developmental changes are the only remaining options.

IV. Adequacy of Warning Requirements in the Current Standard and Staff’s Recommended Changes

The subcommittee for Infant Bouncer Seats formed a Warnings Task Group in September 2013, at staff’s request, to address the high number of falls and related head injuries reflected in the

⁴⁰ A common strangulation scenario occurs when caregivers unbuckle the upper body restraints to make children who fall asleep more comfortable.

incident data at the time. CPSC staff worked closely with the task group to make several changes to the warnings on the product and in the instructions to increase the conspicuity and potential effectiveness of the warnings. Staff's recommendations were balloted and a number were accepted by ASTM. Among other changes, the voluntary standard now includes a separate fall hazard warning label to be presented on the front surface of the bouncer seat back; use of a hazard color⁴¹ as background to the safety alert symbol (▲)⁴² and signal word ("WARNING"); stronger, simpler suggested⁴³ warning text; and example labels that include the revised suggested wording and proposed format. Sections 7.11, 8, and 9 of the voluntary standard address the requirements for warnings, markings, and instructional materials. The remaining points of divergence between staff's recommendations and the current ASTM voluntary standard are discussed below; a marked version of sections 7.11, 8, and 9, with staff's proposed revisions, is included as Appendix A.

Staff's Recommendations for Proposed Revisions to Warnings, Markings, and Instructional Literature

The goal of the warnings is to influence behavior—to establish safe behavior among new users of the product, and to change behavior among those who use bouncers in unsafe ways. Well-designed warnings can influence consumer perceptions of injury likelihood and severity, which, in turn, can motivate compliance with warnings. Research starting in the 1970s (*e.g.*, Dorris & Purswell, 1977), however, has demonstrated that warnings often have little or no effect, particularly when compared to design approaches to injury prevention. In addition, warnings are known to be weak with familiar products that consumers perceive to be safe. For a warning to have any effect, consumers must not only notice, read, and comprehend the warning, they must find it credible and personally relevant. In addition, consumers must be able and motivated to comply with the warning consistently. It is important, therefore, that warning labels exploit attention-capturing and motivational potential, to the extent possible, to increase the likelihood of compliance, particularly when design and guarding options are not available. Staff employs the American National Standard for Product Safety Signs and Labels (Z535.4; ANSI, 2011) and related standards as a baseline, in conjunction with relevant literature, to develop warning materials. Based on review of the incident data, and the incidence of high-severity head injuries, in addition to less severe but frequent moderate head injuries reported, staff recommends the following changes to ASTM F2167-15:

(1) Revise the content of the warnings, markings, and instructions as follows:

- (a) add text to the warnings that states to use the restraints "...even if baby is sleeping";
 - (b) change the text in the warnings to read, "stop using when baby starts trying to sit up";
- and

⁴¹ That is, orange, red, or yellow, colors that are associated with hazard communication (*e.g.*, Chapanis, 1994).

⁴² The version of the safety alert symbol shown here is based on the default symbol used in the ANSI Z535 series of standards. For consistency, CPSC staff uses this version throughout the memorandum for all instances of the safety alert symbol.

⁴³ ASTM warning language, unless stated otherwise, is presented as content that firms "shall address," rather than as specific wording to be used.

- (c) change the developmental guidance in the instructions, if stated, to read, “from birth (or “0”) until baby starts trying to sit up.”
- (2) Require that the fall hazard label be located on the front surface of the bouncer adjacent to the area where the child’s head would rest, and modify the current visibility test to reflect this requirement.
- (3) Specify a standard format (including black text on a white background, table design, bullet points, and black border) for the warnings on the product and in the instructions.

Staff also recommends that the example warnings contained in ASTM F2167-15 be changed to reflect the text changes and format specifications above. Examples for each warning are presented in Figures 3 and 4. Staff’s rationale and support for the changes recommended are presented in the following sections A through C.

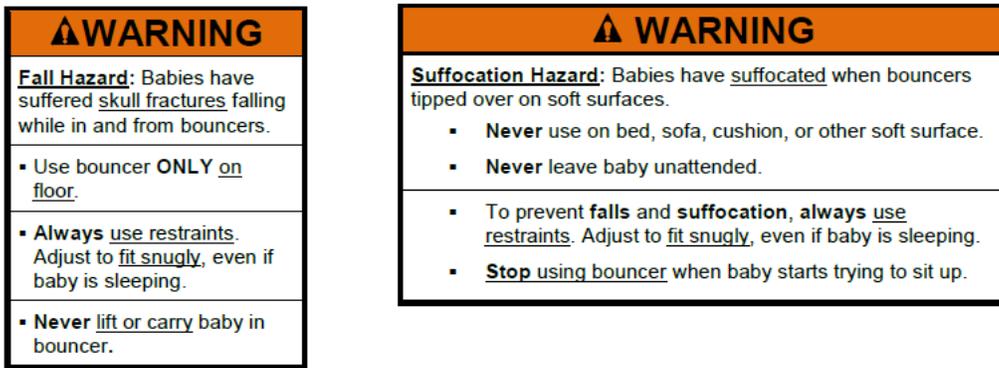


Figure 3. Fall hazard warning (left) and suffocation hazard warning (right).

⚠ WARNING
<p>Fall Hazard: Babies have suffered <u>skull fractures</u> falling while in and from bouncers.</p> <ul style="list-style-type: none"> ▪ Use bouncer ONLY on <u>floor</u>. Baby's movements can shift or tip bouncers off counters, tables, and other surfaces. ▪ Never <u>lift or carry</u> baby in bouncer.
<p>Suffocation Hazard: Babies have <u>suffocated</u> when bouncers tipped over on soft surfaces.</p> <ul style="list-style-type: none"> ▪ Never use on a bed, sofa, cushion, or other soft surface. ▪ Never leave baby unattended.
<ul style="list-style-type: none"> ▪ To prevent falls and suffocation, always use <u>restraints</u>. Adjust to <u>fit snugly</u>, even if baby is sleeping. ▪ <u>Stop using bouncer</u> when baby starts trying to sit up.

Figure 4. Recommended warning language and format for use in product instructions.

A. Content

CPSC staff has two areas of concern with the content of the language for warnings requirements balloted by ASTM involving the use of restraints and use of the product with the developmentally appropriate age group.

In general, guidelines for the development of product warnings agree that warnings should identify the hazards, the consequences, and the means to avoid them (*e.g.*, Madden, 2006; Singer, Balliro, & Lerner, 2003, October). The content of staff's proposed warnings meets these requirements by calling attention to each of the behaviors that are related to the specific hazards identified, and advising caregivers how to avoid those hazards.

1. Reference to Sleeping

The content that staff recommends includes two components that are absent in the warnings sections of the current voluntary standard. First, regarding use of the restraints, staff recommends including the statement: "Adjust to fit snugly, *even if baby is sleeping*." The phrase that addresses sleeping is excluded from the voluntary standard. Some ASTM members stated that the phrase, "Always use restraints," is adequate because the statement allows for no exceptions; the ASTM members contend that the staff's proposed language communicates that the product is intended for use as a place for the child to sleep and encourages such use. The subcommittee voted to have the Warnings Task Group consider alternative wording (*e.g.*, napping); however, the task group decided to ballot the industry-preferred wording, which omits any reference to "sleeping" or "napping." One task group member, concerned that bouncers are not marketed as a

sleep product, asserted that including such language may suggest that manufacturers should bring the bouncers into compliance with requirements for products that are designed for sleep.

Although CPSC staff understands the marketing concerns some manufacturers may have, such concerns are inconsistent with how caregivers use the product, the sleeping activity of infants that are intended to use the product, and the deaths and injuries reflected in the data when caregivers fail to use restraints. Accordingly, staff believes that it is essential to include language that conveys the hazard associated with allowing a child to sleep in a bouncer seat while unrestrained. “Always use restraints” is a part of the warnings and instructions in the current version of the voluntary standard and has been so over many editions. Based on the incident data, which demonstrate that unrestrained infants suffer serious head injuries in falls from surfaces and while they are moved in bouncers, CPSC staff believes that the current requirement is inadequate. Furthermore, the incident data indicate that lack of restraints, and perhaps loose restraints, are a factor in bouncer-related infant fatalities. Removing or loosening the restraints while a child naps or sleeps is a known hazard pattern across infant products that use restraints. Young infants, such as those intended to use bouncer seats, spend more time asleep than awake.⁴⁴ It is inevitable that children those that who spend more than brief periods in an infant bouncer will fall asleep on occasion (and will be placed in a bouncer to sleep for the night under some circumstances), as infants do in strollers, swings, and car seat carriers. Given the ways that bouncer seats are used, as reported by consumers, it is perhaps even more likely that bouncers will be used for sleeping and napping than these other products. For example, bouncers are more portable and lightweight than either strollers or swings, and bouncers are unlike car seat carriers, whose primary purpose is to protect a child in a moving vehicle. It is counterintuitive, and therefore, unlikely to occur to consumers that products made for infants’ use, especially products that have features intended to soothe and comfort children, would be unsafe places for infants to sleep.

In fact, despite industry claims that bouncers are not intended for children to sleep in, some marketing explicitly encourages sleep. For example, one product is advertised to “Help soothe baby to sleep with a plush bouncer featuring music, sounds, calming vibrations and a cozy, deep seat. Your little one will love snuggling into the comfy, deep seat of the [product name] Bouncer! With soothing vibrations and up to 20 minutes of music and nature sounds, baby will drift off to dreamland in no time. And when it’s time to wake up, baby can enjoy the two toys on the removable toy bar.”

Others are more subtle, emphasizing features such as “vibration for baby’s relaxation . . . soothing sounds . . .” and a “canopy [that] shields baby from light,” or describing their products as “dual-purpose.” In addition to bouncing “. . . infants can relax to a calming vibration . . . [in a] cradling seat . . .”

It is also foreseeable that some caregivers will perceive the restraints as uncomfortable and unnecessary (Lerner, Huey, & Kotwal; 2001), particularly for younger users, who may be seen as not yet mobile enough to be at risk of falling out of the bouncer, and even less at risk of falling if

⁴⁴ For example, see the American Academy of Pediatrics website: <http://www.healthychildren.org/English/ages-stages/baby/sleep/Pages/default.aspx>.

the infant is asleep. CPSC staff's recommended warning statement addresses the fact that the child *will* sleep in the bouncer, and addresses caregivers' known inclination to loosen or remove the restraints by specifying that they should do the opposite.

2. *Developmental Guidance*

The second difference between staff's recommended warning content and the content in the current voluntary standard is in the developmental guidance given in the suffocation warning and in the instructions. As discussed above in section III.C of this memorandum, *Design and User Issues*, firms currently promote use of infant bouncers until the child is able to sit upright unassisted. However, children are at risk of injury in infant bouncer seats at earlier stages of development because they lack upper body control, and the upper body is unrestrained while they are actively attempting to sit up, lean, turn, and reach for objects. Staff recommends that the warning label advise caregivers to stop using the product when the child begins trying to sit up. On average, children reach this milestone at 4.8 months.⁴⁵ Staff recommends this milestone based on the data indicating that most witnessed instances in which the child's activities reportedly preceded tip-overs or resulted in them hanging out, or partially out, of the bouncer involved children 5 months of age or younger. The ASTM subcommittee voted to table this issue for future consideration. One member commented that the issue could be addressed through design, that is, by requiring sides that retain the child. Others thought the issue required further research and data. This position was supported at the September 2014 meeting and the original verbiage (*i.e.*, for use from birth until child is able to sit up unassisted/stop using when child is able to sit unassisted) was retained.

B. *Placement*

CPSC staff recommends that the fall hazard warning label be required to be on the front of the product near the infant's head to increase the likelihood that caregivers will notice the warning, and comply with its recommendations, at decision points affecting the child's safety. The language in the voluntary standard requires the fall hazard warning to appear on the front of the product, however, the requirement, as discussed below, is likely to ensure that the warning is frequently covered during use.

Staff recommends requiring that the fall hazard warning label that is depicted on the left in Figure 3 be placed at the top front surface of the bouncer, adjacent to the area where the child's head would rest. This location was adopted for warnings on hand-held infant carriers in 16 C.F.R. part 1225, *Safety Standard for Hand-Held Infant Carriers* ("HHIC"; FR 78, No. 235; 73415, December 6, 2013) and the National Highway Transportation Administration's ("NHTSA") car seat standard, 49 C.F.R. § 571.213 Federal Motor Vehicle Safety Standard ("FMVSS") No. 213. Alternate locations considered by ASTM for the fall hazard label on bouncer seats were lower down, on the crotch restraint, or along the torso. During task group and subcommittee discussions, ASTM members considered, and eventually rejected, placement on the crotch restraint.

⁴⁵ Range, 3–8 months. Bayley, N. (1969). *Manual for the Bayley Scales of Infant Development*. New York, NY: The Psychological Corporation.

Although both the Warnings Task Group and the larger subcommittee agreed that the fall hazard warning label should be moved to the front of the bouncer seat to address the incident data, neither group wanted to require that the label be placed near a child's head. ASTM subcommittee members expressed concerns that: (1) common label materials present potential abrasion and cut hazards if the labels are adjacent to an infant's face; (2) because of the size of the label, this location is design-restrictive for smaller models; and (3) due to space, the location is challenging for firms that use labels in multiple languages.

As noted above, CPSC staff's recommended location for the fall hazard warning is the same as the location recently adopted for warnings on infant car seats that are also hand-held infant carriers. NHTSA adopted the same location for air bag warnings on these products in the late 1990s. HF staff examined car seats and found that heat transfer and sewn-on labels, the latter of which industry identified as a concern, are used on these products. HF staff consulted with the CPSC project manager for the development of the HHIC standard; neither injuries nor space requirements due to the need to produce labels in multiple languages was identified as a concern. Firms that produce infant car seats that are also handheld infant carriers have managed these issues successfully. HF staff also contacted NHTSA staff responsible for routine data review, who confirmed that there have been no complaints of injury of any type resulting from car seat labels near a child's face.

The staff's recommended label is approximately 2.25 inches long and 2.0 inches wide. Hand-held infant carriers that are also infant car seats require a larger⁴⁶ label for both the CPSC-mandated strangulation warning and the NHTSA-mandated air bag warning; review of these products suggests there is at least as much space adjacent the head area, and perhaps more, on many infant bouncer models, as on car seat/hand-held infant carriers. No voluntary or mandatory requirement exists for multiple languages on products sold in the United States; however, given the relatively small size of the proposed warning label, as shown on the left in Figure 3, multiple options appear available to firms. The warning label could appear in a different language on either side of the child's head, as suggested by the Canadian representative to the task group; different labels could be made for different markets; or the label length could be extended to accommodate additional languages, as has been done with infant car seat labels.

Staff acknowledges that the use of labels in multiple languages could pose difficulties with the smallest model bouncers. Staff identified two relatively small exemplar bouncers in staff's possession and placed copies of the warning label in the recommended location. Shown at left in Figure 5, is a bouncer with one copy of the label. To the right in Figure 5, is a bouncer with a narrow style and curved sides, with the label duplicated ten times to simulate the use of several languages. Although staff would recommend an alternative, such as using different labels for different markets, the photographs demonstrate that even on products with less space around the child's head, the label can be applied multiple times.

⁴⁶ The message panel of the air bag warning alone must be no smaller than 30 cm² (11 in.²); the pictogram must be at least 30 mm in diameter (1.18 in.).



Staff believes that placement of the label near the child’s face on the infant bouncer is essential in the effort to influence caregivers’ behavior. A variety of research indicates that the location of a warning plays a vital role in its salience, a crucial factor in effectiveness (*cf.* topic reviews by Lesch, 2006; Silver & Braun, 1999). Most studies, however, involve the placement of a warning in various locations within the instructions, versus on the product, or other manipulations that do not parallel closely the current question, which is whether one location on the front of the product can offer improved effectiveness relative to others. To develop a recommendation on this issue, staff considered practical issues suggested by the incident data, the basics of the visual system, and the nature of visual attention and motivational factors within the context of how caregivers use the products.

In terms of the visual system, either position (*i.e.*, near the head or elsewhere on the front of the seat back) generally would be visible during use of the product because the warning labels are likely to be within the normal visual field. First, in clinical terms, however, the different locations are not equally visible because vision is not equally good in the different areas of the periphery, and the extent of the field from the point of fixation varies. References differ somewhat on the extent of the visual field, depending on whether monocular or binocular view and color, or achromatic vision, are used. However, the references range from 90° to more than 100° to the side of the fixation point, but only 60° above, and 60° to 75° below (Boff & Lincoln, 1988; Spector, 1990). Thus, if the caregiver’s point of fixation is the child’s face, he or she is more likely to have the basic visual capacity to see the label if it is aligned to the side of the child’s head than at any other area on the seat back.

The test procedure for visibility of the fall hazard warning label that is part of the current ASTM standard requires that the label be *visible* on the front surface of the seat back with the Newborn CAMI manikin placed in the seat. In addition to allowing considerable variability in the conspicuity of the label location, a basic flaw in this method is the assumption that what is visible under static test conditions will be visible during routine use. An example of a passing test is shown in the photograph at the top left in Figure 6. In the photo on the top right, the label

in the same location is hidden by a child's doll that is physically more similar to a baby that might use the product.⁴⁷ This second image more closely depicts what a caregiver is likely to see in real life. A label below the shoulder level or along the torso down to the seat bight may be covered by parts of the child's body or clothing, and the area may be covered by a blanket, including an accessory cover that comes with at least one product.⁴⁸ ASTM members briefly discussed revising the test to use the 6-month CAMI Infant manikin in place of the Newborn CAMI. This modification is shown in the bottom left photograph in Figure 6, with the label in a similar location. As in the top row, the bottom left shows a passing test result with the manikin because the label is visible; in the photo at the bottom right, the label is hidden by a doll that presents a more realistic representation of a baby in the seat. Although CAMI manikins are valuable as standardized tools, their use for this purpose is unrealistic because they are rigid, lack joints, do not reflect the normal rounded proportions of a child, and do not have diapers and clothing, as a child does. The photographs demonstrate that a visibility test using a CAMI manikin is not a valid measure of whether caregivers would see label during actual use.

⁴⁷Length = 59 cm (50th percentile: ~3-month-old girl, ~2-month-old boy); head circumference = 42 cm (50th percentile: ~6-month girl, ~4-month-old boy).

⁴⁸ Staff notes that at the time the briefing package was published, the manufacturer discontinued this product.

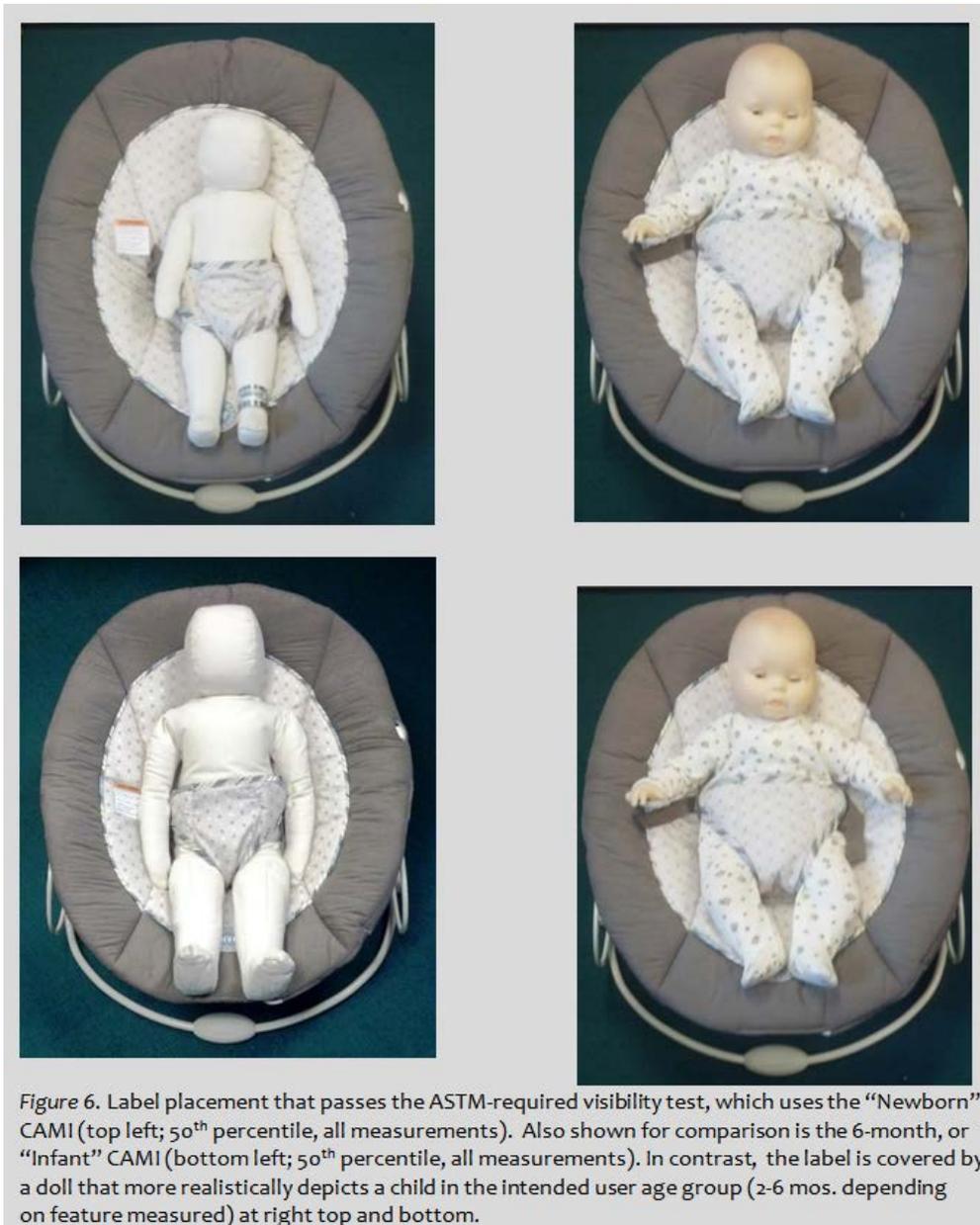


Figure 6. Label placement that passes the ASTM-required visibility test, which uses the “Newborn” CAMI (top left; 50th percentile, all measurements). Also shown for comparison is the 6-month, or “Infant” CAMI (bottom left; 50th percentile, all measurements). In contrast, the label is covered by a doll that more realistically depicts a child in the intended user age group (2-6 mos. depending on feature measured) at right top and bottom.

Although it may seem that placement along the torso guarantees that a caregiver will see the label each time he or she puts the child in the bouncer because of the restraints, both the data and research of visual attention fail to support this supposition. First, as is evident in the incident data, caregivers do not always use the restraints, and probably use them less often than is reported. Second, infant bouncers typically have restraints that use buckles. Fastening the buckles requires the caregiver to focus on them to insert the tines into the buckles. Vision research reveals that it is unlikely that caregivers would see the label along the torso while performing this small task. Although the eye is capable of detecting objects in the periphery during a typical vision test, when our attention is on a manual task we use foveal vision, where acuity is highest, and the field of view narrows. Compared to the visual field measured during vision screening tests, the “useful field of view,” that is, the extent of our vision when our

attention is on a central task, is smaller and variable (typically 1 to 4 degrees of visual angle⁴⁹; Wickens & Holland, 2000). Eye-tracking studies demonstrate that during the performance of visually-guided tasks, fixation is generally limited to objects that are related to the task; little information is taken in from the area outside fixation (*e.g.*, Land, Mennie, & Rusted, 1999; *cf.* review by Land, 2006).

In essence, visibility is an inadequate requirement because what we see at any given moment is not determined by what is visible, but by where our attention is directed (*cf.* review, Chun & Wolfe, 2001). This difference between what is visible and what we perceive may account for the results of tests of NHTSA's (1996) prototype labels for rear-facing infant car seats (61 FR 40784). The standard in effect at the time⁵⁰ required a label on the side of the restraint system (*i.e.*, the seat) that was "designed to be adjacent to the front passenger door of a vehicle" and "visible to a person installing the rear-facing child restraint system in the front passenger seat." As described in the FR notice, the new prototype labels "...included the colors red and yellow, an icon showing a rear-facing child seat in front of a deploying air bag with a red international "NO" slash, and the heading "Danger to Life!" in red letters. It measured approximately 4 inches long and 2 ½ inches wide⁵¹ (see Figure 7). Rear-facing infant seats bearing the new prototypes on the side as described above were installed in a car where a similar, slightly larger label was placed on the right end of the dashboard that faces the door so that it would be visible with the passenger door open. Sixty-six subjects, before taking part in focus groups, were asked to secure an infant-sized doll in the seat and then remove it. Following the exercise, the subjects responded

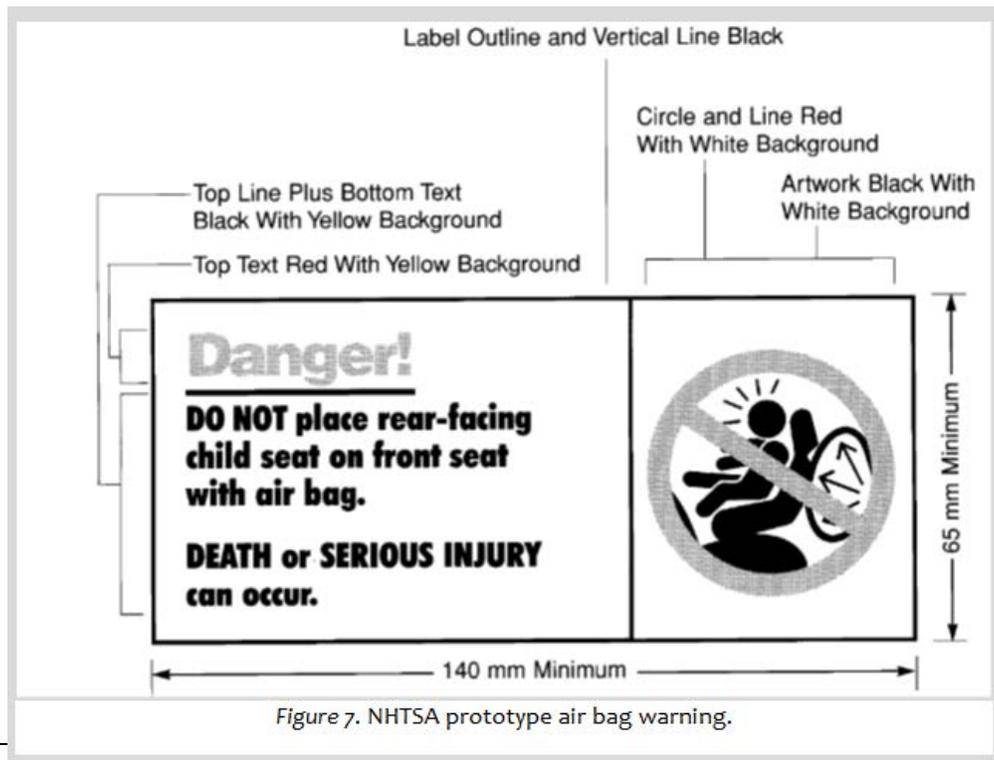


Figure 7. NHTSA prototype air bag warning.

⁴⁹ One degree of visual angle is about the width of an adult thumb held at arm's length.

⁵⁰ S5.5.2(k)(ii) of Standard No. 213, *Child Restraint Systems* (49 CFR 571.213).

⁵¹ The size indicated here is from the NHTSA reference cited above. The figure shows that the prototype label for the car seat was even larger, as 140 mm is 5.5 inches.

to questionnaires that included items about the labels. None of the 66 noticed the label on the dash, and two reported seeing the label on the car seat; one of the two could not identify the color or shape of the car seat label. Following the study above, the subjects served as participants in focus groups and developed recommendations for placement of the warning label. Based on these results and feedback on the labels and locations from focus group participants, as well as comments on the proposed rule, NHTSA revised its requirements to include placement of the air bag warning label in the most conspicuous location on the car seat, “affixed to the outer surface of the cushion or padding in or adjacent to the area where a child’s head would rest.”

More important, NHTSA’s study demonstrates that ensuring that a stimulus is *visible*, that is, that it is available within the visual field, does not mean that it will be perceived. As stated previously, what we perceive at any given moment is determined largely by where and how our attention is focused. We are subject to constant input through our various sense organs, much of which the brain filters out through the process of selective attention, allowing us to focus on what is relevant (Chun & Wolfe, 2001). Visual attention is a highly complex function that is influenced by many factors. Basic stimuli such as motion, light, and color are familiar “eye-catching” qualities associated with the phenomenon of attention capture. However, a broad body of research indicates that important factors in the allocation of attention include the emotional and social salience of stimuli (*e.g.*, Fenske & Raymond, 2006; Raymond, 2009; Anderson, 2013). As described by Brosch and Grandjean (2013), “behavioral findings across many different tasks and paradigms indicate that perception is facilitated and attention prioritized for emotional information.”

The research findings that perception is facilitated by emotional information is important because the developing bond between caregiver and infant is dependent, in part, on eye contact and face-to-face interaction as each perceives and responds to the other’s emotional expressions (Santrock, 2014; *e.g.*, Cohn & Tronick, 1987; Hsu & Fogel, 2003). Furthermore, the human face is among the most important and salient of social stimuli, and faces capture and hold attention (Theeuwes & Van der Stigchel, 2006). This bias toward the human face is evident from infancy. Infants preferentially attend to images of faces (Farroni, Johnson, Menon, Zulian, Faraguna, & Csibra, 2005), and newborns will look longer at pictures of faces that appear to make eye contact than those with an averted gaze (Farroni, Csibra, Simion, & Johnson, 2002).

Staff’s recommended position for the fall hazard warning label near the child’s face is the most conspicuous location on the bouncer because during interactions with the child, that is likely to be the center of the caregiver’s attention. At a very basic level, it is more likely that a caregiver will notice the label if it is near the child’s face because that is where the caregiver is likely to be looking while making choices that affect the child’s safety. As important, placement near the infant’s face also takes advantage of the emotional component of the caregiver-child relationship to make the warning personally relevant, and thus to motivate compliance with the warning.

A warning’s attention-getting power is facilitated if it is placed near the hazard (Wogalter, 2006). Generally, placing a warning near the hazard means placing the warning on the product itself, near the source of danger, rather than in the instructions. In this case, location of the fall hazard warning label next to the child’s face would also link the warning to the potential consequence of the hazard, the risk of head injuries. As mentioned previously, research suggests that explicit and

fear-inducing messages can increase the perception of hazard and injury severity (DeJoy, 1999a, 1999b; Silver & Braun, 1999), which is the purpose of the warning message. That is, the warning is intended to motivate compliance, in part, by creating a sense of fear that one's child will be harmed if one does not comply. Placing the label near the infant's face pairs the consequence, "skull fractures," with the location of the potential injuries (the child's head and face). The pairing of the two has the potential to evoke mental images of the consequences for this particular child should a caregiver fail to comply with the warning, along with a corresponding emotional response. Based on their review, Kalsher and Williams (2006) advise that compliance is likely to increase if a warning can cause the user to imagine how she might feel (*e.g.*, guilty) if the caregiver, or in this case, her child, were injured because of her failure to comply. Staff's recommended location for the fall hazard warning label is more difficult to ignore and is more likely to draw caregivers' attention and influence their behavior than if it were placed elsewhere on the product.

C. Format

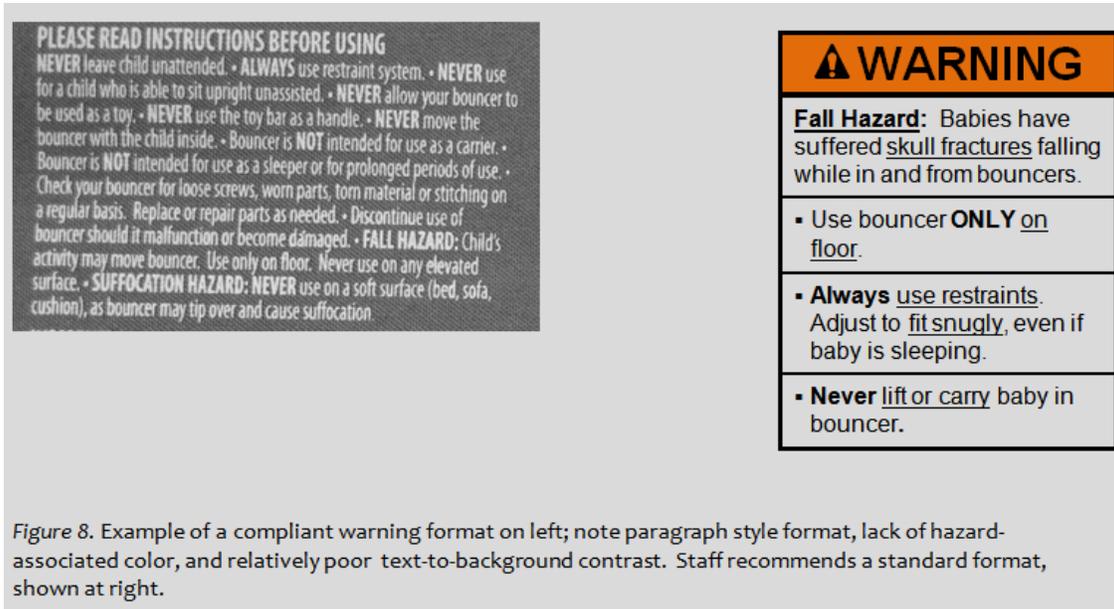
The current standard includes limited provisions for the format of the warnings on the product and in the instructions. On-product warnings must be preceded by the safety alert icon (▲) and the signal word "WARNING" in bold, sans serif, 0.20-in. text against an orange, red, or yellow⁵² background, whichever offers the best contrast against the product material; the background color is not required in warnings presented in the instructions. The remainder of the warnings in both locations must be in contrasting colors and in sans serif-style 0.10-in. text.

During review of product samples for this effort and related work, staff noted that the format of the warnings used on juvenile products varies widely. Particularly poor cases that would meet the current standard in terms of format combine features such as text and background colors that, while contrasting, complement the product material; a condensed sans serif font; and a paragraph presentation style. One such example, which would comply with the current standard if preceded by the safety icon and signal word on a hazard color background, is presented in Figure 8, with one of staff's recommended labels for comparison.

Although the current standard does not require a label format, it does include example labels that depict staff's recommended format, along with advisory language that emphasizes that the labels are "EXAMPLES ONLY," and that the format, wording,⁵³ and highlighting are at the manufacturer's discretion. CPSC staff recommends that to increase conspicuity, readability, and comprehension across products, the format for the warnings be specified to include black text on a white background, brief, bulleted statements organized in table form by hazard and topic, and surrounded by a black border.

⁵² General guidelines for standard warning labels recommend Safety Orange as the background color for use with the "WARNING" signal word. ASTM members asserted that specifying the background color was too limiting because it would not allow for sufficient contrast with materials that are primarily orange in color.

⁵³ The voluntary standard states that the warnings "shall address" certain content. Although it is commonly stated that most firms use the language in the standard, they are free to choose their own wording and to add to the content of the text.



Unfortunately, the hazard scenarios resulting in infant-bouncer injuries and deaths are not straightforward in that they involve a combination of factors. Consequently, the warnings must be longer than is ideal, and yet must gain and hold attention long enough to be read. Staff’s recommended format for the warnings establishes minimum requirements for organization of the hazard information. Good formatting helps attract and maintain attention, as well aiding reading and comprehension. Text presented in bulleted lists is superior to prose for readability and comprehension (e.g., Wogalter, Shaver, & Chan, 2002). In summarizing research on this topic, Wogalter and Vigilante (2006; p. 255-256) noted that the use of a bulleted list entails greater use of white space, which can be used to organize material into concepts, thereby making information acquisition easier. Findings cited in this area include faster reading speeds, better comprehension, superior content recall, greater preference, and better task performance (citing Desaulniers, 1987; Morrow, Leirer, Andrassy, Hier, & Menard, 1998; Wogalter & Post, 1989; Shaver & Wogalter, 2003). The benefits of a structured format are supported by research demonstrating that information is processed more quickly and easily when it is organized into brief chunks (Miller, 1956, 1994; Shiffrin, & Nosofsky, 1994; Chandler & Sweller, 1991; see also Young, Frantz, Rhoades, & Wisniewski, 2006). The Food and Drug Administration (“FDA”) followed these principles in developing the label format requirements for nutrition and over-the-counter medications. Studies comparing the latter to then-existing labels confirmed that the new format (table structure organized by content, bold headings, bulleted lists, etc.) took less time to read, was easier to read and understand, and resulted in more correct product use decisions (FDA, 1999). Guides to good communication also typically recommend small chunks⁵⁴ of material with subheadings, highlighting techniques, and generous use of white space to improve readability (e.g., Fischhoff, Brewer, & Downs, 2011) and Singer and colleagues recommend the use of highlighting techniques to emphasize key information (October, 2003).

⁵⁴ Largely attributed to the work of Miller (1956, 1994), “chunking” refers to the process of organizing and grouping small units of information into larger clusters.

Although caregivers obviously will not stop to read the warning labels in their entirety every time they see the labels, each element of the warnings, particularly on the fall hazard label, is distinct. Any one element may capture attention because of the format and highlighting within, and essential information is brief enough to be read at a glance.

VI. Conclusion

HF staff reviewed the literature regarding the developmental capabilities and limitations of the infants in the age group intended to use bouncers, the use and expectations of infant bouncer seats reported by caregivers, infant bouncer-related incident data, and a variety of sample products along with their warnings and instructions. The issues identified suggested greater complexity than expected in the factors contributing to both fall injuries and deaths. Infant bouncer seats are designed to support a child in a semi-upright position, with the movement of the upper torso unconstrained, while the intended users sleep, reach, lean, push with their feet and legs, and actively work to turn over and sit up. These developmentally appropriate behaviors put them at risk of falling or hanging over the front or sides, turning into the flexible surface of the bouncer seat, or tipping it over.

In addition to the expected incidence of falls from high surfaces, such as kitchen counters, the incident data suggest that (1) failure to use the existing restraints, or perhaps to tighten them sufficiently, is a factor in bouncer related fatalities; (2) infants sleeping or napping in bouncer seats is a factor in bouncer-related fatalities; and (3) both failure to use the restraints and adults carrying or lifting infants in a bouncer seat are factors in head injuries.

Restraining the child's upper body could forestall many, if not most, of the incidents leading to serious injuries and deaths reported; however, the design of current torso restraints also may present a strangulation hazard if used improperly, and are known to be misused by caregivers who perceive them to be uncomfortable. Unless and until alternative restraint systems are made available that do not introduce new hazards, warnings are the only available approach to address these issues.

Staff worked with ASTM to improve the warnings, and the recommendations that have been incorporated in the current voluntary standard include:

- moving the warnings to the front surface of the bouncer;
- requiring a hazard color as the background for the safety alert icon and signal word;
- strengthening and simplifying the suggested wording used in the content to be addressed; and
- including example labels with the suggested wording and recommended format.

Staff believes these changes, although important, are insufficient and recommends that the Commission issue a proposed rule for infant bouncer seats that incorporates by reference ASTM F2167 – 15, with the modifications below to improve and strengthen the requirements stated in the ASTM standard:

- a requirement that the fall hazard label be located in the area adjacent to the area where the child's head would rest;
- a revised test to ensure the fall hazard label is visible when manufacturer-provided accessories (*e.g.*, an infant head insert) are used;
- the addition of text in each warning that addresses use of the restraints if the child is sleeping;
- a requirement for developmental guidance that advises caregivers to stop using the bouncer when the child starts trying to sit up, in the warnings, and in the instructions, to replace the current guidance; and
- a specified format to ensure that the warning content is conspicuous and easy to read and comprehend quickly.

Exact language for these modifications is presented in Appendix A.

References

- Anderson, B. A. (2013). A value-driven mechanism of attentional selection. *Journal of Vision*, 13(3):7, 1–16. <http://www.journalofvision.org/content/13/3/7>, doi:10.1167/13.3.7
- ANSI. (2011). *ANSI Z535.4-2011 American National Standard for Product Safety Signs and Labels*. Rosslyn, VA: National Electrical Manufacturers Association.
- Bayley, N. (1969). *Manual for the Bayley scales of infant development*. New York, NY: The Psychological Corporation.
- Boff, K. R. & Lincoln, J. E. (1988). *Engineering data compendium: Human perception and performance, Vol. I* (p. 104). Wright Patterson Air Force Base, OH: Armstrong Aerospace Medical Research Laboratory.
- Brosch, T. & Grandjean, D. (2013). Cross-modal modulation of spatial attention by emotion. In P. Belin, S. Campanella, T. Ethofer, (Eds.), *Integrating face and voice in person perception* (207-223). New York, NY: Springer Science.
- Chandler, P. & Sweller, J. (1991). Cognitive load theory and the format of instruction. *Cognition and Instruction*, 8(4), 293–332.
- Chapanis, A. (1994). Hazards associated with three signal words and four colours on warning signs. *Ergonomics*. 37(2), 265-275.
- Chun, M. M., & Wolfe, J. M. (2001). Visual attention. In B. Goldstein (Ed.), *Blackwell handbook of perception* (pp. 272-310). Oxford, UK: Blackwell Publishers Ltd.
- Cohn, J. F., & Tronick, E. Z. (1987). Mother-infant face-to-face interaction: The sequence of dyadic states at 3, 6, and 9 months. *Developmental Psychology*. 23(1), 68-77.
- Davis, B. E., Moon, R. Y., Sachs, H. C., & Ottolini, M. C. (1998). Effects of sleep position on infant motor development. *Pediatrics*, 102(5,) 1135-1140.
- DeJoy, D. M. (1999a). Attitudes and beliefs. In M. S. Wogalter, D. M. DeJoy, & K. R. Laughery, (Eds.), *Warnings and risk communication* (pp. 189-219). London/Philadelphia: Taylor & Francis, Inc.
- DeJoy, D. M. (1999b). Motivation. In M. S. Wogalter, D. M. DeJoy, & K. R. Laughery, (Eds.), *Warnings and risk communication* (pp. 221-243). London/Philadelphia: Taylor & Francis, Inc.
- Desaulniers, D. R. (1987). Layout, organization, and the effectiveness of consumer product warnings. In *Proceedings of the Human Factors and Ergonomics Society 31st Annual Meeting* (pp. 56-60). Santa Monica, CA: Human Factors and Ergonomics Society.

- Dorris, A. L., & Purswell, J. L. (1977). Warnings and human behavior: Implications for the design of product warnings. *Journal of Product Liability*. 1, 255-264.
- Farroni, T., Csibra, G., Simion, F., & Johnson, M. H. (2002). Eye contact detection in humans from birth. *Proceedings of the National Academy of Sciences of the United States of America*. 99(14), 9602–9605. Online version June 24, 2002:
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC123187/>
- Farroni, T., Johnson, M. H., Menon, E., Zulian, L., Faraguna, D., & Csibra, G. (2005). Newborns' preference for face-relevant stimuli: Effects of contrast polarity. *Proceedings of the National Academy of Sciences of the United States of America*. 102(47): 17245–17250. Online version November 11, 2005:
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1287965/>
- Fenske, M.J. & Raymond, J.E. (2006). Affective influences of selective attention. *Current Directions in Psychological Science*. 15(6), 312-316.
- Fischhoff, B., Brewer, N. T., & Downs, J. S. (Eds.). (2011). *Communicating risks and benefits: An evidence-based user's guide*. Silver Spring, MD: U.S. Department of Health and Human Services, Food and Drug Administration. Available at:
<http://www.fda.gov/ScienceResearch/SpecialTopics/RiskCommunication/default.htm>.
- Food and Drug Administration [FDA]. (1999). Over the-counter human drugs; labeling requirements; final rule. *Federal Register*. 64(51), 13253-13303.
- Fowler, F. J. Jr. (1995). Improving survey questions: Design and evaluation (pp. 29-30). In L. Bickman & D. J. Rog (Eds.), *Applied Social Research Methods Series (Volume 38)*. Thousand Oaks, CA: Sage Publications.
- Frascara, J. (2006). Typography and the visual design of warnings. In M. S. Wogalter, (Ed.), *Handbook of warnings* (pp. 385- 405). Mahwah, New Jersey/London: Lawrence Erlbaum Associates.
- Kalsher, M. J., & Williams., K. J. (2006). Behavioral compliance. In M. S. Wogalter, (Ed.), *Handbook of warnings* (pp. 313-331). Mahwah, New Jersey/London: Lawrence Erlbaum Associates.
- Haywood, K. M., & Getchell, N. (2009). *Life span motor development* (5th Ed; p. 102). Champaign, IL: Human Kinetics.
- Hsu, H. & Fogel, A. (2003). Stability and transitions in mother-infant face-to-face communication during the first 6 months: A microhistorical approach. *Developmental Psychology*. 39(6), 1061-1082.
- Land, M. F. (2006). Eye movements and the control of actions in everyday life. *Progress in Retinal and Eye Research*. 25, 296–324.

- Land, M., Mennie, N. & Rusted, J. (1999). The roles of vision and eye movements in the control of activities of daily living. *Perception*. 28, 1311-1328.
- Lerner, N. D., Huey, R. W., & Kotwal, B. M. (2001). *Product profile report* (Contract CPSC-S-00-5205). Washington, DC: Consumer Product Safety Commission.
- Lesch, M. F. (2006). Consumer product warnings: Research and recommendations. In M. S. Wogalter, (Ed.), *Handbook of warnings* (pp. 137-146). Mahwah, New Jersey/London: Lawrence Erlbaum Associates.
- Madden, M. S. (2006). The duty to warn in products liability. In M. S. Wogalter, (Ed.), *Handbook of warnings* (pp. 583-588). Mahwah, New Jersey/London: Lawrence Erlbaum Associates.
- Marques, S. (2015). Health Science analysis of infant bouncer seat-related deaths and injuries. Memorandum to S. Wanna-Nakamura, Ph.D. Bethesda, MD: Division of Pharmacology and Physiology, Directorate for Health Sciences, U.S. Consumer Product Safety Commission.
- McCallion, R. (2015). "Staff's review and evaluation of ASTM F2167-15, *Standard Consumer Safety Specification for Infant Bouncer Seats*, for incorporation by reference into staff's draft proposed rule." Memorandum dated 30 June 2014 to S.C. Wanna-Nakamura, Ph.D., Infant Bouncer Seats Project Manager.
- Miller, G. A. (1956). The magical number seven, plus or minus two: Some limits on our capacity for processing information. *Psychological Review*. 63, Mar 1956, 81-97.
- Miller, G. A. (1994). The magical number seven, plus or minus two: Some limits on our capacity for processing information. *Psychological Review*. 101, 343-352.
- Morrow, D. G., Leirer, V. O., Andrassy, J. M., Hier, C. M., & Menard, W. E. (1998). The influence of list format and category headers on age differences in understanding medication instructions. *Experimental Aging Research*, 24, 231-256.
- Newby, E. A., & Rock, I. (1998). Inattention blindness as a function of proximity to the focus of attention. *Perception*. 27, 1025-1040.
- NHTSA. (1996). Federal motor vehicle safety standards; occupant crash protection: Notice of proposed rulemaking. *Federal Register*. 61,(152), 40784-40809.
- Raymond, J. (2009). Interactions of attention, emotion and motivation. In N. Srinivasan (Ed.) *Progress in Brain Research, Volume 176* (pp. 293-308).
- Santrock, J. W. (2014). *Child development* (14th ed., pp. 285-286). New York, NY: McGraw-Hill Education.

- Shaver, E. F. & Wogalter, M. S. (2003). A comparison of older vs. Newer over-the-counter (OTC) nonprescription drug labels on search time accuracy (pp. 826-830). *Proceedings of the Human Factors and Ergonomics Society 47th Annual Meeting*. Santa Monica, CA: Human Factors and Ergonomics Society.
- Shiffrin, R. M., & Nosofsky, R. M. (1994). Seven plus or minus two: A commentary on capacity limitations. *Psychological Review*. 101(2), 357-361.
- Silver, N. C. & Braun, C.C. (1999). Behavior. In M. S. Wogalter, D. M. DeJoy, & K. R. Laughery (Eds.), *Warnings and risk communication* (pp. 245-262). London/Philadelphia: Taylor & Francis, Inc.
- Singer, J. P., Balliro, G. M., & Lerner, N. D. (2003, October). In T. Smith (Ed.), *Manufacturer's guide to developing consumer product instructions* (p. 48). Bethesda, MD: U.S. Consumer Product Safety Commission. Available at: <http://www.cpsc.gov/PageFiles/103077/guide.pdf>.
- Spector, R. H. (1990). Visual fields. In H. K. Walker, W. D. Hall, J. W. Hurst, (Eds.). *Clinical methods: The history, physical, and laboratory examinations* (3rd Ed.). Boston: Butterworths. Chapter 116. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK220/>; accessed 5.15.2014.
- Theeuwes, J. & Van der Stigchel, S. (2006). Faces capture attention: Evidence from inhibition of return. *Visual Cognition*. 13(6), 657-665.
- Tversky, A. & Kahneman, D. (1980). Judgment under uncertainty: Heuristics and biases. In P. N. Johnson-Laird & P. C. Wason (Eds.), *Thinking: Readings in cognitive science*. Cambridge, UK: Cambridge University Press.
- Vredenburg, A. G., & Zackowitz, I. B. (2006). Expectations. In M. S. Wogalter, (Ed.), *Handbook of warnings* (pp. 345-354). Mahwah, New Jersey/London: Lawrence Erlbaum Associates.
- Wogalter, M. S., Frederick, L. J., Magurno, A. B., & Herrera, O. L. (1997). Connoted hazard of Spanish and English warning signal words, colors, and symbols by native Spanish language users. *Proceedings of the 13th Triennial Congress of the International Ergonomics Association, IEA*. 3, 353-355.
- Wogalter, M. S. (2006). Communication-human information processing (C-HIP) model. In M. S. Wogalter, (Ed.), *Handbook of warnings* (pp. 51-61). Mahwah, New Jersey/London: Lawrence Erlbaum Associates.
- Wogalter, M. S., Kalsher, M. J., Frederick, L. J., Magurno, A. B., & Brewster, B. M. (1998). Hazard level perceptions of warning components and configurations. *International Journal of Cognitive Ergonomics*. 2 (1-2), 123-143.

- Wogalter, M. S., & Post, M. P. (1989). Printed computer instructions: The effects of screen pictographs and text format on task performance. *Proceedings of Interface 89*, 6, 133-138.
- Wogalter, M. S., Shaver, E. F., & Chan, L. S. (2002). List vs. paragraph formats on time to compare nutrition labels. In P.T. McCabe (Ed.) *Advances in ergonomics 2002* (pp. 458-462). London: Taylor & Francis.
- Wogalter, M. S., & Vigilante, W. J., Jr. (2006). Attention switch and maintenance. In M. S. Wogalter, (Ed.), *Handbook of warnings* (pp. 245-265). Mahwah, New Jersey/London: Lawrence Erlbaum Associates.
- World Health Organization (WHO) Multicentre Growth Reference Study Group. (2006). Reliability of motor development data in the WHO Multicentre Growth Reference Study. *Acta Paediatrica*, Supplement 450, 47-55. Electronic version accessed September 5, 2013.
- Yang, T. (2015). Infant bouncer seats-related deaths, injuries, and potential injuries; January 1, 2006 – February 2, 2015. Memorandum to S. Wanna-Nakamura, Ph.D. Bethesda, MD: Division of Hazard Analysis, Directorate for Epidemiology, U.S. Consumer Product Safety Commission.
- Young, S. L., Frantz, J. P., Rhoades, T. P., & Wisniewski, E. C. (2006). Revisions of labeling for personal watercraft: Label development and evaluation. In M. S. Wogalter, (Ed.), *Handbook of warnings* (pp. 723-737). Mahwah, New Jersey/London: Lawrence Erlbaum Associates.

APPENDIX A: Staff's Recommended Changes to Labeling Sections of ASTM F2167-15
Consumer Safety Specification for Infant Bouncer Seats

The sections below display the relevant content of the current version of ASTM F – 2167 *Consumer Safety Specification for Infant Bouncer Seats* with staff's recommended changes. Additions based on staff's recommendations are shown as underlined text and deletions are shown as ~~strike-throughs~~. Note that Section 8.3.3.1 calls for the test specified in Section 7.11.; the sections are not out of sequence.

7.11 Fall Hazard Label Visibility Test:

~~7.11.1 Place infant bouncer seat on the floor.~~

7.11.2 Place and secure the Newborn CAMI dummy (Fig. 2) in the infant bouncer seat.

~~7.11.3 Visibility Tests With and Without Accessories and Toy Bars:~~

~~7.11.3.1 Visibility With CAMI Dummy Restrained in Seat~~ While standing in front of the product with the Newborn CAMI dummy installed, verify that the required warnings are visible and not obscured by any part of the dummy.

~~7.11.3.2 Visibility with Accessories (Excluding Toy Bars)~~ Infant bouncer seats that include any accessory(ies) that could potentially obscure the fall hazard warning shall comply with visibility requirements of ~~7.11~~ both with such accessory(ies) in place (in all configurations and combinations) and with the accessory(ies) removed.

7.11.1 Visibility with Accessories Excluding Toy Bar Identify and install each accessory unrelated to the toy bar that could obscure the warning label during a caregiver's interaction with the occupant. Place the bouncer on the floor.

7.11.1.1 Face the front of the bouncer from a distance of 1.0 ft (0.3 m and verify that all warning text is visible and not obscured by the accessory(ies).

7.11.1.2 A label on the bouncer seat back surface that is obscured by an accessory such as an infant insert would meet the visibility requirement if the label is plainly visible and easily readable on the accessory.

7.11.2 Visibility with Toy Bar and Related Accessories Identify and install the toy bar and related accessory(ies) that could obscure the warning label during a caregiver's interaction with the occupant. Place the bouncer on the floor.

7.11.2.1 Face the front of the bouncer from a distance of 1.0 ft (0.3 m and verify that all warning text is visible and not obscured by the toy bar and related accessory(ies).

~~7.11.3.3.2.2 Visibility With Toy Bar~~ If any part of the required warnings A fall hazard label that is partly obscured by a toy bar or its ~~attached toys~~ related accessories, but is visible with a shift of the observer's head position, would meet the visibility requirement, ~~then this is considered acceptable.~~

8. Marking and Labeling

8.1 Each product and its retail package shall be marked or labeled clearly, legibly, and permanently to indicate the following (note that an upholstery label required by law shall not be used to meet the requirements of 8.1):

8.1.1 The name of the manufacturer, distributor, or seller, and either the place of business (city, state, and mailing address, including zip code), or telephone number, or both.

8.1.2 A code mark or other means that identifies the date (month and year as a minimum) of manufacture.

8.2 The manufacturer shall change the model number whenever the infant bouncer seat undergoes a significant structural or design modification or a change that affects its conformance to this consumer safety specification.

8.3 Warnings:

8.3.1 *Warning Groups and Header*—Each infant bouncer seat shall be labeled with two groups of warning statements: a fall hazard warning and a suffocation warning. ~~Both~~ Each warning statement groups shall be preceded by a header consisting of the safety alert symbol “▲” and the signal word “**WARNING**.”

8.3.2 *Warning Format*—The background color for the safety alert symbol and the signal word shall be ~~either~~ orange, red or yellow, whichever provides best contrast against the product material. The safety alert symbol and the signal word shall be in bold capital letters not less than 0.2 in. (5 mm) high. The remainder of the text shall be characters whose upper case shall be at least 0.1 in. (2.5 mm) high. All elements of these warnings shall be ~~in contrasting color(s)~~, permanent, and in sans serif, non-condensed style font. Precautionary statements shall be indented from hazard statements and preceded with bullet points. The warning label and the panel containing the signal word “WARNING” shall be surrounded by a heavy black line. Message panels within the labels shall be delineated with solid lines between sections of differing content. The background color in the message panels shall be white and the text shall be black. If an outside border is used to surround the heavy black lines of the label, the border shall be white and the corners may be radiused.

8.3.3 *Warning Locations:*

8.3.3.1 The fall hazard warnings label in 8.3.4.1 shall be on the front surface of the infant bouncer seat back so as to comply with the visibility requirements in adjacent to the area where a child’s head would rest, so that the label is plainly visible and easily readable. If one or more accessories are provided with the bouncer that could obscure the warning label during use, the visibility of the label shall be verified in accordance with 7.11.

8.3.3.2 The suffocation warnings in 8.3.4.2 shall be conspicuous on the product.

8.3.4 The statements in the two warning groups shall address the following:

8.3.4.1 *Fall Hazard:*

Fall Hazard: Babies have suffered skull fractures falling while in and from bouncers.

- Use bouncer **ONLY** on floor.
- **Always** use restraints. Adjust to fit snugly, even if baby is sleeping.
- **Never** lift or carry baby in bouncer. [NOTE: Bouncer seats with a handle(s) intended for use to lift and carry a child are exempt from including this warning statement.]

8.3.4.2 *Suffocation Hazard:*

Suffocation Hazard: Babies have suffocated when bouncers tipped over on soft surfaces.

- **Never** use on a bed, sofa, cushion, or other soft surface.
- **Never** leave baby unattended. To prevent falls and suffocation:
- **Always** use restraints. Adjust to fit snugly, even if baby is sleeping.
- **Stop** using bouncer when baby starts trying to sit up. ~~Never use for a child able to sit up unassisted.~~

8.3.5 ~~Figs. 10-12 label formats below are presented as EXAMPLES ONLY for the display of the required warnings.~~ The safety alert symbol “▲” and the signal word “**WARNING**” shall be as specified above, but with the option of background colors as described above. The warning statements’ wording content, as well as the use of any underlining, capital lettering, or bold typeface, or a combination thereof, are at the discretion of the manufacturer.

9. Instructional Literature

9.1 Instructions must be provided with the infant bouncer seat and shall be easy to read and understand. Assembly, maintenance, cleaning, operating, and adjustment instructions and warnings, where applicable, must be included.



Fig. 10

9.1.1 The instructions shall contain statements that address each of the following:

9.1.1.1 Read all instructions before use of the infant bouncer seat.

9.1.1.2 Keep instructions for future use.

9.1.1.3 Do not use this infant bouncer seat if it is damaged or broken.

9.1.1.4 Instructions on how to use the restraint system.

9.1.1.5 Instructions must indicate the manufacturer's recommended maximum weight, height, age, developmental level, consistent with the warning statement in 8.3.4.2, or combination thereof of the occupant for which the infant bouncer seat is intended. If the infant bouncer seat is not intended for use by a child for a specific reason (insert reason), the instructions shall so state this limitation.

9.2 Warning statements with the instructional literature.

9.2.1 The instructions shall contain the warning statements as defined in 8.3.4 and these warnings shall use the format specified in 8.3.1 and 8.3.2, excluding the background color requirements for the header.

9.3 Instructions for infant bouncer seats that use more than one battery in one circuit shall address the following:

9.3.1 Do not mix old and new batteries.

9.3.2 Do not mix alkaline, standard (carbon-zinc), or re chargeable (nickel-cadmium) batteries.

9.3.3 Remove batteries before putting infant bouncer seat into storage for a prolonged period of time.

10. Keywords

10.1 bouncing motion; caregiver facilitated action; infant seat

⚠ WARNING
<p>Suffocation Hazard: Babies have <u>suffocated</u> when bouncers tipped over on soft surfaces.</p> <ul style="list-style-type: none"> ▪ Never use on bed, sofa, cushion, or other soft surface. ▪ Never leave baby unattended.
<ul style="list-style-type: none"> ▪ To prevent falls and suffocation, always use restraints. Adjust to <u>fit snugly</u>, even if baby is sleeping. ▪ Stop using bouncer when baby starts trying to sit up.

Fig. 11

⚠ WARNING
<p>Fall Hazard: Babies have suffered <u>skull fractures</u> falling while in and from bouncers.</p> <ul style="list-style-type: none"> ▪ Use bouncer ONLY on floor. Baby's movements can shift or tip bouncers off counters, tables, and other surfaces. ▪ Never lift or carry baby in bouncer.
<p>Suffocation Hazard: Babies have <u>suffocated</u> when bouncers tipped over on soft surfaces.</p> <ul style="list-style-type: none"> ▪ Never use on a bed, sofa, cushion, or other soft surface. ▪ Never leave baby unattended.
<ul style="list-style-type: none"> ▪ To prevent falls and suffocation, always use restraints. Adjust to <u>fit snugly</u>, even if baby is sleeping. ▪ Stop using bouncer when baby starts trying to sit up.

Fig. 12

**TAB E: Durable Nursery Products: Summary of Infant
Bouncer Seat Recalls from January 1, 2006 to Present**

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

Memorandum

Date: July 9, 2015

TO : Suad C. Wanna-Nakamura, Ph.D.
Infant Bouncer Seats Project Manager
Division of Pharmacology and Physiology Assessment
Directorate for Health Sciences

THROUGH: Howard N. Tarnoff
Acting Assistant Executive Director
Office of Compliance and Field Operations

Mary F. Toro, Director
Division of Regulatory Enforcement,
Office of Compliance and Field Operations

Carolyn Manley
Team Lead, Division of Regulatory Enforcement
Regulated Children's Products, Office of Compliance and Field Operations

FROM: Keysha L. Walker
Compliance Officer
Division of Regulatory Enforcement, Regulated Children's Products
Office of Compliance and Field Operations

SUBJECT : Durable Nursery Products: Summary of Infant Bouncer Seat Recalls
from January 1, 2006 to Present

PURPOSE

This memorandum summarizes the product safety recalls involving infant bouncer seats conducted by Office of Compliance and Field Operations ("Compliance") staff since 2006.

COMPLIANCE RECALL INFORMATION

Since January 1, 2006, Compliance staff conducted two bouncer seat recalls involving two different firms, as shown in Table 1. The first recall was in April 2007. This recall involved Oeuf, LLC infant bouncer seats. The product was recalled after six reports of tubular steel frame breakage. No reported injuries were associated with the product at the time of the recall.

The recall involved approximately 1,400 units.⁵⁵ The second recall in July of 2009 involved BabySwede LLC BabyBjörn® Babysitter Balance and Babysitter Balance Air bouncer chairs. Small, sharp metal objects found in the padded area of the bouncer chair can protrude through the fabric, posing a laceration hazard to children. No reported injuries were associated with the product at the time of the recall. The recall involved approximately 6,500 units.⁵⁶

Table 1
Bouncer Recalls, January 1, 2006 to Present

Date of Recall	Firm	Reason	Number Recalled	Press Release Number
04/18/2007	Oeuf, LLC	Tubular metal frame breakage	1,400	PR07-162
07/28/2009	BabySwede LLC	Protrusion of small sharp metal objects	6,500	PR09-287

⁵⁵ CPSC link to recalled product: <http://www.cpsc.gov/en/Recalls/2007/Infant-Bouncer-Seats-Recalled-Due-to-Frame-Failure/>.

⁵⁶ CPSC link to recalled product: <http://www.cpsc.gov/en/Recalls/2009/BabySwede-LLC-Recalls-Bouncer-Chairs-Due-to-Laceration-Hazard/>.

TAB F: Initial Regulatory Flexibility Analysis of the Staff-Recommended Proposed Standard for Infant Bouncer Seats and the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Infant Bouncer Seats Standard

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**UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814**

Memorandum

Date: August 3, 2015

TO : Suad C. Wanna-Nakamura, Ph.D.
Project Manager, Infant Bouncer Seats
Division of Pharmacology and Physiology Assessment
Directorate for Health Sciences

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

Deborah V. Aiken, Ph.D.
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 Staff-Recommended Proposed Standard for Infant Bouncer Seats and the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Infant Bouncer Seats Standard

I. Introduction

ASTM F2167-15 is the current ASTM International (“ASTM”) standard for infant bouncer seats (“infant bouncers” or “bouncers”). Staff recommends that the Commission issue a proposed rule under the requirements of section 104 of the Consumer Product Safety Improvement Act (“CPSIA”) that incorporates by reference the most recent ASTM standard for infant bouncer seats, with several modifications to the requirements for product warnings and instructional literature.

This memorandum evaluates the potential economic impact of the staff-recommended infant bouncer seat standard on small entities, including small businesses, as required by the Regulatory Flexibility Act (“RFA”). 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 notice of proposed rulemaking (“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, staff cannot rule out a significant impact for six of the 12 (50

percent) known small suppliers of bouncers to the U.S. market. Accordingly, we have prepared an IRFA and pose several questions for public comment to help us with our assessment.

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

1. a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
2. a description of the reasons why action by the agency is being considered;
3. a succinct statement of the objectives of, and legal basis for, the proposed rule;
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 possible, of all relevant federal rules which may duplicate, overlap, or conflict with the proposed rule.

II. The Product

An infant bouncer seat is defined in ASTM F2167-15, *Standard Consumer Safety Specification for Infant Bouncer Seats*, as “a freestanding product intended to support an occupant in a reclined position to facilitate bouncing by the occupant, with the aid of a caregiver or by other means.” It is intended for “infants who have not developed the ability to sit up unassisted approximately 0 to 6 months of age.” These products vary widely in price; they can be purchased for as little as \$20, but can also easily cost more than \$200.

The standard does not cover infant rockers, which is subject to a voluntary ASTM standard (F3084), or infant swings which is covered by both a voluntary ASTM standard (F2088) and a mandatory standard (16 CFR part 1223). Some infant bouncer seats fall into more than one product category. For example, several firms produce infant rockers that become bouncers with the use of a stop. Also, a few firms produce infant swings that, given the design, can act (and are marketed) as bouncers when the power is turned off.

III. The Market for Infant Bouncer Seats

Staff identified 22 firms (including large and small) supplying infant bouncer seats to the U.S. market, although there may be additional firms as well. These firms primarily specialize in the manufacture and/or distribution of children’s products, including durable nursery products. The majority of the 22 known firms are domestic (including 8 manufacturers and 10 importers). The remaining four firms are foreign manufacturers.⁵⁷ Staff expects that the infant bouncer seats

⁵⁷ Determinations were made using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites.

of 17 of these firms are already compliant with ASTM F2167 because the firms either: (1) have their bouncers certified by the Juvenile Products Manufacturers Association (“JPMA”) (six firms); (2) claim compliance with the voluntary standard (ten firms); or (3) have been tested to the ASTM standard by CPSC staff (one firm).⁵⁸

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

Based on National Electronic Injury Surveillance System (“NEISS”) injury estimates⁵⁹ and data on the number of infant bouncers in use from CPSC’s Durable Nursery Product Exposure Survey (“DNPEs”),⁶⁰ staff found that the risk associated with bouncer use is approximately 10 emergency department-treated injuries per 10,000 infant bouncers in use annually [(2,100 injuries ÷ 2.09 million infant bouncers in use in U.S. households) x 10,000].

Section 104 of the CPSIA requires the CPSC to promulgate a mandatory standard for infant bouncer seats that is substantially the same as, or more stringent than, the voluntary standard if the Commission determines that a more stringent standard would further reduce the risk of injury associated with such products.

CPSC staff worked closely with ASTM to develop the revised requirements, test procedures, and warning labels that have been incorporated into ASTM F2167 since the rulemaking process started in January 2013 in an effort to reduce this risk. However, not all of Division of Human Factors (“HF”) staff’s warning label recommendations were adopted into the most recent version of the voluntary standard, ASTM F2167-15. Therefore, staff recommends that the Commission incorporate by reference ASTM F2167-15, including the remaining modifications proposed by HF staff in the proposed standard to more completely address the fall hazard pattern seen in the incident reports.⁶¹

V. Requirements of the Proposed Rule

CPSC staff recommends adopting the voluntary ASTM standard for infant bouncer seats (F2167-15) with additional changes to the warning labels (in particular, the location of the fall hazard warning label) and a test to ensure the visibility of those labels on the product. Firms

⁵⁸ JPMA typically allows six months for products in their certification program to shift to a new standard once it is published. The version of the standard that firms are likely testing to currently is ASTM F2167-14. Two newer versions of the standard have been published since then, but neither will become effective for JPMA certification purposes before September 2015. Additionally, many infant bouncer seats are expected to be compliant with ASTM F2167-14a without modification, and firms compliant with earlier versions of the standard are likely to remain compliant as the standard evolves.

⁵⁹ Memorandum from Ted Yang, Division of Hazard Analysis, Directorate for Epidemiology, dated May 18, 2015, Subject: Infant Bouncer Seats-Related Deaths, Injuries, and Potential Injuries; January 1, 2006 – February 2, 2015.

⁶⁰ Melia, K.L. and J.L. Jenkins (November 2014). *Durable Nursery Products Exposure Survey (DNPEs): Final Summary Report*. U.S. Consumer Product Safety Commission, prepared by Westat.

⁶¹ Memorandum from Catherine A. Sedney, Senior Engineering Psychologist, Division of Human Factors, dated August 4, 2015, Subject: Human Factors Assessment of Hazard Patterns and Mitigation Strategies in Infant Bouncer Seats.

whose bouncers comply with the voluntary standard would only require changes to meet the staff-recommended modifications to the warning labels, while firms whose bouncers do not meet the voluntary standard would require the changes needed to conform to the performance requirements *and* the warning label changes recommended by CPSC staff.

A. ASTM F2167-15

Some of the more significant requirements from ASTM F2167-15 that might require product modification for firms whose bouncers do not comply with the voluntary standard are presented below; changes that were made since the staff review and consultation process began in January 2013 noted in italics.⁶²

- Locking and latching mechanisms—intended to prevent unintentional folding of the infant bouncer seat while in use.
- Restraint systems—intended to ensure the integrity and effectiveness of restraint systems, which are required and must include both a waist and crotch restraint. Additionally, the bouncer’s restraint system must be designed such that the crotch restraint has to be used whenever the waist restraint is used.
- Stability—intended to prevent bouncers from tipping over while in use. Sideward and rearward stability and forward stability are tested separately. *ASTM independently modified the sideward and rearward test procedure in F2167-14, increasing the incline of the test fixture from 12 degrees to 20 degrees, making it more severe. Similarly, the forward stability test was made more severe in F2167-14a, by applying the test weight further out on the seat and using the manufacturer’s recommended maximum weight if greater than the 21 pound minimum weight application.*
- Slip resistance—intended to prevent more than nominal slipping when the infant bouncer seat is placed on a slightly inclined surface (10 degrees).
- Structural integrity—intended to ensure that the infant bouncer seat remains intact (e.g., no small parts, hazardous sharp points or edges, exposed coil springs, or problems that would cause the product to no longer support a child) after dynamic and static testing that mimics longer term use by using weights in excess of the typical user.
- Drop test—intended to ensure that the infant bouncer seat remains intact if dropped from a height of three feet.
- Disassembly/collapse—intended to prevent disassembly or collapse by testing frame attachment points in excess of forces they would likely see when carried or slid across a surface.
- Toy bar attachment integrity—intended to ensure that either toy bars can withstand being used to carry the bouncer, or that they obviously cannot be used as a handle (i.e., the toy bar detaches before the bouncer completely lifts off the floor).

⁶² Additional information on the ASTM standard and how it addresses various hazard patterns can be found in memorandum from Richard McCallion, Mechanical Engineer, Office of Hazard Identification and Reduction, dated June 26, 2015, Subject: Staff’s Review and Evaluation of ASTM F2167-15, *Standard Consumer Safety Specification for Infant Bouncer Seats*, for Incorporation by Reference into Staff’s Draft Proposed Rule.

- *Batteries—intended to address incidents of leakage, corrosion, and overheating. This addition to ASTM F2167-14a includes: (1) compartment marking requirements; (2) containment requirements; and (3) requirements and a test method to prevent hazards that can result from the misinstallation of batteries.*

The voluntary standard also includes: (1) torque and tension tests to ensure that protective components cannot be removed; (2) requirements to prevent entrapment and cuts (minimum and maximum opening size, coverage of exposed coil springs, small parts, hazardous sharp edges or points, smoothness of wood parts, and edges that can scissor, shear, or pinch); (3) marking and labeling requirements, *which were revised for version ASTM F2167-15 to incorporate some of the CPSC-recommended changes, including moving the fall warnings to the front of the bouncer and using a hazard color for the warnings, as well as some modifications to the wording and formatting;*⁶³ (4) requirements for the permanency and adhesion of labels and warnings; (5) requirements for instructional literature; and (6) toy accessory requirements. ASTM F2167-15 includes no reporting or recordkeeping requirements.

B. Staff-Recommended Warning Label Changes

As part of the voluntary standard review and consultation process, HF staff proposed changes to the ASTM warnings to strengthen them, particularly the fall hazard portion of the warnings. Some of those suggestions were incorporated into ASTM F2167-15. Staff recommends that the Commission include all of the HF staff recommendations as part of the proposed standard in the NPR. The specifics of these recommendations can be found in Tab D.⁶⁴

All firms would be affected by the staff-recommended warning label changes. Each firm would need to modify the text of the warnings for both the product and the instruction manual. The fall hazard warning would need to be re-located next to the child's head⁶⁵ and be visible when accessories are in use (such as a toy bar or an infant insert used for supporting a smaller child's upper body).

To assist in the evaluation of the economic impact of the draft proposed rule, EC staff contacted several ASTM members and supplier representatives. We contacted nine firms (four of which responded) and had informal discussions with approximately five other firm representatives at the ASTM meetings. Seven of these nine representatives were concerned that insufficient room exists on some bouncer models to accommodate a fall hazard warning adjacent to the infant's head, particularly if the warning is presented in multiple languages. While other warning labels (in particular the suffocation warning label) can remain in their current location, apart from the fall hazard label, which would offset the space problem, a number of suppliers questioned the logic of separating these labels from both product liability and aesthetic standpoints. In sum, several supplier representatives thought that the warning label changes might require that they reconsider the entire design of their bouncers in order to meet the

⁶³ Sedney, 2015.

⁶⁴ Sedney, 2015.

⁶⁵ The warning was only recently moved to the front of the bouncer (ASTM F2167-15).

requirements of the staff-recommended proposed rule while simultaneously meeting the needs of the consumers that purchase their products, thus incurring costs beyond what would typically be expected with a simple label change.

The staff-recommended location for the fall hazard warning label is based in part on the location of the strangulation hazard warning label for hand-held infant carriers, which in turn, is based on the National Highway Traffic Safety Administration (“NHTSA”) airbag warning placement on car seats. Staff has compared the location and orientation of NHTSA air bag warnings to the likely locations on bouncer seats from each known bouncer supplier. If only two or three languages are used, it appears likely that any product design could accommodate the new labels, even if the firm chose to include both the fall hazard and suffocation warnings on the front of the bouncer in a comparable location. However, some firms operate in several foreign markets with differing warning label requirements and supply warnings in many more than three languages. While the draft proposed rule only requires that the warnings are presented in English, affected firms may need to develop a unique product to meet U.S. requirements or alternatively, redesign the product (by increasing the size of the seat back primarily) to accommodate warning labels in multiple languages if they choose to produce a single product that simultaneously conforms to U.S. and all other trading partners’ requirements. At this time, we do not know how affected firms will respond and have no basis for estimating the costs due to the location of the fall hazard warning labels. We welcome comments on this issue and, in particular, estimates of the costs of making these changes. We are further interested in receiving input on whether the costs would be considered “economically significant” as in constituting an impact greater than one percent of revenue (or a similar economic benchmark or criteria).

Staff is also recommending that the proposed rule include a test to ensure the visibility of warning labels. The test would replace the visibility procedure ASTM adopted in F2167-15 and eliminate the use of the CAMI dummy. Based upon visual review of bouncers (as well as their accompanying inserts to convert the bouncer to a product for use with a smaller infant) on the market, most firms would not have a significant problem ensuring visibility. In cases where the existing insert would obscure any warning label placed on the bouncer adjacent to the child’s head, firms would have two options to comply. First, they could modify their insert, making it narrower (several bouncer suppliers already use this type of insert). Second, firms could keep their wider inserts and add duplicative warning label(s) to the insert. Either of these options would add some additional costs to bouncer production, as would any modifications to accessories to ensure warning visibility, but they are not expected to be high.

Four firms provided estimates of the cost and/or timeframe that would be required to modify warning labels to comply with the staff-recommended modifications. Cost estimates ranged from 8 cents to 50 cents per bouncer unit, depending on the types of changes the firm believes are needed. If several changes to materials, dyes, and/or application processes are needed, costs will tend toward the higher end of the range. Generally, a straightforward modification to an existing label would not generate costs that would be considered significant relative to any of the infant bouncer firm’s revenues. However, some firms believe that the changes go beyond a simple modification of the existing label; retrofitting or redesign might be required to provide sufficient space for the fall hazard warning label(s) on the front of the bouncer, by the child’s head, which could create significant economic costs. Firm representatives that EC contacted estimated that it

would generally take 1 - 4 months to modify their warning labels, but longer (about one year) to get the new bouncers incorporating the fall hazard warnings to market. Staff is seeking information on the degree to which redesign or retrofitting will be necessary to meet the new warning label requirements, and any estimates of the costs associated with needed redesigns/retrofits.

VI. Other Federal or State Rules

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

VII. Impact on Small Businesses

CPSC staff is aware of approximately 22 firms (large and small) currently marketing infant bouncer seats in the United States, 18 of which are domestic. Under U.S. Small Business Administration (“SBA”) guidelines, a manufacturer of infant bouncer seats is categorized as small if it has 500 or fewer employees, and importers and wholesalers are considered small if they have 100 or fewer employees. Staff limited our analysis to domestic firms because SBA guidelines and definitions pertain to U.S.-based entities. Based on these guidelines, about 12 of the 22 firms are small—five domestic manufacturers and seven domestic importers. Additional unknown small domestic infant bouncer seats suppliers may be operating in the U.S. market.

A. Small Manufacturers

The economic impact of the staff-recommended proposed bouncer standard should be small for the five small domestic manufacturers, apart from third party testing costs. The bouncers of all of these firms already comply with the ASTM voluntary standard currently in effect for testing purposes (F2167-14). These firms are expected to remain compliant with the voluntary standard as it evolves, because they follow and, in at least three cases, actively participate in the standard development process. Therefore, compliance with the voluntary standard is part of an established business practice. ASTM F2167-15, the version of the voluntary standard upon which the staff-recommended mandatory standard is based, will be in effect by the time the mandatory standard becomes final and these firms are likely to be in compliance based on their history.

None of these firms typically includes more than four languages in their warnings (two firms use two languages; two firms use three languages; and one firm uses four languages). Based upon inspection of their products and the space available for the warnings, redesign should not be required for any of the bouncers supplied by the known small manufacturers. The firm using four languages might opt to redesign to give their product(s) a less cluttered appearance. However, discussions with a firm representative contacted by EC staff indicated that they were not concerned about the location of the warning labels.

Under section 14 of the CPSA, once the new infant bouncer seat requirements become effective, all manufacturers 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 C.F.R. part 1107) (“1107 rule”). Third party testing will include any physical and mechanical test requirements specified in the final infant bouncer seats rule. Manufacturers and importers should already be conducting required lead testing for bouncers. Third party testing costs are in addition to the direct costs of meeting the infant bouncer seats standard.

All infant bouncer seats sold by U.S. manufacturers are currently tested to verify compliance with the ASTM standard, though not necessarily via third party. Thus, the impact to testing costs will be limited to the difference between the cost of third party tests and the cost of current testing regimes. As a frame of reference, suppliers have estimated that testing to the ASTM voluntary standard typically costs about \$560-\$800 per model sample. Based on an examination of firm revenues from recent Dun & Bradstreet or ReferenceUSAGov reports, the impact of third party testing to ASTM F2167-15 is unlikely to be economically significant for most small manufacturers (*i.e.*, testing costs will be less than 1 percent of gross revenue). While it is unknown how many samples will be needed to meet the “high degree of assurance” criterion required in the 1107 rule, over 24 units per model would be required to make testing costs exceed one percent of gross revenue for the small manufacturer with the lowest gross revenue. One firm has a much larger number of infant bouncer models than the other small manufacturers, however, and its testing costs could exceed 1 percent of gross revenue if as few as seven units per model were required for testing. Note that this calculation assumes the rule would generate *additional* testing costs in the \$560-\$800 per model sample range. Given that all firms are conducting some testing already, this likely overestimates the impact of the rule with respect to testing costs. However, we do not know specifically how much the third party requirement adds to testing costs or precisely how many models are needed to meet the “high degree of assurance” criterion and cannot rule out a significant economic impact. We welcome comments regarding incremental costs due to third party testing (*i.e.*, how much does moving from a voluntary to a mandatory third party testing regime add to testing costs, in total and on a per test basis). In addition, staff would like comments regarding the accuracy of assuming that a “high degree of assurance” can be achieved with fewer than seven samples.

B. Small Importers

1. Small Importers with Compliant Infant Bouncer Seats

Five small importers of infant bouncer seats are currently in compliance with the voluntary standard and would likely continue compliance as new versions of the voluntary standard are published. The bouncers supplied by these firms would, for the most part, only require modifications to meet the warning label changes.

The placement of the new warnings could potentially require significant changes to existing models of imported bouncers. Imported bouncers tend to be produced to broadly meet the current requirements for several trading partners simultaneously, including the labeling requirements for multiple countries. Producers for international markets typically address labeling requirements for their various trading partners by simply providing a warning that covers all required safety

issues in multiple languages. However, the draft proposed rule's specificity regarding warning label location could make simple replication of the warning label in multiple languages impractical due to space constraints on the front surface of the back of the bouncer. While only the English-language warning would be required for products sold in the United States, this could mean that foreign producers will need to design a product for the U.S. market. One solution could be as straightforward as reducing the number of languages used for warnings on U.S.-bound bouncer seats. Regardless, having a differing product for the U.S. market could create logistical problems or costs, which could be passed on to importers.

We have no information regarding the degree to which foreign producers tend to pass on increases in regulatory costs to importers and are seeking comment on this topic. Because we lack information on the costs to importers associated with complying with the draft proposed rule, we are unable to rule out a significant impact for three of the five importers of compliant bouncers. We begin our discussion of potential impacts by assuming that, when possible, firms would prefer to develop a U.S.-specific product with fewer warning labels rather than exit the bouncer market or develop a bouncer with sufficient room to accommodate warnings in languages for both their U.S. and foreign markets. Developing such a bouncer would address the requirements in the draft proposed rule, while ensuring that the appearance of their bouncers remains comparable to their competition's products (for which one to three languages is typical). Staff requests feedback from the public, particularly from small importers, on the portion of regulatory compliance costs typically borne by importers, as well as information on the costs of developing a compliant bouncer for the U.S. market.

Staff believes that one importer would not likely experience a significant economic impact based on comparing redesign cost estimates provided by suppliers (around \$200,000 to \$300,000) to its annual revenue, even if its supplier passed on 100 percent of the costs of redesign. Staff requests feedback on the cost estimate for product redesign, as well as how that cost level might differ if the redesign focused exclusively on warning label changes and the logistical problems it might create. Based upon examination of this firm's revenues and the revenues associated with the sale of bouncers, this firm also could likely exit the market without experiencing a significant economic impact.

If product redesign costs \$200,000 and the supplying firm only passed on roughly 50 percent of the expected redesign costs, then two of the remaining four importers would not likely experience significant economic impact. Staff requests input on whether it is reasonable to assume, in the absence of alternative information, foreign suppliers will share up to 50 percent of the costs of redesign, as well as information supporting any alternative estimates of the relative portions of cost sharing that is typical for an importer and its supplying firm. If the supplying firm were unwilling or unable to limit cost pass through, then one of these firms could probably exit the market without significant economic impact as sales of bouncers are likely to contribute less than one percent to its overall revenue.

The fourth importer would likely only avoid significant economic impact if their supplier absorbed 100 percent of the cost of a redesign. Dropping bouncers from their product line could be an option. However, it is likely that the sales revenue generated by bouncer sales exceeds one percent of their overall revenue. This importer is an exclusive distributor for their supplier's

products in the U.S., so an alternative supplier is not an option. Staff requests information on the relationship between exclusive distributors and their suppliers, particularly as it pertains to willingness to shoulder redevelopment costs to maintain a U.S. market presence.

Neither annual revenue nor bouncer sales revenue was available for the final small importer of compliant bouncers; therefore, no assessment of impact could be made.

2. Small Importers with Noncompliant Infant Bouncer Seats

Two firms import bouncers that do not comply with the voluntary standard. The bouncers for these firms will require changes to come into compliance with the voluntary standard as well as modifications to meet the staff-recommended warning label requirements. Similar to the case of importers of compliant bouncers, the staff-recommended location of the warning labels on the front of the bouncer adjacent to the head could present a problem, since one firm typically uses nine languages while the other uses six. These importers may need to tailor a product for the U.S, which could be logistically difficult or costly, especially for a small firm with low sales volume.

The size of the economic impact on the two firms with noncompliant infant bouncer seats will depend upon the cost of the changes required and the degree to which their supplying firms pass on any increases in production costs associated with changes in the product needed to meet the mandatory standard. Again, we do not have any information on the proportion of compliance costs passed on and are seeking public comment on this topic. It is possible that these two importers could discontinue the sale of infant bouncer seats altogether, as the product does not appear to represent a substantial portion of either firms' product lines. However, one of the two firms would likely only avoid a significant economic impact if their supplier absorbed 100 percent of the cost of a redesign and it seems likely that their bouncer sales might exceed 1 percent of their annual sales revenue as well. Again, we do not have specific information on bouncer sales revenues, and cannot rule out a significant economic impact for either firm.

Both of the small importers with noncompliant bouncers are directly tied to their foreign suppliers and finding an alternate supply source would not be a viable alternative for these firms. However, given this close relationship, it seems likely that the foreign suppliers would have an incentive to work with their U.S. subsidiaries to maintain an American market presence. Staff is interested in information regarding the relationship between foreign producers and their U.S. subsidiaries and whether such relationships decrease the likelihood that the subsidiary experiences a significant economic impact due to a rule.

3. Third Party Testing Costs for Small Importers

As with manufacturers, all 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. The majority of bouncer importers are already testing their products to verify compliance with the ASTM standard, and any costs would be limited to the incremental costs associated with third party testing over the current testing regime.

We were able to obtain revenue data for one of the small importers with noncompliant bouncers. For that importer, third party testing costs, considered alone and apart from any additional performance requirements due to the draft proposed rule, would not exceed one percent of gross revenue unless around 12 units per model required testing to provide a “high degree of assurance.” While staff believes that it is unlikely that any importer would need to test more than 12 samples, we are seeking information regarding the validity of that assumption. We had no basis for examining the size of the impact for the remaining importer of noncompliant bouncers.

It is important to note that our analysis of the impact of the draft proposed rule have evaluated the impacts of complying with performance requirements and third party testing requirements independently. Firms will, in fact, experience the costs jointly. It is possible for testing costs, when evaluated independently, to not create significant economic impact (and vice versa). Staff is seeking information on the extent to which performance requirements and testing costs evaluated jointly generate significant economic impact even when each component evaluated independently is not expected to lead to significant impact.

C. Summary of Impacts

CPSC staff is aware of 12 small firms, five domestic manufacturers and seven domestic importers, currently marketing infant bouncer seats in the United States. Of the five manufacturing firms, EC staff does not believe that any should experience a significant economic impact due to the requirements of draft proposed rule. One manufacturer could be significantly impacted by the third party testing and certification requirements under the 1107 rule, which are triggered once the new infant bouncer seat requirements become effective. Of the seven small importers, two appear to have the option of exiting the bouncer market altogether and should not experience a significant economic impact even if they choose to do so. Based upon current information, we cannot judge how any of the remaining five importers will need to adjust their products to comply with the draft proposed rule and cannot quantify or otherwise estimate the size of the impact. Therefore, we cannot rule out a significant economic impact for six of the 12 firms (50 percent) operating in the U.S. market for bouncers. We ask for public comment on the questions posed above to better assess whether these firms will experience a significant impact due to the draft proposed rule.

VIII. Alternatives

Three alternatives are available to the Commission that may minimize significant economic impact on small entities: (1) adopt ASTM F2167-15 with no modifications;⁶⁶ (2) adopt ASTM F2167-15 with the staff-recommended modifications, except for the warning label location specificity; and (3) allow a later effective date.

⁶⁶ As discussed in the briefing memo, adopting the voluntary standard with no modifications is an option if the Commission determines that a more stringent standard would not further reduce the risk of injury associated with infant bouncers.

Section 104 of the CPSIA requires that the Commission promulgate a standard that is either substantially the same as the voluntary standard or more stringent. Therefore, adopting ASTM F2167-15 with no modifications is the least stringent rule allowed by law. This alternative would reduce the impact on all of the known small businesses supplying infant bouncers to the U.S. market. If it were adopted, it should eliminate any economic impact related directly to complying with the staff-recommended proposed rule for all five of the known small domestic manufacturers and the five small importers with compliant infant bouncers, all of whom are expected to comply with ASTM F2167-15 by the time the final rule becomes effective. Firms with compliant products, however, would continue to be affected by third party testing requirements.

Alternatively, the Commission could adopt a more stringent proposed rule that is still less stringent than the staff-recommended proposed rule by adopting ASTM F2167-15 with the staff-recommended modifications, except for the requirement that the warning labels on the product be located next to the occupant's head. With the exception of impacts due to third party testing, this would eliminate most of the impact on small manufacturers (all of which sell compliant bouncer seats), leaving them with only minor costs associated with changing the wording and format of their warning labels. The impact on the five small importers of compliant bouncers would be similarly reduced.

Finally, the Commission could reduce the staff-recommended proposed rule's impact on small businesses by setting a later effective date. A later effective date would reduce the economic impact on firms in two ways. One, firms would be less likely to experience a lapse in production/importation, which could result if they are unable to comply and third party test within the required timeframe. Two, firms could spread costs over a longer time period, thereby reducing their annual costs, as well as the present value of their total costs. Staff specifically requests comments on the 6 month effective date, as well as feedback on how firms (particularly small importers) would likely address the proposed rule.

IX. 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 C.F.R. part 1112. Consequently, staff recommends that the Commission propose an amendment to 16 C.F.R. part 1112 that would establish the NOR for those testing laboratories that want to test for compliance with the bouncers final rule. 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 bouncer standard will not have a significant adverse impact on small laboratories. Moreover, based upon the number of laboratories in the U.S. 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 bouncer seat 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 bouncer 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. As a consequence, the Commission could certify that the NOR for the infant bouncer seat standard will not have a significant impact on a substantial number of small entities.