April 18, 2016

Office of the Secretary
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

Re: CPSC Docket No. CPSC-2012-0034/ Agency Information Collection Activities: JPMA Comments : Crib Bumpers

Dear Mr. Stevenson:

The Juvenile Products Manufacturer's Association ("JPMA") appreciates the opportunity to comment on the Consumer Product Safety Commission's ("CPSC") February 16, 2016 Federal Register request, "Agency Information Collection Activities; Proposals, Submissions, and Approvals: Crib Bumpers" (CPSC Docket No. CPSC-2012-0034).

The Juvenile Products Manufacturers Association (JPMA) is a North American not-for-profit trade organization representing 95% of the prenatal industry including the producers, importers, and distributors of a broad range of childcare articles that provide protection to infants and assistance to their caregivers. JPMA appreciates the collaborative nature that our Association continues to have with CPSC on improving the safety of juvenile products.

JPMA hopes that these comments will assist the Commission in its understanding of the crib bumper industry as a whole, the safety protocols that are in place in the manufacturing of the product, and the willingness of manufacturers to collaboratively work together to address any potential hazards as demonstrated through enhanced standards at ASTM.

In response to the CPSC's question, JPMA submits the following responses:

What test data or other information is available to identify the specific features or characteristics of a crib bumper that might contribute to a risk of suffocation?

In an ongoing effort to create the safest products, safety experts, representatives of CPSC, Health Canada , consumer groups, retailers and manufacturers working within the confines and subject to the requirements of consensus under ASTM requirements for development of standards enacted ASTM F 1917-12, Infant Bedding and Related Accessories, which was published on August 9, 2012 ("ASTM"). Enhancements to the standard applicable to bumpers can be viewed in the following sections, among others:

Bumper Tie Strength Test Method (Section 6.3 & 7.4): Establishes a test method to ensure bumper pad ties do not detach from the bumper pad. A tensile force of 20 lbs is applied to the bumper pad tie(s). The force is applied evenly within 5 seconds and maintained for an additional 10 seconds.

Enhanced Bumper Pad Warnings (Section 8.2.1): Establishes revised warnings which read, "To reduce the risk of suffocation, keep top of bumper up and in position. DO NOT allow bumper to sag down or in toward the sleeping surface. DO NOT use bumper if sagging cannot be corrected. To prevent entanglement or strangulation, position ties to outside of crib and be sure they are secure. Remove bumper when child can sit up unaided or can pull to a standing position."

Bumper Thickness Standard (Section 6.2 & 7.3 & FIG. 1): Establishes a test fixture through which each bumper segment must pass through. The bumper end is inserted into the fixture with a 5 lb static weight attached to the protruding end. The bumper is positioned vertically, and the technician allows the weight to slowly draw the bumper through the opening. The bumper must slide through the fixture over its entire length. In recent months, this Subcommittee continues to evolve the standard to modify language to ensure all bumper segments have labels, and that there is permanency to the labels within the standard.

The ASTM Standard requirements applicable to bumpers was developed with consideration of testing airflow and hazard data available to the subcommittee. When adopted it was adopted without opposition from CPSC or any NGO participants.

What objective, repeatable test methods, procedures or measures exist to assess the firmness of bedding, mattresses, and other possible sleep surfaces? To what extent, if any, can such tests, procedures or measures be used to assess whether these materials present a risk of suffocation by smothering?

Crib bumpers have a long history of usage over decades and are typically comprised of fabric panels that contain some form of padding with ties or straps to attach them to the crib. Generally, they are intended to line the lower, inside portion of an infant's crib along the rails. Padding thickness, material composition, and the number of component pieces varied, but the widely adhered to current ASTM Standard has been effective at reducing such variability and reasonably reducing suffocation hazards.

As regards inquiry related to global marketplace testing, please note that the Australian Standard for Sleep Surfaces: Test for Firmness seems to provide a test method to help minimize the risk of infant asphyxiation by identifying sleep surfaces that exhibit less than a specified firmness providing a horizontal plane intended to support an infant. These involve horizontal planes with the full weight of the child directed downward.

Additionally, Intertek currently has two tests that it can perform to measure suffocation and CO2 re-breathing. These tests are not required for any product and to our knowledge are proprietary to Intertek only. These tests measure the product(s) compared to the potential of comparator products of known hazard level. The test was developed closely with Dr. William W. Fox, Division of Neonatology, Children's Hospital of Philadelphia as well as Dr. Thomas H. Shaffer, Director of Respiratory Physiology and Pediatrics, Alfred I DuPont Institute in an effort to design a physical model and develop a test methodology to quantitatively assess the potential suffocation hazards posed by various types of materials and consumer products.

To what extent does the test device specified in Australian/New Zealand Standard AS/NZS 8811.1:2013, Methods of Testing Infant Products, Method 1: Sleep Surfaces—Test for Firmness, [(2)] accurately and reliably assess the potential risk of suffocation associated with a sleep surface?

It can screen out excessively soft horizontal surfaces intended as support to an infant in a horizontal plane.

To what extent would a test to accurately and reliably identify hazardous soft bedding or sleep surfaces be relevant to vertically-mounted surfaces, such as crib bumpers?

As previously referenced, Intertek has developed a test to determine the potential of a bumper to cause a suffocation injury or fatality throughout its foreseeable use. Suffocation Assessments are typically performed in the worst case scenario, which was determined to be an infant with their face against the products. The test methodology uses an anatomically representative mannequin of approximately 1 month due to the representation of being the most at risk age group. In addition no hazard data supports the existence of an increased suffocation risk so as to constitute a substantial hazard as that term is defined under CPSA or otherwise indicates that vertical bumper padding that meets current ASTM specifications present such hazard.

The 1998 Mechanical Model Testing of Rebreathing Potential in Infant Bedding Material by Carleton, Donoghue, and Porter looks at rebreathing in the prone position. Bumpers were not cited in any of the 29 death reenactments. Additionally, Intertek tests for poly-filled bumpers show significantly lower than high hazard comparators and an extremely low level of hazard for the creation of a hazardous condition for carbon dioxide rebreathing.

What safety benefits do crib bumpers offer to consumers? What data are available to demonstrate such benefits?

In 2011, JPMA commissioned a third party review of previous studies of crib bumper pads by Exponent Failure Analysis, a leading engineering and scientific consulting firm providing

solutions to complex technical issues.[1] Based on such finding and the paucity of hazard data demonstrating that such ASTM compliant products present an increased risk of suffocation, as further discussed below, claims of increased risk to infants from traditional crib bumpers meeting the ASTM requirements were and continue to be unfounded. The data and studies reviewed led Exponent to note methodological problems that were apparent in the criteria previously cited to impugn such products and demonstrated that such data did not establish such hazards. The available data and published scientific studies disclosed no primary proximate causation between use of traditional ASTM compliant crib bumper pads and an increased risk of infant fatality. Finally, according to the Consumer Product Safety Commission (CPSC) the greatest risk is to an infant sleeping in a prone position or in a crowded sleep environment that includes pillows, cushions and adult bedding. Such data has already been submitted as part of the record in relation to JPMA's accepted Petition for Rulemaking. The CPSC has indicated that in its review so far they have found no direct primary causal connection between such traditional crib bumpers and infant fatality. JPMA submitted a FOIA request to the CPSC requesting any incidents where ASTM compliant bumpers were determined to have caused suffocation fatalities to any child. No such information has been provided in response. A survey of JPMA membership, whose companies have been in business anywhere between 1-3 years to more than 35 years, found there was not a single such incident reported, regardless of numbers sold. Based on the foregoing it is reasonable to assume that none exists or it would have been disclosed as required by law.

When used according to manufacturer's instructions, properly designed crib bumper pads can help prevent limb entrapment and head injuries. Reporting on CPSC's www.saferproducts.gov website indicate that limb entrapment, lacerations and contusions continue to be the most widely reported risk of injury with crib side rails and headboards which must meet CPSC imposed mandatory spacing requirements. Baby cribs are a federally regulated children's product with the advent of crib regulations in the 1970s, which resulted in requirements for aspects of crib performance and construction, including slat spacing and mattress fit as a means to increase safety.[2]The most recent updates to federal safety standards took effect June 28, 2011, and include the ban of traditional drop-side cribs, more durable mattress supports and crib slats, improved hardware ban of drop-side cribs due to reported failures with the drop rail, which created openings in the crib and were associated with infant entrapments.[3] Infants have been reported to have become wedged or entrapped between the crib mattress and a partially detached drop side. Between 2005 and 2010, CPSC announced recalls involving greater than 7 million drop-side

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[1] Exponent Report, dated September 16, 2011

[2] Tinsworth & McDonald, 2002

[3] CFR 75(248); CPSC 10-225

cribs. In some CPSC-reviewed fatalities,drop-side rails or the hardware for the drop side were installed incorrectly, despite the appearance of the rail functioning as intended.[4]

Crib bumpers have demonstrably reduced such injuries over many years. Product innovation will continue to result in a wide variety of traditional and alternative bumpers and crib rail liners on retail shelves. Parents should have a choice in determining the protection level they want to provide in their baby's cribs.

What, if any, evidence is there to indicate that "rebreathing" of carbon dioxide occurs with crib bumpers and presents a risk of suffocation?

Sleep safety has had a recurrent national education outreach over the past 20 years, is known to manufacturers, and has had a presence in the medical and parenting community. There is a long history of awareness of the hazards associated with higher likelihood of Sudden Infant Death Syndrome (SIDS), accidental suffocation, and/or strangulation during infant sleep. Among the hazards include prone sleep position; bed sharing; placing an infant in an adult bed; placing soft primarily adult bedding materials, including pillows, into cribs with babies; and infant exposure to smoke.[5] The Consumer Product Safety Commission (CPSC) began work in 1994 to identify consumer products, product characteristics, and factors that may contribute to the suffocation of infants; and, in fact, pillows were highlighted in that study. National news releases by the CPSC were launched to report this information in February 1995 and again in April 1996, which included highlighting the fact that up to 30% of 6,000 babies whose deaths are attributed to SIDS may have suffocated to death when placed on top of items, such as pillows and comforters.[6] In 1992, the American Academy of Pediatrics (AAP) recommended that infants only sleep in a non-prone position as a strategy for reducing SIDS rates. The Back to Sleep Campaign, which was initiated by the AAP in 1994 and supported by a variety of governmental agencies and JPMA, also promoted supine sleeping positions and provided additional recommendations shown to reduce SIDS, which include the elimination of soft objects from the crib, infant exposure to smoking, and bed sharing/co-sleeping, among other things. A more recent national campaign was launched by CPSC and Child Safety Partners in 2010 and included the release of a crib safety video entitled, "Safe Sleep for Babies," and addressed suffocation risks in the sleep environment.[7] Smoking pre- or postnatally results in a significant increase in SIDs risk.[8]

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[4] CPSC 10-225

[5] CPSC Release #95-073; CDC Tobacco Use and Pregnancy; CPSC 11-021; CPSC 96-096; CPSC 02153; First Candle, Frequently Asked Questions on SIDS/SUID.

[6] Scheers, 1995; CPSC 95-073; CPSC 96-096; CPSC 11-0

[7] CPSC 11-021, A Safe Sleep for All Babies; CPSC and Child Safety Partners Launch National Education Campaign on Crib Safety for New and Expectant Parents

[8] e.g., Murkoff et al., 2003; MacDorman et al., 1997

In 2007, Thach et al. raised concerns as to the safety and appropriateness of crib bumper pads as part of an infant sleep environment.[9] In 2008, based on these findings, an article in AAP News commented on the Thach et al paper and reported that parents should keep pillows, including crib bumpers, out of their baby's sleeping area.[10] In 2010, formal investigations into the safety of the infant sleeping environment by the CPSC did not identify bumper pads as a hazardous product or as a significant source of serious injury or death to sleeping infants.[11] Yeh et al., 2011 assert that "the use of crib bumper pads is strongly discouraged because the possibility for serious injury, including suffocation and strangulation," but offered no independent analysis of infant fatalities associated with crib bumpers and relied on Thach et al., 2007.[12]

In 2011, Exponent critiqued the findings of Thach et al. 2007, and presented findings to JPMA and ASTM International. Reanalysis of the same data analyzed by Thach et al. revealed that the Thach and coauthors did not have sufficient evidence to support their conclusions. Exponent issued a report in September 2011, and concluded that based on the available data, the vast majority of incidents were either unrelated to the issues raised by Thach et al., 2007 or contain at least one other factor that could account for the cited fatalities.[13] It turned out that none of the cited studies involved crib bumpers and no attempt was made to apply such research to crib bumpers. These studies did not account for child interaction with the crib bumpers and did not address the effect of any wedging mechanism. In October 2011, an AAP policy statement stated that bumper pads were not recommended because there was potential for suffocation, entrapment, and strangulation, while citing the work of Thach et al., 2007 and Yeh et al., 2011.[14] In May 2013, CPSC staff released a briefing package that discussed their review of all incidents received by CPSC that include mention of a crib bumper and concluded that there was *"no conclusive or persuasive evidence implicating crib bumper pads as the primary cause of death, when the bumpers were used properly in an appropriate infant sleep setting."*[15]More recently, Scheers et al., 2016 performed work similar to Thach et al., 2007 and reviewed bumper-related deaths from the same data reviewed by the CPSC. Remarkably using similar flawed methodology and innuendo, the authors alleged that "most of the deaths were caused by the

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[9] Thach et al., 2007

[10]Bond, 2008

[11]Wanna-Nakamura, 2010

[12] Yeh et al., 2011

[13] FN1.

[14]Moon et al., 2011

[15]CPSC Briefing Package, pp. 15, 43

bumper pads"[16] The flawed analyses of Thach et al., 2007 and Scheers et al., 2016 are the only studies that allege crib bumpers are a potential hazard and the with the data cited the most recent publication fails to distinguish between crib bumpers that meet the ASTM requirements and those that do not.

Crib Bumper CPSC Database Analysis

CPSC database review (INDP, IPII, DTHS, and NEISS) from January 1, 1985 through December 31, 2012, involved an independent analysis of incidents involving crib bumpers, and identified 71 infant deaths, which are reported in the CPSC Staff Briefing Package, dated May 15, 2013. When available, even a cursory review of the In-Depth Investigation reports (IDIs) indicates that numerous incidents evidenced the previously known sleep environment hazards *causally unrelated to bumpers*: including but not limited to the presence of the other items in the crib, pre-existing medical condition of the child,the child being placed to sleep in a prone position, the child being placed to sleep within other child products in the crib, environmental factors, and the use of plastic bumpers (which are no longer manufactured or sold). Consistent with the Exponent analysis of 2011, these incidents involve multiple potential contributing factors unrelated to the crib bumper. This analysis does not reveal any scientific evidence of a causal link between crib bumpers and fatalities. The mere coincidence of a crib bumper present at the time of an incident is not evidence that it substantially contributed to the infant's death. Almost all of these incidents with detailed information available documented other previously identified asphyxia hazards in the sleeping environment that are unrelated to a crib bumper. In a consistent manner, the CPSC concluded that there was *"no conclusive or persuasive evidence implicating crib bumper pads as the primary cause of death, when the bumpers were used properly in an appropriate infant sleep setting."*[17]

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[16] Scheers et al., 2016; A further analysis of cited incidents indicates that most involved other products, preexisting medical conditions, prone sleeping and no indication of ASTM compliant bumpers causing fatalities.

[17] Ibid.CPSC Briefing Package, Ibid.

The current U.S. voluntary standard covering crib bumpers is ASTM F1917-12, Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories ("ASTM F1917-12"). [3] Are there other standards, aside from state or regional bans, that include performance requirements for crib bumpers?

JPMA is not aware of any other standards.

F1917-12 includes a requirement that essentially limits the compressed thickness of crib bumpers to 2 inches. What evidence exists to support this requirement, and what, if any, association exists between this ASTM requirement and the risk of infant suffocation?

The rationale was to define a non-pillow-like bumper, something that the CPSC and others referred to but was never defined. For all the foregoing cited reasons, research, testing and paucity of data indicating a proximate causal connection between ASTM compliant bumper pads, evidence suggests that the ASTM Standard requirements have been effective.

What alternative or additional requirements beyond those specified in ASTM F1917-12 might address the risk of infant suffocation?

As recently noted, the ASTM subcommittee is not aware of any additional requirements that would address the risk of suffocation or they would have likely been incorporated into the standard.

Are incident data or other objective safety information or research available that describe potential hazards associated with mesh-like bumpers or liners? Are similar data or information available on so-called "vertical bumpers," which essentially are a series of small bumpers that individually cover each crib slat, and other bumper alternatives?

JPMA is not aware of any incident data with such products or compliant ASTM products that otherwise establish any proximate causation of a substantial hazard caused by use of such products. Indeed given cited crib related injuries it is reasonably likely that such products reduce the likelihood of injuries involving limb entrapment, contusions and lacerations to the head and other parts of an infant's body.

Thank you for the opportunity to provide our comments. Please do not hesitate to contact me or JPMA staff for any further assistance.

Sincerely,

Rick Locker

Locker Greenberg & Brainin, LLP
General Counsel, JPMA