May 9, 2011

Michele Phinney
Director
Office of Regulation and Policy Coordination
Department of Health and Mental Hygiene
201 W. Preston St.
Room 512
Baltimore, MD 21201

RE: Request for Comment on Use of Bumper Pads in Infant Cribs

Dear Ms. Phinney:

The Juvenile Products Manufacturers Association (JPMA - www.jpma.org) is a national trade organization representing 95% of the prenatal to preschool industry. JPMA represents approximately 250 companies in the United States, Canada, and Mexico who manufacture, import and/or distribute infant products such as cribs, car seats, strollers, bedding, and a wide range of accessories and decorative items. JPMA has been recognized as an organization dedicated to enhancing children's product safety. JPMA's extensive history of leadership in juvenile product safety includes the development of a comprehensive Certification Program to help guide parents and caregivers toward purchasing juvenile products that are built with safety in mind. JPMA continues to work with government officials, consumer groups, and industry leaders on programs to educate consumers on the safe selection and use of juvenile products. *Safe & Sound for Baby* and Baby Safety Month are only a few of the programs JPMA sponsors to keep today's safety conscious parents informed.

We appreciate the opportunity to comment on the April 12, 2011, Maryland Register Notice regarding the request for comment on use of bumper pads in infant cribs. In response to this request, the Juvenile Products Manufacturers Association, Inc. ("JPMA") submits the following comments. JPMA hopes that these comments will assist the Secretary of Health & Mental Hygiene in effectively implementing regulations in a consistent manner based on sound research principles and scientific data.

Crib Bumper Pads Benefits and Suspected Risks
In an effort to address conflicting information on the safety of crib bumper pads, the Juvenile Products Manufacturers Association (JPMA) commissioned an independent analysis of recent studies to evaluate the evidence linking crib bumper pads and infant safety. In 2010, Innovative Science Solutions (ISS) completed a thorough review of published scientific studies evaluating the use of crib bumper pads, and has

concluded there is currently no evidence supporting a causal relationship between crib bumper pad use and infant death. The complete review is due to be published in a peer-reviewed medical journal in the near future.

JPMA felt it was important to have the Innovative Science Solutions study reviewed by an additional research firm to provide further data analysis. JPMA commissioned an additional independent research study, conducted by third party research firm Exponent Failure Analysis Associates. Exponent is currently drafting an output report of their findings, some of which are outlined in this letter. Upon completion we will share this report with you.

Exponent concluded that formal investigations into the safety of the infant sleeping environment by the Consumer Product Safety Commission (CPSC) have not identified bumper pads as a hazardous product or as a significant source of serious injury or death to sleeping infants (Wanna-Nakamura, 2010). Additionally, Exponent concluded that the recent review by Innovative Science Solutions of epidemiological data and published scientific studies did not reveal any affirmative evidence of a causal link between crib bumpers and infant mortality.

In an earlier article, however, *Deaths and Injuries Attributed to Crib Bumper Pads* (Thach et al., 2007), the authors raised concerns as to the safety and appropriateness of crib bumper pads as part of an infant sleep environment. Thach et al. has often been cited as scientific evidence that crib bumpers pose a serious risk of fatality to sleeping infants. For example, a team of researchers (Yeh, et al., 2011) publishing on injuries associated with cribs offered no independent analysis of infant fatalities associated with crib bumpers, nor did they present a specific analysis related to the potential for crib bumpers to mitigate injuries, yet suggested "the use of crib bumper pads is strongly discouraged because the possibility for serious injury, including suffocation and strangulation, greatly outweighs any minor injury they may prevent."

The conclusions of Thach et al. about the suffocation hazards posed by crib bumper pads remain in contrast to the scientific findings of others. Re-analyses of the Thach et al. data is ongoing, and preliminary examination of currently available portions of their data set has raised concerns about the validity of their findings. For example, methodological problems are apparent in the criteria used to select the incidents included for analysis and in the analytical treatment of other potential contributors. In Exponent's re-analysis of the Thach data, they found that 33% of the records included an unrelated product or accident mode, 50% of the records had other confounding factors such as additional items in the crib, and there was too little information to evaluate the additional 17% of incidents. A request has been submitted to CPSC to provide more detailed incident reports to evaluate the 17% of incidents with limited information.

Furthermore, an attempt to recreate the "injury analysis" presented by Thach et al. highlighted similar methodological and analytical concerns. Dr. Thatch has himself admitted that he did not retain data and that there might not be a causal connection. A more thorough review of the injuries that occur to infant children within the crib demonstrates that crib bumpers could serve to mitigate the injury potential (e.g.,

lacerations, fractures) across a variety of the common accident modes (e.g., contact with railings, extremities caught between railings).

Indeed, the vast majority of complaints filed about cribs on the CPSC's recently launched www.safer products.gov web site involve limb entrapment due to narrow spacing of crib spindles and slats as mandated by CPSC regulations. Traditional bumpers add protection without any increased risk to supine sleeping infants.

Of the 3,520 incident reports between November 1, 2007 and April 11, 2010 involving full-size (and undetermined size) cribs, 1,675 reported a crib-related injury. Almost half involved falls, but most of the remaining injuries resulted from children getting their limbs caught between crib slats, falling inside the crib and hitting the crib structure, or getting stuck in gaps created by structural failures. Infants getting their limbs caught between the crib slats alone accounted for approximately 12 percent of the incidents.[1]

Standards Development, Warnings and Labeling and Education Campaigns

ASTM International implemented a Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories in 1995. This standard includes test methods for ribbons, strings and ties and vinyl thickness for bumper pads including a requirement to address the length of bumper ties. A performance requirement for bumper tie strength was approved in April 2011 and will be published in the standard in the coming months.

The ASTM standard also includes warning labels to ensure the bumpers are installed correctly, and removed at the proper time. Regulatory agencies such as the CPSC, as well as organizations dedicated to the health, safety and well-being of infants such as the American Academy of Pediatrics, have identified that a crowded sleep area that includes extra bedding, pillows or comforters or being placed to sleep in a prone position are unsafe sleep practices and present hazards associated with the sleeping environment. Such unnecessary or inappropriate items in cribs represent a much greater threat in infants' sleep environments. The reported injuries and fatalities previously attributed to the use of crib bumpers may have actually been caused by these nonessential, primarily adult bedding, items in cribs.

According to a White Paper written by Suad Wanna-Nakamura, Ph.D. in 2010, CPSC staff has reports of 531 infant deaths associated with pillows or cushions from January 1992 through May 2008; an average of about 35 deaths per year of infants under one year of age (Wanna-Nakamura, 2008). In the vast majority of the deaths, the infants were placed to sleep in the prone position. Half the incidents involved infants placed to sleep on top of a pillow or cushion. Dr. Wanna-Nakamura summarized that it is possible that caregivers placed these products under the baby to make the surface softer and more comfortable for the baby. The other half of the incidents were deaths due to suffocation and positional asphyxia in a crowded sleeping setting where pillows, other bedding material, and clutter were found. Again Dr. Wanna-Nakamura summarized that caregivers, who place their infants to sleep in a prone position that exacerbates the infant's risk of suffocation, are also using pillows and

[1] *www.cpsc.gov/library/foia/foia10/brief/104cribs.pdf.*

other unsafe sleep arrangements. In addition the data reviewed did not adequately and separately consider data that demonstrates the beneficial impact of the implementation of "Back To Sleep" recommendations that have been implemented in the past decade.

To help educate parents on maintaining a proper sleep environment, many bumper manufacturers and retailers enclose the JPMA Naptime to Nightime brochure in their product packaging. This brochure includes tips for creating a safe sleep environment and can be found on the JPMA web site as well. (http://www.jpma.org/sites/default/files/JPMA-11-Naptime-Nightime-FINAL_0.pdf) These tips can also be found on JPMA's web site dedicated to safe sleep, www.cribsafety.org. These resources were developed to educate parents on creating a safe sleep environment. *Naptime to Nightime* was implemented in the 1990's and cribsafety.org was launched in 2010 as part of JPMA's *Make Every Night a Safe Night* campaign.

JPMA has long endorsed the message that when using bumper pads avoid those that are "pillow-like." Bumper pads must fit properly in the crib and tie or snap securely into place. Bumper ties must not exceed nine inches and the bumper pad should be secured along the sides of the crib.

Consumer Product Safety Commission

In a speech to JPMA members in March, CPSC Chairman Inez Tenenbaum stated that in the CPSC's review of the issue *"…so far there is no evidence of a causal connection between crib bumpers and suffocation, when the product is used as intended"* This is consistent with the findings of the JPMA commissioned study. JPMA encourages the Department of Health and Mental Hygiene to point to the same message in discussions with the CPSC and other organizations dedicated to this issue.

Continued Education

JPMA encourages all parties to provide education to consumers on creating a safe sleep environment. The use of adult bedding in the crib is a known factor in suffocation deaths, and though many organizations including JPMA, CPSC and AAP provide education to parents and caregivers, the incident data demonstrates that continued efforts are required to educate parents on a safe sleep environment.

Education to the residents of the State of Maryland should include the following, along with all other tips indicated on the *Naptime to Nightime* brochure:

- To reduce the risk of SIDS, pediatricians recommend healthy infants be placed on their backs to sleep, unless otherwise advised by your physician.

- Only a tight fitted sheet, mattress pad and/or waterproof pad should be used under the baby.

- When using bumper pads avoid those that are pillow-like. Bumper pads must fit properly in your crib and tie or snap securely into place. Bumper ties MUST NOT exceed nine inches. Make sure the bumper pad can be secured along the sides of the crib.

- Use bumper pads only until the child can pull up to a standing position. Then remove them so baby cannot use the pads to climb out of the crib.

- Many bumpers are now sold in four pieces. For each bumper segment, if all ties on that segment cannot be securely attached to the crib DO NOT USE the bumper segment.

- Remove pillows, sheepskins, pillow-like stuffed toys and products not intended as infant bedding from the crib when infants are sleeping. NEVER place additional padding under an infant.

In conclusion, if the state of Maryland determines that it is appropriate to provide input to the CPSC on the safety of these products, the Department of Health & Mental Hygiene should endorse the concept of following a scientific approach to information acquisition and analysis. The state should also refrain from warning specifically about bumpers since analysis by third parties and the CPSC has shown there to be no evidence of a causal connection between crib bumpers and suffocation. The state instead should focus on educating consumers about creation and maintenance of a safe sleep environment.

Based upon the foregoing it is clear that traditional crib bumper pads do not pose a substantial risk to infants; there remains consumer interest in using them particularly to avoid limb entrapment, lacerations, contusions and other injuries cited by CPSC analysis of crib related injuries; compliance with ASTM bedding standards should be widely encouraged and traditional bumper pads cannot be deemed a "hazardous material," under existing Maryland statutory authority, based upon the current record before the state.

JPMA remains fully supportive of safe sleep education. JPMA hopes that these comments will assist the Secretary of Health & Mental Hygiene in effectively implementing regulations in a consistent manner based on sound research principles and scientific data. We expect that your own review will distinguish between risks attributable to prone sleeping on adult bedding or pillow-like products as opposed to reduced risks associated with back sleeping with traditional baby bedding products.

Sincerely,

Michael Dwyer, CAE
Executive Director

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