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STATEMENT OF COMMISSIONER ELLIOT F. KAYE REGARDING RELEASE OF POLICY PAPER ON HAZARDS OF PADDED CRIB BUMPERS

May 17, 2017

As I said last year, clutter in America's cribs is a serious public health issue. Dozens of infants and children die each year from soft bedding in their sleeping environments.[1] I continue to believe these deaths are addressable in many cases.

Toward that end, I am pleased to announce today that I am releasing a paper authored by my Senior Science and Policy Advisor, Dr. Jonathan Midgett, making recommendations on possible performance standards to address the very serious hazards associated with padded crib bumpers. The paper, which is attached, provides a review of the hazard patterns associated with the use of padded crib bumpers, the limited utility of padded crib bumpers and the characteristics of crib bumpers that could render them hazardous.

I reiterate my belief that the public should stop using padded crib bumpers. The overwhelming evidence shows that they do nothing more than contribute to the deadly clutter in many of our nation's cribs. Based on the real risk they present, it is a mystery to me why they continue to be made and sold.

The best practice for a safe sleep environment for children is a properly assembled crib with only an appropriately sized mattress and a tightly fitted sheet. Parents and caregivers should *never* place soft bedding or other padded objects such as padded bumpers, pillows, sleep positioners, stuffed animals, or cushions in a child's crib, bassinet or play yard. When it comes to any child's sleep environment, bare really is best.[2]

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[1] *See* Staff Briefing Package on CPSC Staff Response to the Record of Commission Action on Crib Bumpers (September 9, 2016), Tab E, at 28.

[2] For more information on safe sleep practices or to learn more about common household dangers to children from consumer products, please visit www.cpsc.gov.

Cluttered Cribs and Infant Safety:
Policy Implications of Selling and Using Padded Crib Bumpers and Messaging about Safe Sleep Environments for Babies

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[Addendum: April 2017]

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This paper has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission or CPSC staff.

Executive Summary

The best evidence-based advice for creating a safe sleep environment for newborns recommends a bare crib or bassinet that is free from all cushioned or padded pillow-like objects—Bare is best.

Crib bumper pads have been banned in a few regions of the U.S. In response to this fractured market, the Juvenile Product Manufacturer's Association (JPMA) petitioned the U.S. Consumer Product Safety Commission (CPSC) in 2012 to initiate rulemaking to distinguish "hazardous pillow-like" crib bumpers from "non-hazardous traditional" crib bumpers. In 2016, CPSC staff reported its review of incidents associated with crib bumper pads with the goal of categorizing the incidents that were "likely to be addressable" and those that were "not likely to be addressable" by a rule. In order to help the Commission further evaluate the remaining open policy decisions to potentially prevent suffocation, wedging, entrapment or falls associated with padded crib bumper use, this paper describes the following six additional hazard scenarios related to the use of crib bumpers:

- Bumpers limiting space on the mattress surface inside of a crib
- Bumpers covering key failure points on cribs
- Difficulties installing crib bumpers
- Using a bumper with children who are past the recommended age
- Using a bumper outside of a crib
- Communicating mixed messages about padded objects in a crib

Including these hazard scenarios in the incident analysis meaningfully increases the estimated number of addressable incidents. This white paper concludes with recommendations for creating performance requirements for crib bumpers that would either eliminate padding that conforms to the face or ensure sufficient airflow characteristics to protect newborns.

Purpose

For years, the U.S. Consumer Product Safety Commission (CPSC) has warned consumers against the hazards associated with cluttered cribs, and for good reason. CPSC staff reports, for instance, that clutter, in the form of pillows under or near a sleeping infant, has been shown to be involved in 690 deaths from 1992-2010. Uncluttering infant sleep environments is a real public health challenge in American homes. The agency has implored caregivers to remove all items, including blankets, pillows, soft bedding and stuffed animals from cribs as they are unnecessary and create a suffocation hazard. However, the Commission has not provided a clear message about whether crib bumper pads should be used.

This paper explains the facts relating to CPSC staff reviews of incidents associated with crib bumpers, the hazard patterns associated with the use of crib bumpers, the utility of crib bumpers, and the characteristics of bumpers that could render them hazardous. Recommendations for performance requirements to address hazardous "pillow-like" bumpers are also presented.

Background

The Product

Crib bumpers were invented to prevent children from falling out of a crib between widely spaced crib slats in the years prior to a mandatory crib slat spacing requirement. Now that the spaces between crib slats are required to be narrower, bumpers primarily serve as decorations. Bumpers may be sold as a part of a bedding set that includes other decorative items, such as quilts, dust ruffles, wall hangings and sheets. Sometimes consumers use bumpers to prevent infants from getting their limbs entrapped between the crib slats or to protect against head impacts. Warnings on crib bumpers recommend that the bumpers be removed from the crib when a child can sit up unassisted or can pull to a standing position, typically around 6 months. Bumpers are commonly made of fabric and fiber fill or foam panels that are tied to the crib slats and corner posts. CPSC staff estimates that bumpers cost between $15 and $250. Other products have been marketed as barriers to prevent limb entrapment, such as mesh crib liners and slat covers that wrap around the individual slats in a crib.

The product category has been associated with suffocation risks in the medical literature (Thach, Rutherford & Harris, 2007; Scheers, Woodward & Thach, 2016), resulting in banning the sale of certain crib bumpers in a few regions.

Policies, Regulations and Voluntary Standards

Some prominent organizations with expertise in child care and children's health recommend against the use of crib bumpers. For instance, at the National Institute of

Health, the Eunice Kennedy Shriver National Institute for Child Health and Human Development's (NICHD) "Safe to Sleep" website recommends not using crib bumpers.[1] The National Association for the Education of Young Children's (NAEYC) "Accreditation Criterion 5.A.12: Infant Safe Sleep Environments" prohibits the use of any kind of crib bumper.[2] The American Academy of Pediatrics (AAP) distributes several sources of information for parents imparting safe sleep practices that advise not to use crib bumpers.[3]

Child care facilities in most states prohibit the use of crib bumpers.[4] A major child care facility handbook, *Caring for Our Children* (2011), recommends that bumpers be kept away from sleep environments.

Certain types of crib bumpers have already been banned for several years in two places in the U.S.: Maryland and Chicago.

The State of Maryland, Title 10

Maryland declared certain baby bumper pads to be a hazardous material and banned the sale of "baby bumper pads" after June 21, 2013 using this definition:

> "Baby bumper pads" means a pad or pads of non-mesh material resting directly above the mattress in a crib, running the circumference of the crib or along the length of any of the interior sides of the crib, and intended to be used until the age that an infant pulls to stand.

Maryland law allows mesh liners and slat covers that are sometimes used as alternatives for padded horizontal bumpers. However, mesh liners and slat covers are not recommended for use by Maryland's Department of Health and Mental Hygiene, which spearheaded Maryland's ban.[5]

Chicago Municipal Code § 7-36-112 Crib bumper pads

The city of Chicago also banned all crib bumpers for sale except for mesh liners and slat covers.

Illinois Bill

Illinois is currently considering a law similar to the laws in Maryland and Chicago.

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[1] NICHD: Ways To Reduce the Risk of SIDS and Other Sleep-Related Causes of Infant Death found at https://www.nichd.nih.gov/sts/about/risk/Pages/reduce.aspx
[2] http://www.naeyc.org/files/academy/file/ProgramAdministratorGuideSafeSleep.pdf
[3] http://www.healthychildcare.org/PDF/SIDSparentsafesleep.pdf
[4] Nancy Cowles, Kids in Danger, personal communication, 2016
[5] http://www.dhmh.maryland.gov/pdf/crib%20bumper%20reg%20111612.pdf

ASTM F1917-12 – Standard Consumer Safety Performance Specification for Infant Bedding and Accessories

The industry standard for infant bedding, ASTM F1917-12, covers many different types of bedding products, including bumpers, diaper stackers, fitted sheets, comforters, pillows, and decorative wall hangings. Although the terms "crib bumper," "bumper guard" and "bumper pad" are not defined in ASTM F1917-12, a reasonable definition of these terms is "any product made of any material that is intended to cover the sides of a crib to prevent injury to crib occupants from impacts against the side of a crib or to prevent partial or complete access to any openings in a crib's sides to prevent a crib occupant from getting any part of the body entrapped in the openings." This understanding includes padded crib bumpers, supported and unsupported vinyl bumper guards, mesh crib liners and vertical crib slat covers.

The standard requires bumpers made of fabric and filled with fibrous material, i.e. padded bumpers, to pass a test that entails dropping the bumper through a "bumper thickness test fixture" that is a two-inch wide slot. This unvalidated requirement, based on the thickness limits of sleeping surfaces in other juvenile product categories, effectively limits the thickness of a padded bumper to about 2 inches or thinner. The rationale for this requirement was not supported by consumer groups during the ASTM balloting process.

The standard also requires warning labels that address a risk of suffocation, sagging, strangulation on ties, and removal of the bumper when a child can sit up unaided or can pull to a standing position (in order to prevent climbing out of the crib using the bumper as a step).

<u>The Petition</u>

In a letter dated May 9, 2012, the Juvenile Products Manufacturers Association (JPMA), requested that the U.S. Consumer Product Safety Commission (CPSC) initiate rulemaking to distinguish and regulate "hazardous pillow-like" crib bumpers from "non-hazardous traditional" crib bumpers. In support of their request, JPMA asserted that:

- Certain groups are advocating banning crib bumpers from the marketplace.
- JPMA's commissioned third party review, by an engineering and scientific consulting firm, of incidents associated with crib bumper pads failed to support claims of increased risk to infants from traditional crib bumpers.
- Banning traditional crib bumpers could have unintended consequences, including encouraging caregivers to add unsafe soft bedding to cribs to prevent infant occupants from getting limbs caught between crib slats and prevent bruises from crib sides caused by falls in the crib.
- The performance requirements of the ASTM standard provide a reasonable basis for a mandatory crib bumper performance standard.

On June 18, 2012, the Commission voted unanimously to publish a Federal Register (FR) notice requesting comments on the petition (Docket No. CPSC–2012–0034[6]). The notice was published on June 25, 2012, with a closing date of August 24, 2012, for accepting comments on the petition.

The staff briefed the Commission on details of the relevant incidents in the briefing package dated May 15, 2013 (OS No. 5665).[7] The Commission voted on May 24, 2013 to grant the petition, but with a broader scope than the petitioners requested. The Commission directed the staff to initiate rulemaking[8] to address the risk of injury associated with the use of crib bumpers and to provide the Commission with a briefing package that:

> 1. Described the possible regulatory options the Commission could take to address the risk of injury associated with crib bumpers.
>
> 2. Assessed the effectiveness of any related voluntary consumer product safety standard.
>
> 3. Assessed whether a more stringent standard would further reduce the risk of injury associated with the product.
>
> 4. Explored and, as possible, developed performance requirements and test methods to allow the Commission to identify which types of crib bumpers have characteristics that present safety hazards.
>
> 5. Assessed whether there are any safety benefits provided by crib bumpers.
>
> 6. Reviewed representative samples of crib bumpers, including, but not limited to, mesh bumpers and bumpers that individually cover crib slats (also called vertical bumpers).

On September 12, 2016, agency staff provided the Commission with a briefing package[9] in response to the May 24, 2013 Record of Commission Action noted above. The latest staff package does not fully resolve the issues raised by the incidents. This analysis seeks to address open policy questions.

[6] https://www.regulations.gov/docket?D=CPSC-2012-0034
[7] https://www.cpsc.gov/s3fs-public/pdfs/foia_CribBumpersBriefingPackage.pdf
[8] https://www.cpsc.gov/s3fs-public/pdfs/foia_RCACribBumpersPetition.pdf
[9] https://www.cpsc.gov/s3fs-public/Staff%20Response%20to%20the%20Record%20of%20Commission%20Action%20on%20Crib%20Bumpers%20-%20September%209%202016.pdf

Incident Reviews

In the 2013 staff briefing package, staff provided two analyses of the incidents discussed from different perspectives. The CPSC staff's 2016 briefing package included a third staff incident review of 282 non-fatal and 107 fatal incidents and incidents reported to the agency from January 1, 1990 to March 31, 2016. The non-fatal incidents included 57 entrapments of the arm or leg in between crib slats, 40 head entrapments under or between the bumper and another object, 33 choking on or ingestion of bumper parts, 28 near strangulations or entanglements, and 23 near-suffocations, with the face reportedly pressed against the bumper. All of the fatal incident reports available for analysis were unwitnessed and the victims were almost always younger than 12 months (92%).

Staff had two goals for the incident review. First, staff tried to identify the "primary cause" of the incidents, insofar as it was possible to do so, given that many incidents contained limited information. This "primary cause" analysis led staff to categorizations based on the location of victims in relation to the crib bumper and potentially confounding factors, such as other objects in the crib. Second, staff sought to assess the "addressability" of each incident, which was explained as the "likelihood" that removing the bumper from the incident scene would have affected the outcome of the incident. By assessing "addressability," staff was evaluating the hypothetical effects of a ban on crib bumpers.

Staff Categorizations of Incidents

Based upon its "primary cause" analysis, staff classified the fatal incidents into the following categories (pages 6-7):

> *Incidental (31 fatalities):* A bumper was present in the sleep environment, but there was no evidence of bumper contact or involvement in the fatality.
>
> *Contact Outside Crib (5 fatalities):* The child was in contact with a crib bumper outside an infant crib.
>
> *Entrapment/Wedging (41 fatalities):* The child was entrapped or wedged against the crib bumper. These cases are broken down further, as follows:
>
> > *Against Object in Crib (23 fatalities):* The child was entrapped or wedged between the bumper and another object in the crib, such as a bed pillow, infant recliner, or cushion.
> >
> > *In Perimeter of Crib (12 fatalities):* The child was entrapped between the mattress and the side of the crib, such as cases in which the child slipped into a gap between these two items.

Other (6 fatalities): The child was entrapped between crib slats, under the bumper, or in some other scenario not covered by the previously identified entrapment or wedging categories.

Contact Without Entrapment/Wedging (23 fatalities): The child was in contact with the crib bumper, but there was no indication of entrapment or wedging against the bumper.

Contact with Possible Entrapment/Wedging (7 fatalities): The child was in contact with the bumper, but staff could not determine whether the child was entrapped or wedged against the bumper.

Staff evaluated whether the cases were "*likely*" or "*unlikely to be addressable*" based on their assessment of whether or not the removal of the bumper from the sleep environment would have prevented the fatality. Staff concluded that 72 of the 107 reported fatal incidents are "*unlikely to be addressable*" by Commission action and nine of the 107 reported fatal incidents are "*likely to be addressable*" to some degree. Staff was unable to assess the "addressability" of the remaining 26 of the 107 fatal incidents due to insufficient information.

Differing Interpretations of Case Reports

Researchers inside (Scheers, 2013, Tab F) and outside of the agency (Thach, Rutherford & Harris, 2007; Scheers, Woodward & Thach, 2016), reviewing the same bumper-related incident data, have reported higher numbers of potentially addressable bumper-related fatalities. These researchers arrived at different classifications of the incidents and different conclusions than staff in the Division of Health Sciences. These researchers (Thach, Rutherford & Harris, 2007; Scheers, Woodward & Thach, 2016) emphasized the importance of medical examiners' reports of the injury mechanisms involved in the fatality. In contrast, the Health Sciences staff catalogued confounding factors, such as other objects in the crib or relevant medical conditions, to identify the "primary cause" of the incident (Tab C, page 4, 7; Tab E, page 14).

The Standard to Review Incidents under the Commission's Authorities

If the Commission makes certain findings[10] under the Consumer Product Safety Act (CPSA), the Commission is authorized to issue consumer product safety standards that are reasonably necessary to eliminate or reduce an unreasonable risk or risk of injury "*associated with* such product(s)."[11]

[10] The Commission may issue a rule if it finds that an existing voluntary standard is not likely to eliminate or adequately reduce the risk of injury or if it is unlikely there will be substantial compliance with the voluntary standard. *Id.* § 2058(f)(3)(D)

[11] 15 U.S.C. § 2058(c)-(f), 2056a(b)(1) (emphasis added)

On the other hand, section 104 of the Consumer Product Safety Improvement Act (CPSIA) expands the universe of products that may be reached through regulation in that rules made under section 7 of the CPSA are intended to address "unreasonable" risk of injury whereas section 104 of CPSIA permits the Commission to address the risk of injury, absent the "unreasonable" requirement found in section 7 of the CPSA. Under section 104 of CPSIA, the Commission may issue a standard that is substantially the same as the voluntary standard or a more stringent standard if the Commission determines that more stringent standards would further reduce the risk of injury associated with a product.

Importantly, neither section 104 of CPSIA nor section 9 of CPSA compels an analysis of the "primary cause" of an injury. On the contrary, under either section, the Commission determination hinges on a whether the injuries are *associated with* a product, a far less demanding standard than identifying a primary cause. Under an "association" analysis, the product must play some role in the risk of injury. Accordingly, the Commission does not have to consider "primary causation" to promulgate a regulation under any of its statutory authorities. Therefore, to the extent staff relied on a "primary causation" analysis, our statutory authorities do not support that approach because the bar for regulating is set much lower: the Commission may regulate when it determines there is a risk of injury associated with a product.

Within an analysis that examines a risk of injury associated with a crib bumper, it is helpful to view the chain of events leading up to a crib bumper fatality together in *a system* (Bronfenbrenner, 1979). In the *systems approach*, the risk of infant suffocation is clearly *associated with* padded crib bumpers. Consumers can use and misuse crib bumpers in ways that act in concert with the crib, other objects in the crib, and the crib mattress to create a deadly sleep environment. There are steps the Commission can take to address and reduce these hazards.

To move forward, the Commission needs to consider all of the facts surrounding crib bumper use in sleep environments, including consumer perceptions of public advice, warnings, retail marketing, interior design and decoration, when examining whether standards more stringent than the voluntary standard would further reduce the risk of injury associated with crib bumpers. The realities of childhood, including colds and other respiratory illnesses, should be taken into account when assessing the expected behavioral patterns of caregivers with infants. Furthermore, the contributions of public messaging and marketing of products intended to be used in the creation of sleep environments should be considered. The next section explores alternative explanations of some of the incidents described in the 2016 staff package and makes the case that those alternative explanations establish the requisite "association" needed to regulate.

Hazards Associated with Crib Bumpers

The following observations of contributing factors illustrate how infant suffocation deaths are *associated with* padded crib bumpers. Furthermore, each hazard discussed below affects the overall total number of "addressable" cases.

The Hazard of Limiting Space in the Crib

Staff argued that the cases involving entrapment between pillows or cushions and bumpers at the perimeter of the crib were not addressable by removing the bumper from the crib, stating that, "… the inability of infants to extract themselves from such a position is not dependent upon space around the infant's head; rather, it is a function of the gravitational pull exerted by the weight of the head and upper torso. Thus, deaths of this type would likely have happened even with the bumper removed" (page 11). However, another way of thinking about this scenario is as one of *limited space in the crib* caused by the pillow or cushion plus the added thickness of the bumper. When a child rolls off of a pillow, which should never have been in the crib in the first place, they do not always suffocate in a face down position. They escape harm sometimes because the infant head tends to loll to one side or the other *when there is enough room* for it to do so. If the space next to the pillow is wide enough, a child may have a chance to turn his/her head to the side and so escape a suffocating position. Sadly, in the cases involved in this categorization, the bumper occupied significant space on the mattress, contributing to the likelihood of entrapment by *reducing the space* on the mattress. Removing the bumper or reducing its thickness could possibly be enough to save the child's life.

This same argument about limiting space in cribs also applies to the addressability of some of the 12 fatalities that staff labeled "entrapment in the perimeter of a crib" and "entrapment/wedging, other." Likewise, if a child has a broken mattress support system, as in one of the cases, a bumper could get in the way of the victim falling out of an opening in a broken crib by limiting the space available through an opening. Falling out would be preferable to being positionally asphyxiated in a smaller gap. The bumper's presence in a broken crib could exacerbate a bad scenario.

The Hazard of a Covered Crib Side

Some of the other cases categorized as "entrapment in the perimeter of a crib" and "entrapment/wedging, other" involved broken cribs. While staff labeled the majority of these incidents as "unlikely to be addressable" by removal of the bumper, there is another way of looking at these cases. Cribs usually break at the joints of parts, such as where a slat joins a rail, at a corner, or the juncture of the crib side with the mattress support. These key breakage points can be *blocked from view by a crib bumper*, thereby contributing to the risk that caregivers fail to notice the problem. The bumper can also provide some support for a broken part of the crib, such as a broken slat, when the bumper is tied to that or an adjacent part, thereby either masking or giving a false sense of security about the problem. The caregiver may have noticed the crib's broken part sooner, and therefore been motivated to replace the crib sooner, if the bumper had not

been present. The bumper could also have provided enough containment for the infant, or perceived containment, so that the caregiver felt that the child was not endangered by the broken part. In either case, it seems reasonable to say that the presence of the bumper could have posed a risk of harm or negatively influenced the outcome of the incident. As with the previous hazard, taking this hazard pattern into account could increase the total number of addressable cases. This hazard pattern could also be associated with some designs of mesh liners and vertical slat covers.

The Hazard of Installation Difficulties

Another potentially hazardous pattern of bumper installation can be seen in the pictures of some IDIs. Consumers tied their bumpers to the first slat next to the corner post, rather than on the corner post.

Case #25 (IDI #001018HCC2040)

Consumers seemed to tie around the first slat because the crib's construction cannot accommodate the bumper tie at the corner. In this installation, the bumper leans slightly into the crib, resulting in a loose and not taut bumper. Even when the bumper seemed tight at the top, the lower portion would sag more than it should in this position. Loose bumpers could more easily conform to the face than a tight bumper and so block the victim's airways by creating a shallow pocket. Bumpers should be vertical, tight and flush against the crib side. The appearance of an inward leaning bumper in a few incident reports is suggestive of the potential for misinstallation. This is a foreseeable risk. Difficulties installing a bumper with ties are common for cribs with solid panels and those with extra-thick corner posts.

A few investigations in the category of "entrapment/wedging, other" described consumers finding children "under" a crib bumper and these cases have only vague information. It is possible that the bumpers being used did not have enough ties, or the consumers did not tie all of the ties provided on the bumper, or a tie had become untied during use. These possibilities are all clearly foreseeable. Whatever the cause, it seems reasonable to conclude that a very loose bumper could allow a child to wriggle beneath it and get entrapped. This may explain some of the non-fatal cases. In such a case, the removal of the bumper may have helped prevent some of these kinds of incidents.

Additional ties on the bottom of the bumpers might help, but consumers forgetting or avoiding tying them is foreseeable use. As with the previous hazards, the total number of addressable incidents increases after taking this hazard pattern into consideration. This hazard pattern could also be associated with some designs of mesh liners and vertical slat covers.

The Hazard of Using Crib Bumpers with Children Past the Recommended Age

Many incident reports involved children who were probably old enough to sit up unassisted and begin to pull to a standing position. These children should have crib bumpers removed from the crib because they might use the crib bumper to climb out. The incidents mention this possibility although the events were not witnessed. It is challenging for consumers to anticipate when they should remove their bumpers and consequently, many people use bumpers beyond the recommended time that bumpers should be removed from the crib. Since older children are the most likely to get their limbs entrapped in the slats, the urge to keep the bumper in place is difficult for some parents to resist. While it is not known how many times a child has used a crib bumper to climb out of a crib and subsequently fallen, such a fall has the potential to be deadly. At least one fatality (record #16 in Tab D) in the "Incidental" categorization recounts that a child climbed out of his crib and was killed when he became entrapped between the crib side and a nearby dresser. While the method that the child used to escape his crib is speculative, it was a reasonable explanation of the event. The fact remains that using a bumper too long definitely has the potential to be lethal. Removing the bumper, or removing the padding of the bumper that made it substantial enough to give the child a climbing advantage, could have helped prevent this incident. Some of these kinds of incidents also could be addressed by Commission action. This hazard pattern could also be associated with some designs of mesh liners and vertical slat covers.

The Hazard of Using a Crib Bumper Outside of a Crib

Eight fatal cases involved the use of a crib bumper outside of the crib. Given that this usage is facilitated by the padded bumper, it is foreseeable use (as staff noted in Tab E). The traditional bumper pad has ties that lend themselves to being tied to other objects, like toddler beds, and their internal padding makes them into a readily-available cushion that can be used in other products, such as bassinets and play yards. Removal of the padded bumper from the marketplace may have prevented some (not all) of these uses. Some of these incidents could also be addressed by Commission action. Some designs of mesh liners could be used for other purposes outside of a crib, but would not serve as well in such roles as traditional bumper pads which are more padded and rigid.

The Hazard of Mixed Messages about Padded Objects in the Crib

Staff noted that "many consumers continue to put soft bedding in cribs, despite warnings against such practices" (page 14). The discussion of clutter in the crib in Tab E (page 28) recounts an injury rate associated with pillows that rivals the most injurious juvenile products that the agency has ever regulated:

> Incident data show clear involvement of pillows in 690 deaths over a period of 18 years (1992-2010), which has led HS staff to conclude that such products cause about **38 deaths/year** in children/infants aged 0-12 months (emphasis added).

***This means that one baby dies every ten days in the U.S. because of a desire to make them more comfortable*.** The perception that babies need cozy and cushioned surroundings is one of the most dangerous perceptions that a new parent can have. This perception leads to bassinets and cribs being overloaded with pillows, comforters, large blankets, stuffed animals, padding and other soft bedding, thereby creating a very hazardous environment for an infant.

Where does this deadly perception come from? When shopping for their new baby's nursery, new parents encounter a dizzying array of choices in crib bedding. Thanks to public outreach by agency staff and consumer advocates, many juvenile product retailers have stopped showing cribs with comforters and pillows in their stores and advertisements, but many crib bumper options remain with plush, cozy textures.

While considering buying plush, cozy nursery decorations, the public is admonished that "Bare is Best" when it comes to the crib. Add to that the perceptions by many that a bumper is a safety device for preventing head injuries. How can bare be best when a two-inch thick strip of padding is placed into the crib "for safety's sake"? This is a confusing, mixed message being created by the existence of *padded* crib bumpers on the market. The *padding* is the mixed message that is contributing to consumer misperceptions of safety. CPSC and consumer advocates say one thing and the bumpers on the store shelf, celebrity nursery photo shoots and sometimes marketing displays show something else. Mixed messages undermine the best advice, which is to lay a child to sleep in a bare crib with just a mattress and a tight, fitted sheet. Staff's 2016 briefing package acknowledges that added pillows and plush objects are a serious public health problem (page 14).

This mixed message sent by the presence of traditional padded bumpers in the marketplace could be playing a role in many of the cases that were deemed "incidental" in the 2016 staff package (page 9). The "incidental" categorization referred to cases in which a bumper was present in the crib, but not directly tied to the incident. "Incidental" cases often involved pillows, nursing pillows, folded quilts, comforters, positioners and similar hazardous items that should not have been placed in a crib with a sleeping infant.

In light of the mixed message presented to consumers by the presence of padded bumpers on the market, it seems likely that the removal of the padded bumper from the market would have an effect on the perceptions of the suitability of placing padded and plush objects in a crib. Given the inordinately high number of pillow-related suffocations in the data, any improved clarity in messaging on bare sleeping environments for babies should be considered as an *injury prevention strategy*, i.e., something that is addressing the injury problem.

Staff classified 31 reports as "incidental," yet some number of them might have been prevented if padded bumpers were not allowed on the market. The same argument about unmixing messages could be applied to some of the five fatalities in which a child was found in contact with a bumper outside of a crib (page 10) and some of the 23 incidents categorized as "entrapment/wedging against an object in the crib," often involving a plush item like a pillow, as well.

In arguing that a ban on crib bumpers could have the unintended consequence of forcing consumers to add soft bedding to a crib as a makeshift bumper, staff asserted that "continued and *consistent messages* (italics added) about keeping soft bedding such as pillows and folded quilts out of cribs are important, and would be even more so in the event of a ban" (Page 14-15). The need for consistent messaging is important when considering whether the padded bumper's presence in the market is contributing to an inconsistent message about padding or pillows being allowed in the crib. The experiences of Maryland's and Chicago's bans have not seemed to increase the use of makeshift bedding. It may be that the unmixing of the message has played a positive role in the public education narrative about safe sleep that has overcome the likelihood of using makeshift bedding. Also relevant, the allowance of a mesh liner in those regions could be providing caregivers with a means of mitigating limb entrapment worries, further decreasing the likelihood of using makeshift bumpers.

To conclude this section, the Commission can and should address these six hazard patterns, each of which involved incidents associated with padded crib bumpers that create or contribute to the risk of injury.

The Limited Utility of Crib Bumpers: Preventing Minor Injuries at the Risk of Fatal Injuries

Supporters of bans on crib bumpers, such as those legislated in Maryland and Chicago, believe that the policy for bumpers is best considered in light of the *utility* of bumpers. Bumpers are essentially decorations that also happen to limit limb entrapments which are, by and large, *very minor* injuries. Head impacts with crib structures appear to be exceedingly rare (Chowdhury, 2010, p. 39) and are most likely occurring to children old enough to stand, which is long after a crib bumper should be removed from the crib. Ban supporters believe that since a bumper serves little or no purpose, it is reasonable to ban it from sale, thereby eliminating at least one potentially hazardous object that has been used in conjunction with known hazards like pillows. They object to creating a standard for an object with limited utility that has contributed to, even in a supporting role, fatal incidents. Additionally, ban supporters argue that consumer use of other hazardous objects like pillows and other clutter in the crib is promoted by popular nursery aesthetics that send mixed messages that create a perception that cribs need to be plush and cozy. This view is widespread, therefore adding other plush objects to a sleep setting with a bumper has become foreseeable use.

Opponents to a ban argue that the utility of crib bumpers is protection against a child bumping his/her head against the slats and preventing limbs from getting caught between the slats of the crib. Both of these uses are seldom needed, however, or are desired by some caregivers for a very short period because bumpers are supposed to be removed from the crib by the time a baby can sit up unassisted, around 6 months. Once a child can pull to a stand, the crib bumper can be used as a step and facilitate climbing out, so manufacturers label bumpers to instruct consumers to remove them after about the age of 6 months. Limb entrapments do happen, but they are minor injuries and they overwhelmingly occur to children who are too old to be using bumpers anyway. A petition comment submitted by consumer safety advocates in 2012 noted this fact:

> A recent review by Kids In Danger of SaferProducts.gov reports on crib incidents showed that 88% of the children involved in slat entrapment were eight months or older. Manufacturers recommend removing bumpers when a child starts to pull to a stand - -usually between 5-8 months. There is no evidence children don't get their limbs entrapped with bumper pads in place and most incidents involve cribs and children where bumper pads should not be present.[12]

In the 2010 staff briefing package for the federal mandatory crib rule, Chowdhury (2010) found that children getting their *limbs caught between the crib slats* was the second-most frequent cause of injuries, although minor ones. These experiences cause caregivers to want some way to prevent limb entrapments. An inability to buy some kind of barrier to fill the gaps between crib slats could lead to unintended consequences. Actively prohibiting the use of crib bumpers *without some alternative* may cause some consumers experiencing repeated limb entrapments to resort to makeshift bumpers such as using rolled up blankets, pillows or other cushions. But, if the Commission were to regulate bumpers in such a manner that allowed for mesh liners or other designs with high levels of airflow, as was done in Maryland and Chicago, the market would retain a product that prevents limb entrapments. Furthermore, the experience in Maryland and Chicago does not seem to have caused an increase in consumer use of pillows or other additions in the crib to make up for the lack of padded crib bumpers on the market.

A limb entrapment prevention product does not need to be plush and padded to work. The voluntary standard already limits the thickness of bumpers to about two inches with a test that requires the bumper to pass through a slot in a rigid fixture designed to exclude thicker bumpers. Very thick (more than 2 inches thick) bumpers have been sold in the past, but are not common. However, the fact remains that anyone could make a truly "pillow-like" bumper right now and market it to the American public. What is needed is a defensible performance requirement to limit crib bumpers to those that are not "pillow-like." The most obvious pathway forward for injury prevention is to provide the public with a means of preventing limb entrapments in crib slats without allowing for padded

[12] Submitted by Kids In Danger, Consumer Federation of America, and Consumers Union on "Petition Requesting a Performance Standard to Distinguish and Regulate 'Hazardous Pillow-Like' Crib Bumpers from 'Non-hazardous Traditional' Crib Bumpers" (CP 12-2) on August 21, 2012; downloaded from https://www.regulations.gov/document?D=CPSC-2012-0034-0004

bumpers. This approach would answer the JPMA's petition and safeguard infants from suffocation hazards. JPMA's petition uses the term "pillow-like" to describe the potentially hazardous crib bumper. This term "pillow-like bumpers" refers to a phrase used in a CPSC staff letter, dated June 22, 1999, signed by Ronald Medford, the Assistant Executive Director of the Office of Hazard Identification and Reduction:

> CPSC's position on the use of bumper pads may also need clarification. Because pillows in the infant's sleeping environment pose a potential suffocation hazard for infants, bumper pads that are "pillow-like" should also be regarded as potentially hazardous and should not be used.

While agency staff in the past used the term "pillow-like" in public education and voluntary standards development, the term was never defined either qualitatively or quantitatively. The term "pillow-like" remains vague and subjective, causing confusion. An objective definition of the term "pillow-like" using performance criteria such as a probe, airflow or compression test of some kind has not been designed for crib bumpers.

The next section explores the options for making a performance requirement, or some combination of requirements, to prevent hazardous "pillow-like" bumpers from being sold.

A Path Forward to Addressing Hazardous Bumpers

When is a bumper too thick and plush? This open question gets at how to define "pillow-like," a term used in the past by the agency to describe something retailers should avoid selling and caregivers should avoid buying and using.

Thickness and Firmness

Being concerned about the potential for suffocation from "pillow-like" bumpers, the ASTM standard subcommittee limited bumper thickness to about 2 inches using a simple test that requires a bumper to pass through a slot in a smooth, rigid fixture. If it gets stuck in the slot, the product fails. The justification of the 2 inch requirement is that it was drawn from other ASTM standards with padded products that are not known for being associated with suffocation hazards. The problem with this logic is that the other standards, such as play yards, apply the 2 inch restriction to *mattresses*. Mattresses are made with very different materials than bumpers and are generally much more firm than bumpers. Two inches of foam and vinyl do not have the same performance characteristics as two inches of fiber fill and cotton fabric.

The ASTM thickness requirement is essentially a proxy for limiting the "softness," that is the ability of a product to conform to the face of an infant, and, possibly, the air permeability of a bumper. Thickness correlates in most common fabric materials with conformability and air permeability—plus, it is easier to test than conformability and permeability. The facial conformity characteristics of a mattress made of foam and plastic

cannot be equated to the facial conformity characteristics of a bumper made of fiber batting and fabric. The materials are too different to be equated.

Another problem with using thickness as a proxy for facial conformity is that it allows for the use of certain known hazardous materials that would easily pass the test. For instance, a bumper could be made of several loose layers of plastic film, such as that used in dry-cleaning bags. This material would readily serve to prevent limb entrapments and would easily slide through the 2 inch slot used for the ASTM thickness test, but would present a lethal hazard if placed in a crib. Thin plastic is highly conformable to the face, but very thin and impermeable to airflow and very capable of holding pockets of carbon dioxide.

Moving away from traditional bumpers, to products that would not need to pass the bedding standard, one could design a fabric shield to affix to the outside of a crib slat such that limb entrapments would be prevented, but such a device would never fit through a 2 inch slot. The point of considering this is not that this product would be a hazard, but to illustrate that thickness is not the best test for screening hazards because it would exclude some potential designs to prevent limb entrapment.

Thickness is underperforming as a performance requirement. The standard or a future regulation needs to move away from thickness.

A Better Performance Requirement

A better requirement than thickness would be a test for facial conformity. Such a test would have several features. The first step would be to limit the requirement so that it only applies to products intended to be affixed to the inside of a crib side. The second step is to not limit the requirement to fabric items, but to allow any type of material. Slat covers, for instance, are fabric-covered foam. Rigid plastic could also be employed in the construction.

Many cribs are made with solid panels and these solid panels are not associated with suffocation hazards. It stands to reason that the facial conformity characteristics of a hazardous bumper fall somewhere between a solid board and a pillow. A bumper that does not allow for airflow needs to be firm enough or shaped in such a manner so that it cannot conform to the face of an infant or hold pockets of carbon dioxide. This will require a test of facial conformity characteristics.

The 2016 staff briefing package recommended further exploration (page 17) of a potential firmness test from the Australian/New Zealand standard, AS/NZS 8811.1:2013 which was based on the pioneering case-control study by Schlaud, et al. (2010) of sleep surfaces found under victims diagnosed with SIDS. The advantage of this test fixture, essentially a weight with a thin metal probe on one side, is its simplicity. The test weight and shape, however, were not validated on vertical surfaces. That test was intended for screening mattresses and was not intended to represent facial conformity. The staff pilot

testing of that test fixture on bumpers showed virtually all of the bumpers passing the test (Tab G of the 2016 package).

A surrogate face could be invented that can be pressed into a bumper to gauge the likelihood that the bumper can conform to an infant's face enough to simultaneously cover the nose and mouth. Like the AN/NZS standard's firmness gauge, it could have an indicator or marking that shows the level of conformation that would occlude an infant's airways. Any probe or fixture used to represent an infant's face should represent the worst case scenario for facial conformity. The worst case, that is the hardest to pass, would be the smallest face with the smallest features because this would require the least product conformation to fail.

Another option is to invent a test of airflow based on worst-case inhalation and exhalation data whereby air is drawn through a bumper into some standard fixture. Unpublished pilot tests using airflow by Schechter and Raynor (2016) were submitted to staff by an industry commenter on the petition. Their discussion highlights inspiratory and expiratory pressures measured in the medical literature which could provide a benchmark anatomical target to create a facial conformity test. They report that Kassim, et al. (2015) "… found at birth a mean±SD maximal inspiratory pressure of 89±19 cm H_2O and mean expiratory pressure of 61.8±13.5 cm H_2O." Schechter and Raynor also identified studies of the normal newborn time to take a breath and for exhalation (Schmalisch, et al, 2005) and cross-sectional area of the nose (Djupesland & Lyholm, 1998). Schechter and Raynor concluded that "… normal tidal respiration is associated with inspiratory pressures of <10 cm H_2O, and the publications cited show that infants can generate maximum inspiratory and expiratory pressures up to 100 cm H_2O" (page 16). It seems reasonable to suggest these facts as a starting point for the creation of a minimal airflow requirement for bumpers, taking into account the need to provide a margin of safety for infants with compromised breathing (worst-case scenarios):

- The pressures for breathing in and out range between <10 – 100 cm H_2O.
- The time to take a breath is 0.65±0.14 seconds.
- The time to exhale is 0.98±0.24 seconds.
- The cross-sectional area of the nose is 21 mm^2.
- The diameter of the nasal airway is 5.2–6.7 mm.

Performance requirements to reduce the risk of injury associated with padded crib bumpers could be developed by accomplishing, at a minimum, the following tasks:

> *Facial Conformity Test*: Based on known anthropometric parameters, develop a means to demonstrate that a crib bumper is firm enough to not conform to the face of an infant.
>
> *Airflow Test*: Based on known infant inhalation and exhalation requirements and anthropometric parameters, develop a means to demonstrate that a crib bumper matches or exceeds the airflow characteristics of mesh or mesh-like materials.

Warnings and Labeling: Compose warnings and instructions to explain all of the types of cribs on which the product can and cannot be installed, clear advice about how to install the product, when to stop using it, and how to construct a safe sleep environment. Require instructions to be on the product because instructions for this type of product will be discarded in most cases.

Conclusion

Deaths and injuries are associated with the use of crib bumpers. This discussion considered the policy implications of six hazard scenarios that can result in suffocation, wedging, entrapment or falls:

- limiting space on the mattress surface inside of a crib,
- covering key failure points on cribs,
- difficulties installing crib bumpers,
- using a bumper with children who are past the recommended age, and
- using a bumper outside of a crib, and
- communicating mixed messages about padded objects in a crib.

Broadening the focus of the analysis to include these hazard scenarios increases the total number of addressable incidents. In light of the limited utility of padding inside of crib bumpers and the alternative offered by a mesh crib liner for preventing limb entrapments in crib slats, the Commission could proceed with rulemaking to create performance requirements for crib bumpers that would eliminate padding that conforms to the face and require sufficient airflow characteristics to protect our most vulnerable population in their most vulnerable setting.

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Addendum – April 4, 2017

Commission Action

On October 19, 2016, the Commission voted (3-2)[13] to add to its Fiscal Year 2017 Operating Plan a direction to CPSC staff to initiate rulemaking under section 104 of the Consumer Product Safety Improvement Act (CPSIA) to address the risk of injury or death associated with the use of crib bumpers. Additionally, on November 3, 2016, Chairman Kaye and Commissioners Adler, Robinson and Mohorovic issued a joint statement urging consumers not to use padded crib bumpers.[14]

Ohio: Senate Bill 332

Ohio passed a bill in 2016 that bans the sale of non-mesh crib bumper pads, effective on April 6, 2017. Ohio allows for the sale of mesh crib bumper pads for a three-year period, provided the mesh crib bumper pads meet standards promulgated by the CPSC. If the CPSC does not promulgate standards for the air permeability of mesh crib bumper pads within three years, mesh bumpers will also be banned.

Other States

Illinois, Missouri, Vermont, and New York have considered bills similar to the laws in Maryland, Chicago, and Ohio.

Disclaimer: This paper has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission or CPSC staff.

[13] https://www.cpsc.gov/s3fs-public/MinutesCommissionMeetingFiscal2017OperationsPlan.pdf
[14] https://www.cpsc.gov/s3fs-public/Joint%20Statement%20on%20Padded%20Crib%20Bumpers%20FINAL%2011.3.16.pdf