

BRIEFING PACKAGE:

CPSC Staff Response to the Record of Commission Action on Crib Bumpers



September 9, 2016

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The contents of this package have not been reviewed or approved by the Commission and do not necessarily represent its views.

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Tab A: 2013 Record of Commission Action Regarding Crib Bumpers.

Tab B: Memorandum from Samantha Li and Mark Bailey, Directorate for Economic Analysis, “Economic Considerations Related to Crib Bumpers.” June 1, 2016.

Tab C: Memorandum from Adam Suchy, Mathematical Statistician, Hazard Analysis Division, Directorate for Epidemiology, “Overview of Crib Bumper Incidents Reported From January 1, 1990 to March 31, 2016.” April 22, 2016.

- Tab D: Tables of Fatal Incidents.
- Tab E: Memorandum from Suad Wanna-Nakamura, Ph. D., Directorate for Health Sciences, “Analysis of Deaths Citing Crib Bumpers Reported from January 1, 1990 to March 31, 2016.” June 22, 2016.
- Tab F: Memorandum from Timothy P. Smith, Senior Human Factors Engineer, Division of Human Factors, Directorate for Engineering Sciences, “Human Factors Assessment of Warning Requirements for and Safety Benefits of Crib Bumpers.” May 6, 2016.
- Tab G: Memorandum from John Massale, Mechanical Engineer, Laboratory Sciences Directorate, Mechanical Division, “Existing Voluntary Standards and Testing Methods Associated with Crib Bumpers.” June 20, 2016.

EXECUTIVE SUMMARY

In this briefing package, staff of the U.S. Consumer Product Safety Commission (CPSC or “Commission”) updates the Commission on the status of staff activities in response to the Commission’s 2013 Record of Commission Action for Crib Bumpers. Specifically, staff has:

- evaluated updated incident data involving crib bumpers;
- assessed the potential addressability of these incidents by Commission action;
- described the potential safety benefits of bumpers;
- discussed the effectiveness of current voluntary standard requirements pertaining to bumpers, as well as the likely effectiveness of more stringent requirements; and
- identified the regulatory options the Commission may consider to address the risk of infant suffocation associated with crib bumpers.

A search of CPSC data sources identified 107 fatal incidents that were reported to CPSC from January 1, 1990, to March 31, 2016, in which a crib bumper was present in the sleep environment, in addition to 282 nonfatal incidents or reported concerns associated with bumpers during the same timeframe. Thirty-one of the 107 reported fatalities had no evidence of bumper contact or involvement and, therefore, were classified as “incidental.” An additional five reported fatalities involved bumper contact outside a crib, which staff considered out of scope in the original 2013 Petition Briefing Package. Of the remaining 71 reported fatalities, 41 involved entrapment or wedging scenarios, such as the infant becoming entrapped or wedged between the bumper and another object inside the crib, or becoming entrapped or wedged in the perimeter of the crib, between the mattress and the crib side. These latter fatality reports consistently involved incidents of broken cribs or older cribs that likely did not meet current crib slat and mattress spacing requirements.

In addition to classifying the reported fatalities into hazard patterns, staff attempted to assess the likely addressability of these fatalities through Commission action. Staff concluded that such an assessment was necessary to enable staff to assess the voluntary standard and to evaluate regulatory options. Staff made this assessment by examining the information available in the incident reports to determine whether the fatality still would have occurred if the bumper were not present in the sleep environment. Staff chose this approach because fatalities that would have occurred even if the bumper were removed are incidents in which the bumper likely did not increase the risk of injury, and for which improved performance requirements, or even a ban, would likely have had no effect. The primary difficulties in making such assessments are that all of the incidents were unwitnessed, and incident reports varied in the type and amount of information available or provided when describing the incident scenario. In addition, most cases included other confounding factors, such as the child having a medical condition or illness at the time of the incident, the child being in a prone sleep position, the presence of pillows and other suffocation hazards, and the presence of specialized infant products and other clutter that tend to crowd the sleeping area and contribute to entrapment hazards. Nevertheless, staff believed that attempting to make such an assessment was the best way to determine the likely contribution of the crib bumper to the fatality, and to avoid giving undue weight to incidents in which the contribution of the bumper appeared unfounded.

Based on the available information, staff concluded that 72 of the 107 reported fatal incidents, which include the 31 incidental cases described above, are unlikely to be addressable by Commission action. Thus, improved performance requirements, or even a ban, are unlikely to have had an effect on these deaths. In contrast, 9 of the 107 reported fatalities are likely to be addressable to some degree. The incident reports for the remaining 26 fatalities lacked sufficient details to determine whether the crib bumper contributed to the fatality, so the addressability of these incidents is unknown. Some portion of these 26 fatalities also might be addressable by Commission action.

Crib bumpers generally are promoted as providing two safety benefits: (1) preventing infants from getting their limbs caught between crib slats, and (2) protecting infants from impacts against the sides of a crib. During rulemaking activities for full-size and non-full-size baby cribs, CPSC staff found that infants getting their limbs caught between crib slats accounted for many incidents involving full-size cribs and cribs of an undetermined size, and that some injuries requiring hospitalization involved limb entrapments or impacts with the crib structure after the child fell in the crib. Although staff is aware of incidents involving limb entrapments even when a bumper is installed in a crib, there are few incidents of this type, and bumpers likely prevent some incidents and injuries involving limb entrapment or crib-structure impact that otherwise would have occurred. Eliminating crib bumpers also might result in some caregivers using other soft bedding as an alternative protective barrier against the crib structure because consumers have been known to engage in similar behaviors, even in the presence of contrary warnings in the sleep environment.

ASTM F1917, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*, includes several performance requirements that are relevant to, or specifically directed to crib bumpers. The performance requirement most directly aimed at addressing the potential suffocation hazard is a 2-inch maximum thickness requirement. The 2-inch dimension is based on similar thickness requirements in ASTM standards for other padded items with which infants interact, including sleep surfaces such as play-yard pads. Given the effectiveness of this dimension in addressing suffocation hazards in similar products, staff doubts that a more stringent thickness requirement would be effective at reducing suffocations on bumpers. Staff has considered the addition of a “firmness” performance requirement, which makes sense in principle, but such a requirement seems unlikely to have a large impact on suffocations because bumpers that would fail the firmness requirement considered by staff already fail the ASTM thickness requirement. Crib bumper performance requirements that reflect the properties of alternative products, such as vertical bumpers or mesh liners, might have prevented about three to six of the nine fatal incidents that staff has concluded are likely to be addressable to some degree. Staff also has considered several revisions and additions to current warning requirements. However, several issues are likely to limit the effectiveness of such changes, so few fatalities are likely to be addressed by this approach.

Important factors to consider when evaluating the possible regulatory options intended to address the suffocation risk associated with crib bumpers include the societal costs associated with bumper pad injuries and deaths, and the likely benefits that might be derived by reducing the societal costs in the future. Based on the staff review of fatalities reported to CPSC from 1990 through March 2016, up to about 0.46 reported deaths annually, or about one reported death every 2 years, on average, may be addressable by a product safety rule. Given an estimated 5.3

million bumper pads in use, staff estimates societal costs of about \$0.75 per bumper pad in use per year. Furthermore, based on an expected product life of 1 to 2 years, the present value of the societal costs over a bumper pad's useful product life, at a 3 percent discount rate, would amount to about \$0.75 to \$1.44 per bumper, on average. This range represents an estimate of the maximum value of potential benefits per unit that a 100-percent effective remedial action—that is, one that eliminates the risk and prevents all deaths—could achieve. Less effective remedial actions would have correspondingly smaller expected benefits.

The Commission's statutes provide four different rulemaking pathways that the Commission could follow, in theory, to address the suffocation risk associated with crib bumpers:

1. develop a rule under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA),
2. develop a rule under section 7 of the Consumer Product Safety Act (CPSA),
3. develop a rule under section 3 of the Federal Hazardous Substances Act (FHSA), or
4. develop a ban under section 8 of the CPSA.

Staff notes that section 104 of the CPSIA only applies to “durable infant or toddler products,” and staff has concluded that crib bumpers probably would not be considered durable products by existing economic and commercial definitions. Staff notes that the Commission is not limited to the economic definition of “durable” when determining whether crib bumpers are a “durable infant or toddler product” under Section 104. To pursue rulemaking under the CPSA or FHSA, the Commission must find that crib bumpers present an unreasonable risk of injury or constitute a hazardous substance. Based on staff's review of the incidents, making such findings would likely prove difficult.



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

This document has been electronically
approved and signed.

DATE: September 9, 2016

MEMORANDUM

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Mary T. Boyle, General Counsel
Patricia H. Adkins, Executive Director
DeWane Ray, Deputy Executive Director for Safety Operations

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

Timothy P. Smith, Project Manager, Crib Bumpers Project
Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Staff Briefing Package in Response to 2013 Record of Commission Action on Crib Bumpers

I. INTRODUCTION

Staff of the U.S. Consumer Product Safety Commission (CPSC or “Commission”) has prepared this memorandum and briefing package in response to the 2013 Record of Commission Action pertaining to the Crib Bumper project.

II. BACKGROUND

A. JPMA PETITION

On May 9, 2012, the Juvenile Products Manufacturers Association (JPMA or “the petitioner”) submitted a petition (CP 12-2), requesting that the Commission initiate rulemaking to distinguish and regulate “hazardous pillow-like” crib bumpers from “non-hazardous traditional” crib bumpers under sections 7 and 9 of the Consumer Product Safety Act (CPSA). The petitioner asserted that some groups were advocating that crib bumpers be banned from the marketplace, despite evidence to the contrary about the safety of traditional crib bumpers.¹ The petitioner expressed concerns that banning traditional crib bumpers would lead parents and other caregivers to create unsafe “makeshift” products—for example, adding soft bedding to cribs—to serve as a protective barrier from the tight dimensions and hard wooden surface of the crib slats. The

¹ The petitioner stated that CPSC had previously found no primary causal connection between traditional bumpers and infant fatality, and provided a third party review of previous studies of crib bumper pads to refute claims of increased risk to infants from traditional crib bumper use.

petitioner included a copy of proposed ASTM International (ASTM) performance and labeling requirements, which the petitioner believed provided a reasonable basis for a mandatory crib bumper standard. These included a requirement for maximum bumper thickness, a strength requirement for bumper ties, and required warnings about suffocation, strangulation, and fall hazards. These requirements are very similar to the ones that ultimately were incorporated into the relevant ASTM voluntary standard in 2012 (see below), after CPSC received the petition.

On May 15, 2013, CPSC staff delivered to the Commission a briefing package containing staff's initial assessment and recommendation for Commission action ("Petition Briefing Package"; Midgett, 2013). Although there was a difference of opinion among staff regarding the extent to which crib bumpers might pose a risk to infants, staff concluded that "[s]ome evidence suggests that crib bumpers may increase the risks present in unsafe sleep settings," and recommended that the Commission grant the petition. On May 24, 2013, the Commission voted unanimously (3–0) to grant the petition, and as part of the Record of Commission Action, directed CPSC staff to:

- provide the Commission with a briefing package that describes the regulatory options the Commission may take to address the risk of injury associated with crib bumpers, including a staff assessment of the effectiveness of any related voluntary consumer product safety standard, as well as an assessment of whether a more stringent standard would further reduce the risk of injury associated with crib bumpers;
- explore and, as possible, develop performance requirements and test methods that identify which types of crib bumpers have characteristics that present safety hazards; and
- assess whether crib bumpers provide any safety benefit.²

Tab A includes a copy of the 2013 Record of Commission Action regarding crib bumpers.

B. THE PRODUCT AND MARKET

Crib bumpers, also referred to as "bumper pads," "bumper guards," or just "bumpers," are infant bedding accessories that traditionally consist of one or more padded fabric panels that attach to the interior perimeter of a crib and function as barriers between the infant and the sides of the crib. These products are marketed as preventing injury to infants from impacts against the sides of a crib and preventing limb entrapments between crib slats. Bumpers also are used to decorate the infant's sleep environment and commonly are promoted as making a crib more "cozy" or comfortable. The warnings on these products recommend that bumpers be removed when a child can sit up unassisted or can pull to a standing position; an infant generally would reach one of these milestones when about 6 months old.

As staff discussed in the original Petition Briefing Package, many different kinds of bumpers have been available over the years. Some bumpers have little padding, while others have several inches of padding and can even take on the appearance of pillows. Bumpers commonly attach to

² The Commission stated that staff's assessment should include a review of representative samples of crib bumpers, and should include an assessment of mesh bumpers and bumpers that individually cover crib slats, also known as vertical bumpers.

a crib with ties that are secured to the corner posts or crib slats, but other fastening methods exist. Various combinations of fabric or vinyl, stuffed with fiberfill or foam, have been used. Less frequently, bumpers might be made from rigid plastic mesh or firm foam.

The market also includes so-called “vertical” bumpers, which essentially are a series of small bumpers that individually enshroud each crib slat, and similar alternatives that cover two slats at a time, sometimes referred to as “mini” bumpers. These products generally claim to offer benefits that are comparable to traditional bumpers while allowing airflow through the sides of a crib. Other bumper variants exist that look similar to traditional bumpers but are marketed with claims of being “breathable.” Mesh crib liners are another alternative to traditional crib bumpers that claim to be breathable, but these liners tend to be thinner than traditional bumpers and lack padding because they are not aimed at preventing impact injuries.

As staff of CPSC’s Directorate for Economic Analysis (EC) discusses in Tab B, information from the recent CPSC Durable Nursery Products Exposure Survey of U.S. households with children younger than 6 years old indicates that about 5.3 million crib bumpers are in use in households. The total number of bumpers in use might be somewhat higher than this number, because some bumpers may be in use in households in which young children do not reside, such as the homes of older adults who provide care for grandchildren. In addition, the survey did not include childcare facilities and lodging establishments, such as hotels. However, bumper usage in these other households and facilities is probably low.

EC staff estimates that 63 entities produce or distribute crib bumpers to the U.S. market. Publicly available information is insufficient to identify the size and dollar sales of most firms. Crib bumpers may be sold separately or as one component of a set of infant bedding articles. Retail prices for individual bumpers range from \$15 to \$250, depending on the brand; prices for bumpers sold with bedding collections range from \$100 to \$1,200, depending on the brand and the number of items in the set.

C. RELEVANT U.S. STANDARDS AND LEGISLATIVE ACTIVITIES

ASTM F1917, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*, contains requirements for infant bedding and accessories, including crib bumpers, in the United States. The current version of the voluntary standard was published in 2012 (ASTM F1917 – 12). This standard includes several performance and labeling requirements that are specific to or relevant to crib bumpers, including bumper-thickness and tie-length limits, in addition to required warning language that must appear on each bumper. A detailed discussion of these requirements appears later in this memorandum.

The city of Chicago, IL, and the state of Maryland have banned the sale of crib bumpers. Specifically, beginning on April 5, 2012, the sale or lease of any “crib bumper pad,” as a separate item or as an accessory to a crib, became illegal in Chicago.³ Similarly, Maryland’s Department of Health and Mental Hygiene (DHMH) published final regulations that declare

³ Chicago, Ill., Mun. Code § 7-36-112. The code defines a crib bumper pad as “any padding material, including but not limited to a roll of stuffed fabric, which is designed for placement within a crib to cushion one or more of the crib’s inner sides adjacent to the crib mattress.”

“baby bumper pads” to be a hazardous material that may not be shipped or sold to a purchaser in Maryland, effective June 21, 2013.⁴ The Maryland regulation states that a “new” ASTM voluntary standard for these products might replace the ban if the DHMH Secretary determines that products complying with the ASTM standard are not a danger to public health and safety. The regulation also states that the Secretary may suspend the regulation if the CPSC affirmatively finds that the benefits of certain bumpers exceed the risks. According to the DHMH website, the Maryland ban does not apply to mesh crib liners or to vertical bumpers that wrap tightly around each individual crib rail.⁵

CPSC staff is aware of other pending legislative actions related to “crib bumper pads” in Illinois, Missouri, and New York:

- Illinois House Bill (HB) 3761 seeks to ban the sale of bumpers in Illinois, and Illinois HB 2653 seeks to mandate that all bumpers sold or leased within the state meet ASTM F1917 – 12. Both bills explicitly exempt mesh liners.⁶
- Missouri HB 2578 seeks to ban the sale or lease of bumpers in Missouri. The definition of “crib bumper pad” exempts mesh-like products.⁷
- New York Senate Bill 7041 (“S7041”) seeks to ban the sale or lease of bumpers in the state of New York and to prohibit the use of such bumpers in child care facilities or places of public accommodation. This bill exempts mesh-like products and explicitly exempts mesh liners.⁸

III. UPDATE AND REVIEW OF REPORTED INCIDENTS

As staff of CPSC’s Directorate for Epidemiology, Division of Hazard Analysis (EPHA), discusses in Tab C, since the original Petition Briefing Package, staff conducted a broad search of CPSC data sources⁹ using product codes and text searches to identify bumper-related incidents or concerns that were reported to CPSC from January 1, 1990, to March 31, 2016—a

⁴ Md. Code Regs. 10.11.07. The regulation defines a “baby bumper pad” as: “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 a stand.”

⁵ See <http://phpa.dhmh.maryland.gov/mch/SitePages/crib-bumpers.aspx>.

⁶ HB 2653 defines a “crib bumper pad” as “any padding material, including, but not limited to, a roll of stuffed fabric, that is designed for placement within a crib to cushion one or more of the crib’s inner sides adjacent to the crib mattress, but not including mesh liners.” HB 3761 includes an essentially identical definition, except the phrase “but not including mesh liners” is replaced with a separate sentence that states: “‘Crib bumper pad’ does not include mesh liners.”

⁷ HB 2578 defines a “crib bumper pad” as “a pad or pads of nonmesh material including, but not limited to, a roll of stuffed fabric that is designed for placement within a crib to cushion one or more of the crib’s inner sides adjacent to the crib mattress.”

⁸ S7041 defines “crib bumper pads” as “a pad or pads of non-mesh material resting directly above the mattress in a crib, running the surface area of the crib or along the length of any of the interior sides of the crib,” and further states that “‘crib bumper pad’ does not include mesh liners.”

⁹ Specifically, staff searched the DTHS (Death Certificates), INDP (In Depth Investigations), IPII (Injury and Potential Injury Incidents) and NEISS (National Electronic Injury Surveillance System) databases. Staff also examined associated autopsy reports and medical examiner (ME) or pathologist reports, as applicable.

period of more than 26 years. This timeframe is merely an extension of the timeframe staff used in the original Petition Briefing Package, which also examined incidents starting in 1990. In keeping with the original Petition Briefing Package, staff included in its analysis all incidents and reports that mention a crib bumper in the sleep environment or for which staff could determine that a crib bumper was present, even if a bumper was not mentioned explicitly (*e.g.*, a crib-related death in which the in-depth investigation report did not mention a bumper but included a photograph showing that a bumper was installed). Because staff kept the scope very broad, identifying a case as in scope does not necessarily mean that the presence of the bumper was relevant to the incident. This issue is discussed in more detail below, particularly regarding staff's review of the reported fatalities.

A. REPORTED NONFATAL INCIDENTS

EPHA staff's search identified 282 nonfatal incidents and reports of concerns associated with crib bumpers over the 26-year period. Thirty-nine percent (110) of the nonfatal incidents resulted in injury, 57 percent (161) were coded as having no injury, and the remaining 4 percent (11) did not report whether an injury occurred. The age of the child was reported in 213 cases, and most of these cases (163 incidents, or 77 percent) involved a child younger than 12 months old.

Some of the more common hazard scenarios identified among the nonfatal incidents include:

- slat entrapments of the arm or leg (57 incidents);
- head entrapments under or between the bumper and another object (40);
- choking on or ingestion of bumper parts, such as decorative fabric or stuffing (33);
- near-strangulations or entanglements, typically involving a loose bumper tie (28); and
- near-suffocations, with the face reportedly pressed against the bumper (23).

Thirty-seven incidents were classified as "concerns," which include cases that did not directly involve a child, but rather, were problems foreseen by the parent or complainant. Many of these incidents involved difficulty installing the bumper or poor fit in a crib.

Staff identified 25 relevant cases involving bumpers through the National Electronic Injury Surveillance System (NEISS). In these instances, a caregiver brought the child to a NEISS emergency department to be treated for an injury associated with a bumper pad. NEISS member hospitals constitute a probability sample of approximately 100 hospitals in the nation. Twenty-five cases are too few to support a reportable national estimate. For analytical purposes, the 25 cases are considered as incident reports and constitute a minimum number of emergency department-treated injuries associated with crib bumpers.

B. REPORTED FATAL INCIDENTS¹⁰

During the 26-year period examined, staff identified 107 fatal incidents in which a crib bumper was present in the sleep environment.¹¹ All but 8 of the 107 incidents involved a bumper inside a crib. Of the eight incidents involving a bumper outside a crib, three occurred in a bassinet, two in a toddler bed, one in a daybed, one in a play pen, and one on a mattress on the floor. More than half (67) of the reported fatalities have occurred since 2005.¹² Ninety-two percent (98) of fatalities were infants younger than 12 months old, and 63 percent (67) were no older than 4 months. Four fatalities involved children 2 years old or older.

None of the reported fatal incidents was witnessed, but the cause of death in these incidents generally was reported as asphyxia, suffocation, sudden unexpected infant death (SUID), or sudden infant death syndrome (SIDS), a type of SUID. Often, the sleeping environment also included soft bedding, such as pillows or blankets, or stuffed dolls. To staff's knowledge, all bumpers involved in these incidents were traditional crib bumpers.

The multidisciplinary CPSC Crib Bumpers project team thoroughly reviewed the 107 reported fatalities and classified these incidents into the following mutually exclusive hazard patterns or scenarios:

- *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.

¹⁰ These fatal incidents reported to CPSC do not constitute a statistical sample of known probability and do not necessarily include all fatalities from January 1, 1990, to March 31, 2016, where a bumper pad was present in the sleeping environment. However, the reported fatalities do provide at least a minimum number of fatalities during the time period.

¹¹ This total includes 68 of the 71 fatal incidents cited in the Petition Briefing Package. Staff determined that 3 of the original 71 fatal incidents were out of scope because they involved a mesh-sided crib and no bumper was present (2 cases), or staff later found the incident to be a case of an adult overlaying a child in an adult bed without a bumper (1 case).

¹² The year 2005 does not have any particular significance. EPHA staff presented the data in 5-year intervals, and 2005 was the start of one of the intervals.

- *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.

More detailed descriptions of these hazard patterns appear below. Tab D includes tables that summarize the incidents, organized by hazard pattern.

In addition to classifying the reported fatalities into hazard patterns, staff assessed the likely addressability of these fatalities by Commission action. Staff concluded that this assessment was necessary to enable staff to respond to the Commission's direction, as part of its 2013 Record of Commission Action for Crib Bumpers, to review the voluntary standard and evaluate regulatory options. To make this assessment, staff examined the information available in the incident reports to determine the extent to which the bumper's presence contributed to the fatal outcome. Specifically, staff reviewed the fatal incidents with the following question in mind: would the fatality have occurred if the bumper were not present? Staff chose this approach because fatalities that would have occurred even if the bumper was not present are cases in which the bumper did not increase the risk of injury, and improved performance requirements, or even a ban, would have had no effect on the fatality. In contrast, the remaining fatal incidents would be ones that potentially could be addressed by existing performance requirements,¹³ improved performance requirements, or a ban.

The primary difficulties in making such assessments are that all of the incidents were unwitnessed, and the incident reports varied in the type and amount of information available or provided when describing the incident scenario. For example, the quality of some very old incident reports rendered them partially illegible. Some reports provided ambiguous or generic information that did not anticipate a retrospective analysis of this scope, and reenactment photographs or illustrations of how the child was found often were not available. In addition, most cases included other confounding factors, such as the child having a medical condition or illness at the time of the incident, the child being in a prone sleep position, the presence of pillows and other suffocation hazards, and the presence of specialized infant products and other clutter that tend to crowd the sleeping area and contribute to entrapment hazards. Despite these difficulties, staff believes that these incident reports and the information gathered from in-depth investigations are a very rich source of information from which to assess the likely contribution of the crib bumper to the fatality, and the best way to avoid giving undue weight to incidents in which the contribution of the bumper appeared unfounded. Staff collaborated across disciplines to assess the available information and reached consensus on the hazard scenario and

¹³ For those bumpers manufactured before the 2012 ASTM voluntary standard.

circumstances surrounding each fatal incident. This allowed staff of CPSC's Directorate for Health Sciences (HS) to make their best physiological determination.

Based on its review, staff has concluded that 72 of the 107 reported fatal incidents are "unlikely" to be addressable by Commission action, and 9 are "likely" to be addressable to some degree. Staff notes that "unlikely" does not mean impossible, particularly given the uncertainties surrounding many incidents. Yet, these are cases in which staff believes that there was sufficient information to conclude that removing the bumper most likely still would have resulted in death. CPSC staff was unable to assess the addressability of the remaining 26 fatalities because the incident reports lacked sufficient details to determine whether the crib bumper likely contributed to the fatality. These "unknown" incidents typically involved scenarios in which the child was found with his or her head between the bumper and the mattress, pillow, or other soft bedding in the sleep environment; however, staff could not determine the precise orientation of the child's face. Thus, removing the bumper from the environment might have prevented some of these fatalities.¹⁴

Because addressability was assessed in terms of the complete removal of the bumper from the sleep environment, the numbers above indicate the number of reported fatalities that likely could be prevented by maximally stringent Commission action, such as a ban on all bumpers and similar products intended to be installed on the side of a crib. Thus, a ban on all bumpers and similar products would likely have prevented 9 of the reported fatalities and might have prevented some unknown portion of an additional 26 reported fatalities.¹⁵ However, alternative actions, such as improved performance requirements or labeling, or replacing bumpers with alternatives, like vertical bumpers or mesh liners, might prevent only a portion of these fatalities. The likely effectiveness of these other approaches is discussed later in this memorandum.

How staff arrived at the totals above is summarized below, by hazard pattern, and discussed in detail by HS staff in Tab E. In addition, the tables of fatal incidents in Tab D, referenced earlier, include staff's addressability classification for each fatal incident.

1. Incidental

Staff classified 31 of the 107 reported fatalities as "Incidental." These are incidents in which a bumper was present in the sleep environment, but there was no evidence of bumper contact or involvement in the fatality. Staff only classified a reported fatality as "Incidental" if:

- the bumper was not mentioned at all in the incident report,¹⁶ or was mentioned only as being present, but without any mention or indication of involvement;

¹⁴ However, staff notes that most incidents not classified as "unknown," and for which the precise orientation of the face could be ascertained, were ones in which the face was known not to be into the bumper.

¹⁵ If one assumes that unreported infant fatalities in a sleep environment containing a crib bumper occur in the same proportions to those reported to CPSC, then a ban on all bumpers and similar products intended to be installed on the side of a crib would likely have prevented eight percent of the fatalities in which a bumper was present (9 reported fatalities that are likely to be addressable ÷ 107 reported fatalities with a bumper present).

¹⁶ For example, the report described a crib-related death and included a photograph in which a crib bumper was visible; however, the report never mentioned the bumper.

- there was no evidence that the victim was in contact with the bumper at the time of the incident; or
- the cause of death is known to have been exclusively medical in nature and unrelated to the bumper.

Except for those few cases in which the cause of death was known to be exclusively medical, and one case that refers to contact with the top of the head with what appears to have been a bassinet cover rather than a bumper, staff did not classify a reported fatality as “Incidental” if any part of the victim was known to be in contact with the bumper at the time of the incident, even if the victim’s face clearly was not into the bumper.

Examples of fatal incidents that staff classified as “Incidental” include:

- A child was found prone with nothing near the face, and the crib bumper about 6 inches away. (Incident 5)
- A child suffered a severe asthma attack, which caused cardiac arrest. The child had a history of such attacks, and the bumper was specifically determined not to be the cause of death. (Incident 18)
- A child was found prone below a full-size pillow with her head turned to the side. There was no mention of bumper involvement or contact. (Incident 38)
- A child was found within foam wedge positioners with his face pressed against one side of the positioner. No other bedding was near his face. Bumpers, although installed on the crib, were not in contact with the child or mentioned in the reports. (Incident 52)
- A child was found face-down in a sleep positioner, having reportedly suffocated in the blankets, pillow, and sheets that were doubled-over onto the mattress pad. Figure 1 shows an incident reenactment copied from the associated in-depth investigation report. (Incident 58)
- A child was found prone and face-down with a quilt wrapped around her neck. The quilt reportedly was “very constricting.” A bumper was present but was not mentioned as being relevant to the incident, in contact with the child, or otherwise playing a role. (Incident 62)
- A child was found prone and face-down on a decorative quilt that was spread over the mattress. Bumpers were installed, but the report states that there was no indication that the bumpers were found near the victim’s face. (Incident 68)
- A child was found on his back with a nursing pillow and a large stuffed animal over his face. A bumper was installed, but there is no mention of its involvement or contact with the child. (Incident 82)
- A child was found by the father partially prone on a blanket in a crib. The father stated that nothing was obstructing the child’s nose or mouth. The cause of death was



FIGURE 1. Image from IDI associated with incident 58, showing child’s position when found.

determined to be positional asphyxia, due to sleeping prone on soft bedding. (Incident 103)

Given the criteria staff used to classify incidents as “Incidental,” staff concludes that all 31 incidents are unlikely to be addressable by revisions to crib bumper requirements or by a ban on all bumpers.

2. *Contact Outside Crib*

In five reported fatalities, a child was found in contact with a crib bumper outside an infant crib—specifically, in a toddler bed, bassinet, or small daybed.¹⁷ In the original Petition Briefing Package, staff considered such incidents to be out of scope because they involved the use of a bumper in a sleep setting for which it was not intended (see Midgett, 2013; Scheers, 2013; and Wanna-Nakamura, 2013). Despite this, three of these cases are likely to be addressable to some degree because the fatality most likely would not have occurred had the bumper been absent from the sleep environment. Two of these three cases involved a child hanging or becoming suspended on a bumper that was installed in a toddler bed or small day bed; another involved the suffocation of a 5-year-old boy with disabilities in a toddler bed.

Staff concluded that two of the five fatalities involving bumper contact outside a crib are unlikely to be addressable. In one case, the child was in contact with the bumper, but was face-down on the mattress. In the other case, the child’s face was into the bumper. Although the latter case intuitively seems addressable by removing the bumper, both of these cases involved a rocking bassinet or cradle that HS staff believes likely came to a halt in a fixed, tilted position, based on HS staff’s expertise with this product category and information available in the autopsy reports. HS staff notes that this scenario can lead to death by positional asphyxia, even without the presence of a bumper, which is why the mandatory bassinet standard, 16 C.F.R. Part 1218,¹⁸ includes a performance requirement to prevent such a scenario from occurring. Thus, staff concluded that these deaths would have occurred even if the bumper were not present. Staff acknowledges, however, that death by positional asphyxia would take more time than suffocation by nose and mouth occlusion, so the presence of the bumper may have hastened or accelerated the infant’s death. Had a crib bumper not been present, it is conceivable, although unlikely, that a caregiver could have discovered the child and intervened before the positional asphyxia led to the fatality.

3. *Entrapment/Wedging Against an Object in Crib*

Twenty-three reported fatalities involved a child becoming entrapped or wedged between the bumper and another object in the crib, such as a bed pillow, infant recliner, or cushion. Staff has concluded that 15 of these 23 fatalities are unlikely to be addressable, as discussed below. Staff cannot assess the addressability of the remaining eight fatalities with the available information.

¹⁷ Two cases involved a bassinet, two involved a toddler bed, and one involved the small daybed. Three other “Incidental” cases involved a crib bumper outside an infant crib; however, none of these three cases appear to have involved bumper contact or contribution to the fatality.

¹⁸ This standard incorporates by reference ASTM F2194 – 13, *Standard Consumer Safety Specification for Bassinets and Cradles*, with modifications.

Some of the fatalities that are unlikely to be addressable involve entrapment where the child's face is known to have been pointing into the mattress or otherwise away from the bumper, including pointing into the object that was causing the entrapment. For example, 12 incidents involved entrapment between a pillow or cushion and the bumper-covered crib side, and in these cases the child usually was found prone and face-down into the mattress. HS staff has concluded that removing the bumper is unlikely to have prevented these fatalities because 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.

Some fatalities do involve entrapment with the face pressed into the bumper, but the circumstances were such that removing the bumper still would likely not have mattered. For example, staff concluded that none of the five fatalities involving entrapment against an infant recliner is likely to have been addressable by removing the bumper from the environment. All five cases involved infant recliners that were produced by the same manufacturer and have since been recalled.¹⁹ In four of these cases, the infants were found with their upper torsos tilted backwards and their necks hyperextended beyond the edge of the infant recliners, as illustrated in Figure 2. Although the infant's face was into the bumper in these cases, HS staff concluded that this hyperextension was the likely cause of these deaths, and most likely would have occurred and resulted in death, even against a crib side without a bumper installed. Staff notes that death by neck hyperextension would be somewhat longer than death by smothering with complete or near-complete occlusion of the nose and mouth. Thus, it is conceivable that a caregiver could discover the child and intervene. However, staff considers this unlikely because it is dependent on several factors, such as intended sleep time and how often the sleeping child is monitored by a parent.



FIGURE 2. Image from IDI associated with incident 80, showing child's position when found.

4. *Entrapment/Wedging in Perimeter of Crib*

Twelve reported fatalities involved a child becoming 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. The incidents in this hazard pattern consistently involved cribs with crib integrity issues, such as broken slats or missing hardware, or older cribs that likely did not meet the mandatory crib standard. Either scenario can result in excessive gaps between the mattress and crib frame, which is a well-known entrapment hazard.

¹⁹ See <http://www.cpsc.gov/en/Newsroom/News-Releases/2013/Nap-Nanny-and-Chill-Infant-Recliners-Recalled-by-Baby-Matters-LLC-After-Five-Infant-Deaths-CPSC-Firm-Settle-Administrative-Litigation-/>.

Staff has concluded that 8 of these 12 fatalities are unlikely to be addressable because they involved entrapment between two rigid components of a crib, which can result in body or head compression that can lead to death, regardless of a bumper's presence. Some cases were specifically identified as "compression asphyxia" involving the torso. Two of the 12 fatalities are likely to be addressable because they involved a child hanging on the installed crib bumper. However, these two cases involved missing crib slats or a detached crib side, and the fatalities most likely would not have occurred but for these crib integrity issues. The addressability of the remaining two fatalities is unknown because of limited information on the position of the infant's face.

5. *Entrapment/Wedging, Other*

Six reported fatalities involved a child becoming entrapped in some manner other than the previously identified entrapment or wedging categories, such as an entrapment between crib slats or under the bumper. Staff has concluded that three of these six fatalities are unlikely to be addressable. One of these cases involved neck hyperextension, the addressability of which staff discussed previously. The other two cases involved entrapment by something other than the bumper (e.g., crib slats), with the face not pointed into the bumper. Staff was unable to assess the addressability of the remaining three fatalities because staff could not determine the position of the child's face. One of these cases involved a broken mattress support system, which caused the mattress to tilt down in one corner.

6. *Contact Without Entrapment/Wedging*

In 23 of the reported fatalities, the child was found in contact with the crib bumper but there was no indication of entrapment, wedging, or the child otherwise being held against the bumper. Staff has concluded that 10 of these 23 fatalities are unlikely to be addressable, and 4 are likely to be addressable. The addressability of nine fatalities is unknown.

Because incidents in this hazard pattern do not involve entrapment or wedging, staff's assessment of their addressability depends almost entirely upon the orientation of the child's face. For example, 10 fatalities that staff concluded are unlikely to be addressable involved physical contact with the bumper, but contact was with the top of the head, back of the head, or another part of the body, other than the face. Given that the face was not actually into the bumper, and the child was not wedged or entrapped, removing the bumper is unlikely to have prevented these fatalities. The four fatalities that are likely to be addressable generally involved the child positioned with his or her face "into" the bumper without entrapment. However, staff classified one of these four cases (incident 44) as "likely," with reservations, because of the suspicious circumstances surrounding the incident and the child's multiple serious health issues. The nine "unknown" cases generally involved head contact with the bumper, but the orientation of the child's face was unclear.

7. *Contact with Possible Entrapment/Wedging*

Seven reported fatalities involved a child who was found in contact with the bumper, but the associated incident reports lacked sufficient detail for staff to determine whether the child was entrapped or wedged against the bumper. These cases typically described the victims as being

found with their face “wedged between” the mattress and the bumper pad; however, the incident details were such that staff could not tell whether the face of the child was truly entrapped in this space, or if the term “wedged” was being used to describe the orientation of the face relative to the two surfaces.

As suggested above, the cases in this hazard pattern already have limited or ambiguous details about whether the incidents involved an entrapment, and in four of these cases the position of the face relative to the bumper also was unclear. Thus, the addressability of these four cases is unknown. In three cases, however, there were sufficient details to allow staff to conclude that the fatalities are unlikely to be addressable. In two of these three cases, the child was found prone with the face into the mattress. In the other case, the fatality occurred a year after a reported incident with a bumper, and HS staff is unconvinced that the two are related.

C. OTHER BUMPER-RELATED INCIDENT DATA REVIEWS

In February 2016, the *Journal of Pediatrics* published an article titled, “Crib Bumpers Continue to Cause Infant Deaths: A Need for a New Preventive Approach” (Scheers, Woodard, & Thach, 2016).²⁰ This publication described 42 infant deaths from 1985 to 2012 that the authors directly attributed to the presence of crib bumpers, and 6 additional fatalities that the authors consider likely related to bumpers. The lead author, NJ Scheers, Ph.D., is a former CPSC employee, who previously had prepared an analysis of crib bumper deaths that was incorporated into the original crib bumper Petition Briefing Package (Scheers, 2013). The analysis of infant deaths in the 2016 article appears to be identical to the assessment that Dr. Scheers completed for the 2013 briefing package. The new analysis of the injuries by Scheers and colleagues was not available to staff.

As HS staff discusses in Tab E, staff took a different approach than Scheers and colleagues when evaluating the data for the current briefing package. CPSC staff reviewed and evaluated all of the available records for each case file, including first responder’s reports, medical examiner reports, coroner investigation reports, scene reenactments, autopsies, patient medical histories, and CPSC investigational findings. Staff believes that the current approach is more consistent in defining scenarios and the likelihood that the bumper contributed to the fatalities.

IV. SAFETY BENEFITS OF BUMPERS

Crib bumpers generally are promoted as providing two safety benefits: (1) preventing infants from getting their limbs caught between crib slats, and (2) protecting infants from impacts against the sides of a crib. Consistent with these claims, the original petition, public comments on the petition, and online consumer reviews refer to traditional crib bumpers as protecting active babies against limb entrapments and head impacts. In the Commission’s Final Rule for Full-Size and Non-Full-Size Baby Cribs, published on December 28, 2010 (75 Federal Register 81766), CPSC staff noted that infants getting their limbs caught between crib slats accounted for about 12 percent of the 3,520 incidents involving full-size cribs and cribs of an undetermined size. Staff also noted that some injuries requiring hospitalization involved limb entrapments or impacts with the crib structure after the child fell within the crib.

²⁰ This article was initially published online on November 24, 2015.

EPHA staff has found that slat entrapments of the arm or leg account for 57 of the 282 reported nonfatal incidents associated with crib bumpers (see Tab C). However, as staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF), notes in Tab F, in about one-third (18) of these cases, a bumper was not present at the time of the incident; the incident was identified as bumper-related because the consumer mentioned a bumper as a possible solution, stated that he or she did not want to use a bumper, or said that they were advised to use a bumper to prevent future incidents. Although the residual 39 nonfatal limb-entrapment incidents illustrate that crib bumpers do not completely prevent access to the side of a crib, bumpers still can provide a safety benefit, if their presence effectively limits injuries. Thirty-nine limb entrapments associated with crib bumpers over a 26-year period is a small number of incidents, and only 28 of these 39 nonfatal incidents reportedly resulted in some type of injury. Thus, staff can confirm only about one injury per year, on average, involving limb entrapment in a crib with a bumper installed.²¹ Because a bumper functions as a barrier between the child and the side of a crib, bumpers likely prevent some incidents and injuries involving limb entrapment or crib-structure impact that otherwise would have occurred. According to EC staff, more than half of the estimated 9.2 million cribs in use are equipped with crib bumpers (see Tab B). Thus, it seems reasonable to conclude that the number of incidents and injuries cited in the previous paragraph, regarding the Commission's Final Rule for Full-Size and Non-Full-Size Cribs, would increase if crib bumpers did not exist or were removed from the market. Staff is unable to quantify this increase, however.

As staff noted earlier in this memorandum, Chicago, IL, and Maryland have banned the sale of crib bumpers. A claim advanced by the original petitioner that staff must consider seriously is that eliminating or banning crib bumpers may encourage caregivers to use other soft bedding or makeshift materials as an alternative protective barrier against the crib structure. Staff is not aware of any data on these types of consumer behaviors in the locales that have enacted a ban on crib bumpers, and cannot say with certainty whether consumers are likely to engage in these behaviors. However, many consumers continue to put soft bedding in cribs, despite warnings against such practices.²² In addition, some of the reported fatalities that staff examined involving crib bumpers included cases of consumers using cushions as makeshift crib sides, or using the bumper to restrict the child's access to openings or gaps. Staff also is aware of other crib-related incidents in which soft bedding was used to fill in gaps. Thus, it seems reasonable to conclude that at least some consumers are likely to use soft bedding to restrict a child's access to the side of a crib if bumpers were not available. Using soft bedding in this way would likely lessen any increase in incidents and injuries involving limb entrapments and impacts with the crib structure. However, because soft bedding is a known suffocation hazard, such use most likely would increase the incidence of fatal suffocations in cribs. Continued and consistent messages about

²¹ Staff recognizes, however, that there may be additional slat-entrapment incidents involving cribs with bumpers installed that were not captured because they did not report the presence of the bumper.

²² For example, the Commission's Final Rule for Full-Size and Non-Full-Size Baby Cribs noted that extra bedding in cribs accounted for the majority of infant deaths in cribs or other sleeping products (75 FR 81766). The Final Rule references CPSC staff's briefing package, which states: "The number one hazard shown in the fatality data is associated with caregivers adding extra bedding, such as pillows or comforters, to the cribs"; and "[b]oth ASTM F 1169-10 and F 406-10 [the then-current ASTM voluntary standards for full-size and non-full-size cribs] already contain labeling requirements that point out the deadly nature of this hazard" (Howell & Edwards, 2010, p. 12).

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.

V. EFFECTIVENESS OF ASTM F1917

As staff mentioned earlier, the voluntary standard ASTM F1917, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*, establishes requirements for crib bumpers in the United States. The current version of this standard, ASTM F1917 – 12, includes several performance requirements that are relevant to or specific to crib bumpers, including the following:²³

- Bumper “attachment means”—flexible ribbons, strings, hook and loop straps, ties, and similar devices used to attach a bumper to a crib—must not exceed 9 inches.
- Bumpers must be capable of being secured at or near all corners and at the midpoints of the long sides of the crib, or, if the bumper is intended for circular cribs, must be capable of being secured at intervals not exceeding 26 inches.
- Bumpers manufactured of fabric and filled with a fibrous material must be capable of being pulled its full length through a test fixture containing a 2-inch slot, essentially limiting the maximum thickness of a bumper to 2 inches.
- Bumper ties must not fully detach from the bumper after a 20-pound tensile force is applied perpendicular to, and away from, the ties’ attachment point.

As ESHF staff discusses in Tab F, ASTM F1917 – 12 also specifies product and packaging marking requirements, including required warning labels, for crib bumpers. Specifically, the voluntary standard states that each crib bumper or crib bumper panel²⁴ must include the following warning statements:²⁵

WARNING

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.

²³ See Massale (2013) for a more complete discussion of F1917 – 12 requirements.

²⁴ If the bumper consists of multiple panels that can be used separately.

²⁵ The version of the safety alert symbol (a symbol used to indicate a hazard and composed of an equilateral triangle surrounding an exclamation mark) 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.

The voluntary standard specifies letter height requirements for this warning text and states that warnings must be formatted in accordance with the current version of ANSI Z535.4, *American National Standard for Product Safety Signs and Labels*. The standard also states that the warning labels must be “permanent” and “conspicuous”; however, the standard neither defines these terms, nor specifies performance requirements for assessing conformance to these two requirements. The standard does not specify requirements for instructional literature that would accompany crib bumpers or any other infant bedding or accessories covered by the standard.

A. ADEQUACY OF PERFORMANCE REQUIREMENTS

1. *Bumper Thickness*

Based on the available incident data, the risk of suffocation is the primary hazard associated with crib bumpers. As HS staff notes in Tab E, and as staff of CPSC’s Directorate for Laboratory Sciences, Division of Mechanical Engineering (LSM), notes in Tab G, the ASTM 1917 performance requirement that is most directly aimed at addressing the potential suffocation hazard is the 2-inch maximum thickness requirement. According to the standard, other ASTM standards for padded items with which infants interact, such as play yard pads, have similar maximum thickness requirements, and items up to 2 inches thick are “not known to present a suffocation hazard” (subsection X1.1). HS staff helped develop the 2-inch maximum thickness requirement for the other standards referenced in ASTM F1917, and staff believes that this dimension is adequate for those applications, where the padding is being used under the infant as a sleep surface. For example, HS staff notes that the 2-inch surface thickness has not been known to present a suffocation hazard as a sleep surface when used in a play yard. Given this finding, staff has concluded that there is no evidence to support a more restrictive thickness requirement, particularly considering that bumpers are oriented vertically, rather than being positioned directly under the infant.

2. *Bumper Firmness*

An additional performance requirement that staff has considered for crib bumpers that may be relevant to the suffocation hazard would be to specify a limit on the “softness” of a bumper, or to specify some minimum level of bumper “firmness.” As HS staff notes in Tab E, surface firmness—that is, the ability of a surface to conform around a child’s face—is an important factor related to suffocation hazards. Although the thickness requirement addresses firmness somewhat, in that a bumper with more filling will be thicker and will tend to conform to the face more readily than a bumper that is thinner and contains less filling, the thickness requirement does not measure firmness directly. Additionally, staff can conceive of a bumper that would meet the F1917 maximum thickness requirement, yet be filled with unusually soft or spongy material that would readily conform to the face of an infant.²⁶

²⁶ Such material, in fact, might be what would allow the bumper to pass the maximum thickness test, because the test involves pulling a bumper through a test fixture rather than measuring the bumper thickness.

An Australian/New Zealand standard, AS/NZS 8811.1:2013, *Methods of Testing Infant Products: Part 1: Sleep Surfaces—Test for Firmness*, is the only known standard that contains a performance test of this type. The test method is intended to assess the firmness of infant mattresses and other horizontal sleep surfaces for “excessive compression.” As LSM staff discusses in Tab G, the test is performed using a device that consists of a circular disk of a certain size and weight, with an

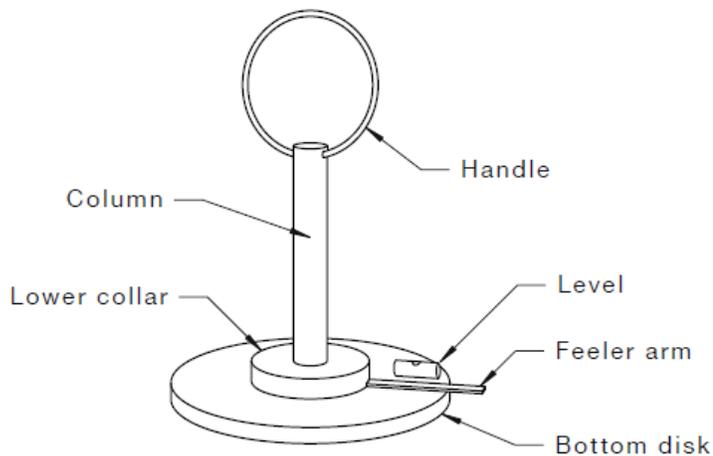


FIGURE 3. Test device from AS/NZS 8811.1:2013.

attached “feeler arm” that extends over the edge of the disk. An illustration of this device appears in Figure 3. The device is placed on the sleep surface, which compresses under the device’s weight. If the compression is enough to cause the feeler arm to touch the sleep surface, the surface fails the test and is considered not sufficiently firm. The test method was developed to replicate, consistently and objectively, the subjective assessments of appropriate sleep surfaces, in terms of firmness, previously made by an expert panel. A similar test method was developed independently in Germany, as part of a study of infant suffocations (Shlaud et al., 2010), but it used a two-piece apparatus consisting of a base plate, which is set upon the sleep surface, with a circular hole into which a cylindrical weight was inserted. The vertical distance that the weight drops into the surface is then measured. The performance of the AS/NZS 8811.1 test device reportedly matches that of the German apparatus.

HS staff believes that the test method specified in AS/NZS 8811.1 has some value and could add an extra measure of safety to provide additional protection against mechanical suffocations with crib bumpers. Thus, although it is unclear whether such a requirement would have addressed any of the nine fatalities that staff has determined to be likely to be addressable, HS staff recommends that the ASTM Infant Bedding subcommittee consider adopting this test method as an additional performance requirement for crib bumpers in ASTM F1917 (see Tab E). Staff notes, however, that ASTM F2933, *Standard Consumer Safety Specification for Crib Mattresses*, has not yet adopted the AS/NZS 8811.1 performance test, even though infant mattresses are the exact types of products for which this performance test is intended. Reaching consensus with the ASTM Infant Bedding subcommittee to adopt such a requirement for crib bumpers, which are not intended as sleep surfaces, may be even more challenging.

In addition, the testing of crib bumper samples carried out by LSM staff suggests that a “firmness” requirement might not have a large effect on the current bumper market or on the ability to identify hazardous bumpers. As part of its assessment for the Crib Bumpers project, EC staff identified additional manufacturers and retailers of mesh, vertical, and traditional crib bumpers, and identified products that varied in pattern design, thickness, number of ties, and material composition. Based on this updated market research and subsequent team discussions, CPSC staff purchased samples of 19 different products for examination and testing: 16 different crib bumpers and 3 mesh liners. Three of the crib bumpers were “vertical” or “mini” bumpers,

referred to here as “vertical/mini” bumpers. LSM staff examined these 19 new samples as well as 7 samples previously in its possession.

LSM staff’s testing of these 26 total crib bumper samples revealed that the test results for the ASTM F1917 maximum thickness requirement tend to mirror the test results for AS/NZS 8811.1.²⁷ That is, products that passed the maximum thickness requirement of ASTM F1917 also tended to pass the firmness requirement of AS/NZS 8811.1, and products that failed one tended to fail the other. Specifically, LSM staff found that 22 of the 26 samples clearly passed both tests, and one of the 25 samples clearly failed both tests. The remaining three samples passed the maximum thickness requirement, but their ability to pass or fail the firmness requirement depended on the part of the bumper upon which testing was performed. For example, if the test device was centered on a continuous part of the bumper, the bumper would pass; however, if the test device was centered on a seam or crease in the bumper’s surface, the bumper would fail. Because such a failure is not being caused by a lack of firmness, which is what the device is intended to measure, such failures arguably are false ones. Furthermore, staff cannot say with confidence that the two bumper samples that potentially fail the AS/NZS 8811.1 firmness test, but pass the ASTM F1917 maximum thickness requirement, are more hazardous than the bumpers that clearly passed both. Given this, and because the test results for the ASTM F1917 maximum thickness test are highly predictive of the results for the AS/NZS 8811.1 firmness test, adding a firmness requirement for crib bumpers might not have a practical impact on suffocations for bumpers constructed similarly to current products, despite the seemingly obvious benefits of such a requirement.

3. *Bumper Permeability or Continuity (Alternative Products)*

As HS staff discusses in Tab E, a 1991 study reported that the rebreathing of carbon dioxide (CO₂), or hypercapnia, was the cause of multiple infant deaths on infant bean bag cushions. The study hypothesized that this mechanism might be associated with an increased risk of SIDS. In later studies, the authors applied the “CO₂ rebreathing hypothesis” to an infant crib environment and suggested that lowering or dispersing the level of CO₂ would be an effective countermeasure to reduce the risk of SIDS. This hypothesis has led to the development of infant sleep products that often include manufacturer claims of providing increased airflow or reduced CO₂ accumulation within the crib, or describe the products as being “breathable.” These products include:

- vertical or mini bumper sets composed of multiple cushioned pads that enshroud one or two crib slats at a time;
- mesh crib liners, which tend to have little to no padding, but encircle the crib perimeter like a traditional bumper, and claim to be “breathable”; and
- bumper alternatives that look like traditional continuous bumpers, but claim to have “breathable” properties.

²⁷ Additional testing was performed using the German apparatus, but these results were the same as those for the AS/NZS 8811.1 test device. See the LSM staff memorandum in Tab G, for more details.

Like traditional bumpers, these products are intended to provide some protection against impacts with the crib side, against limb entrapments in crib slats, or both, while allowing increased airflow near an infant's face. HS staff has found no published studies demonstrating the effectiveness of these products in reducing the risk of SIDS by preventing rebreathing of CO₂. Moreover, staff is not aware of any safety standards established for such products. Given that the prone sleep position is a known high-risk factor for SIDS and suffocation, HS staff also has expressed concerns that consumers may infer that use of these "breathable" products would allow an infant to be safely put to sleep in the prone position, or that there is a decreased need for caregiver vigilance. However, staff cannot confirm that consumers who use these products are making such inferences.

Staff agrees that in an entrapment scenario in which an infant's face is pressed against a bumper, without special circumstances such as the infant's neck being hyperextended, these products are likely safer than traditional bumpers. However, HS staff also believes that the increased safety of these products is limited to this specific scenario and is not due to the prevention of rebreathing CO₂, but rather, to the prevention of mechanical suffocation, or smothering.

To assess the likely effectiveness of these products on smothering incidents, and thus, the potential effectiveness of performance requirements that reflect the properties of these products, HS staff evaluated whether the nine likely addressable fatalities identified during staff's review of the incidents might have been prevented by the use of a mesh liner or vertical bumper. Staff concluded the following about these nine fatalities:

Mesh Liners

- Three of the nine reported fatalities are likely to be addressable by using a mesh liner. All three cases involved contact without entrapment or wedging.
- Five reported fatalities are unlikely to have been addressable by using a mesh liner. All five cases are ones that involved hanging or strangulation on a bumper, and a continuous mesh liner would pose the same strangulation hazard.
- The addressability of the remaining fatality by using a mesh liner is unknown because this case lacked sufficient information for staff to draw a conclusion.

Vertical Bumpers

- Four of the reported nine fatalities are likely to be addressable by using vertical bumpers. All four cases involved contact without entrapment or wedging, and three of the four are the same cases that also were identified as being addressable by a mesh liner.
- Three reported fatalities are unlikely to have been addressable by using vertical bumpers. Two of these three cases involved bumper contact outside a crib, and therefore, involved products on which vertical bumpers cannot be installed. These two cases also involved installation of the bumper across the bed entrance to keep the

- child in the sleep setting.²⁸ The other case involved entrapment in the perimeter of a broken crib, a scenario that would not be preventable by vertical bumpers.
- The addressability of the remaining two fatalities by using vertical bumpers is unknown. One case lacked sufficient information for staff to draw a conclusion. The other case involved entrapment in the perimeter of the crib because of missing slats. Thus, the effectiveness of vertical bumpers would depend on the size of this gap if vertical bumpers were installed.

Based on the above findings, performance requirements that require bumpers to offer a level of permeability that is similar to mesh liners are likely to have prevented about three, or possibly four, of the nine most likely addressable reported fatal incidents associated with crib bumpers over the 26-year period examined by staff. Performance requirements that only allow for non-continuous bumpers, like vertical bumpers, are likely to have prevented four, or possibly six, of these nine fatalities. LSM staff identified possible approaches and test methods for assessing bumper permeability, but staff has been unable to identify a threshold value for permeability that would be considered acceptable. If staff were to promote a permeability requirement for crib bumpers, staff could use the permeability of existing mesh liners as the default threshold that all bumpers must meet. However, there seems to be little basis for concluding that any level of permeability below this threshold would be unacceptable.

As staff discussed earlier, vertical/mini bumpers are designed to enshroud one or two slats at a time. The intent of these products seems to be to provide some protection against impacts with the crib side, while allowing increased airflow through the crib. These products also claim to keep infants' limbs inside the crib, by narrowing the spaces between the slats; however, reduced open spaces remain to provide the advertised increase in airflow. As ESHF staff discusses in Tab F, during rulemaking for full-size and non-full-size baby cribs, staff of CPSC's Office of Hazard Identification and Reduction (EXHR) specifically considered the possibility of addressing limb entrapment injuries by altering the spacing requirements for crib slats. EXHR staff noted that although limb entrapments occur with high frequency, and some associated fractures have been reported, narrowing the spaces between slats would still entrap the limbs of smaller infants or entrap smaller body parts of larger infants (Midgett, 2010). Accordingly, staff did not recommend altering spacing requirements for crib slats. Although vertical bumpers could be designed to eliminate the spacing between slats, one of the marketed advantages of these products—increasing airflow through the crib—would largely disappear, and the result would be an essentially continuous padded crib side like traditional crib bumpers offer. Vertical/mini bumpers might offer an advantage over traditional bumpers because they may be less prone to sag, but this likely depends on the specific bumper design and accompanying installation instructions.

²⁸ HS staff argues that vertical bumpers are not applicable in these cases because such bumpers cannot be installed in these locations. However, one could argue that if performance requirements were such that only vertical bumpers were available, then such bumpers could not be installed in these locations and, therefore, would not be present to pose a suffocation hazard. If true, these two cases actually are likely to be addressable by vertical bumpers. Yet, consumers might use other substitute products in these locations if the goal is to keep children contained in the sleep environment, and these substitute products could present similar hazards.

B. ADEQUACY OF WARNING REQUIREMENTS

As ESHF staff notes in Tab F, the use of warnings is viewed universally as less effective than either designing the hazard out of a product or guarding the consumer from the hazard, because warnings do not prevent consumer exposure to the hazard. Rather, warnings rely on persuading consumers to alter their behavior in some way to avoid the hazard. Nevertheless, warnings can be useful when redesigning or guarding approaches are not feasible.

The lack of recent strangulation fatalities suggests that the existing warning language that instructs consumers to position ties securely to the outside of the crib has been adequate to address the strangulation hazard. Staff believes that the suffocation-related warning language, which emphasizes properly installing the bumper and making sure the bumper remains properly installed, could be more effective if it included more explicit descriptions of how the bumper should look when it has been installed properly (*e.g.*, “keep bumper tight against side of crib”). However, the available data suggest that few incidents involve loose or sagging bumpers. Thus, such a change is unlikely to prevent many fatalities, even if the warning were effective at getting consumers to comply. The current warnings also instruct consumers to remove the bumper when the child can sit up unaided or can pull themselves to a standing position, but do not explain that removal is important to avoid the possibility of children using the bumper to climb out of a crib. Nevertheless, none of the fatal incidents staff examined clearly involved this scenario. Therefore, the need for additional explanatory material is not indicated by the fatalities analyzed.

ESHF staff has considered several other revisions and additions to current warning requirements that might reduce the risk of death associated with crib bumpers, such as:

- providing additional warning statements about entrapment involving other products in a crib, bumper use in a broken crib, or bumper use in products other than full-size cribs;
- revising the format requirements to clarify that the warnings must conform to all warning format requirements of ANSI Z535.4, or adding more stringent format requirements;
- adding specific placement and permanence requirements for the required warnings; and
- adding requirements for instructional literature that must accompany the products.

The ASTM Infant Bedding Subcommittee Task Group is already considering some of these revisions and additions. However, several issues are likely to limit their effectiveness, so few fatalities are likely to be addressed through such revisions. A detailed discussion of these issues appears in the ESHF staff memorandum in Tab F.

C. VOLUNTARY STANDARD CONFORMANCE

The overall effectiveness of the ASTM voluntary standard not only depends on the adequacy of the voluntary standard provisions, but also on the level of industry conformance to that standard. Comprehensive data on the current level of industry conformance to the ASTM F1917 voluntary standard are not available. However, as staff discussed earlier, EC staff identified additional manufacturers and retailers of mesh, vertical, and traditional crib bumpers, and CPSC staff purchased new samples of 19 different products for examination and testing: 16 different crib bumpers and 3 mesh liners. Three of the crib bumpers were “vertical/mini” bumpers. Although these samples are not necessarily statistically representative of the population of bumpers on the

market, they reflect the range of products currently on the market and provide some insight into whether current crib bumper manufacturers attempt to comply with the voluntary standard.

LSM staff examined the samples to assess the extent to which they conform to various bumper-relevant performance requirements of ASTM F1917 – 12. As staff discusses in Tab G, 18 of the 19 newly purchased samples conform to the 2-inch thickness requirement. All 19 newly purchased samples include an “attachment means” that could be tested for conformance to the standard. All 19 met the strength requirement, and 15 met the 9-inch length requirement.

ESHF staff examined the new sample products in terms of conformance to the ASTM F1917 – 12 warning requirements. As staff discusses in Tab F, nearly half (7) of the 16 bumper samples, which includes all three of the vertical/mini bumper samples, lacked a warning label. Even if one ignores the vertical/mini bumpers, nearly one-third of the remaining bumper samples (4 of 13) did not include a warning. Of the nine crib bumper samples that included a warning, all but one included the required warning content; however, none of the warnings fully conform to the format requirements. Specifically, four of the nine samples fail to meet the letter-height requirements for warning text, and none of the nine samples fully conform to ANSI Z535.4 – 2011. The most common ANSI Z535.4-conformance failure was to the color requirements, which specify that hazard labels relying on the signal word “WARNING” must have a signal word panel consisting of safety black text on a safety orange background; none of the warning labels include an orange signal word panel.

In conclusion, conformance to ASTM F1917 – 12 by the crib bumper industry appears to be mixed, with relatively high conformance to the performance requirements, lower conformance to the warning content requirements, and nonconformance to the warning format requirements.

D. FATALITIES OVER TIME

One possible indication of the effectiveness of the ASTM F1917 voluntary standard in addressing the suffocation hazard—one that could account for the effectiveness of the requirements themselves, as well as conformance to those requirements—would be a reduction in suffocation fatalities after relevant voluntary standard provisions were published. The provisions most directly relevant to the suffocation hazard would be those related to the 2-inch maximum thickness requirement and the warning language requirement pertaining to properly installing the bumper and making sure the bumper remains properly installed. Both requirements were added to the 2012 version of the voluntary standard. In all likelihood, there has not been sufficient time to assess the impact of these provisions. Furthermore, given the overall infrequency of potentially addressable suffocations involving crib bumpers, a pre- versus post-publication assessment of the effect of these provisions on suffocations may prove extremely difficult, even if the post-publication timeframe were longer. Staff notes, however, that the most recent fatality that is likely to be addressable, and therefore, attributable in part to the bumper, happened in 2007 (see staff’s earlier discussion, starting on p. 6). This date was nearly a decade ago and precedes the publication of the bumper-relevant thickness and warning statement requirements in ASTM F1917 by roughly 5 years. Thus, none of the fatalities that staff concludes is likely to be addressable has occurred since the publication of those requirements. Nevertheless, staff is unable to say whether this finding is a result of the voluntary standard requirements.

Staff also points to the lack of strangulation fatalities reported since 1990, as an example of how provisions that are added to the ASTM voluntary standard might be effective in addressing fatalities. Staff is aware of three bumper-tie strangulations that occurred in the 1980s. These cases were presented to the ASTM subcommittee and resulted in a provision that restricted tie lengths to 9 inches (Midgett, 2013). Since then, staff is not aware of any fatal incidents involving strangulation on bumper ties. Although staff cannot directly link the ASTM provision to the apparent elimination of strangulation fatalities, the data suggest that these two could be related.

Related to this issue, staff noted earlier that although staff examined incidents going back to 1990, more than half (67) of the 107 reported fatalities have occurred since 2005, and roughly one-third (41) have occurred since 2010 (see EPHA staff memorandum in Tab C). The implication is that bumper-related fatalities have been increasing. However, these incidents are only reported fatalities and may not represent the true number of fatalities involving bumpers over time. Furthermore, this pattern could be due to increased reporting of bumper presence, rather than increases in bumper-contributing suffocations. This hypothesis is bolstered, somewhat, by EPHA staff's finding that the number of reported fatal incidents in which the bumper was found to be incidental to the fatality also has increased in recent years. For example, about three-quarters (24) of the 31 "Incidental" cases have occurred since 2005, and more than half (17) have occurred since 2010. Thus, the number of bumper-related fatalities having no evidence of bumper contact or involvement has been increasing over time, with most of the fatalities occurring recently. This finding suggests that fatalities in which a bumper was present are more likely to be reported as being associated with a bumper, but that the bumper often is unlikely to have caused or contributed to the death.

VI. PRELIMINARY ESTIMATE OF SOCIETAL COSTS

As EC staff discusses in Tab B, important factors to consider when evaluating possible regulatory options intended to address the suffocation risk associated with crib bumpers include the societal costs associated with bumper pad injuries and deaths, and the likely benefits that might be derived from reducing societal costs in the future.

As staff noted earlier, in its review of the reported fatalities, 72 of the 107 deaths from 1990 through March 2016 are considered unlikely to have been addressable by a product safety rule. Of the remaining deaths, 9 are likely to have been addressable by an effective product safety rule, and the addressability of 26 is unknown, because they were cases in which staff cannot draw a conclusion about whether removing the bumper would have prevented the death. If one were to allocate these 26 "unknown" cases proportionally to the 81 total "likely" and "unlikely" cases, then staff estimates that 12 fatalities (*i.e.*, the 9 deaths likely to be addressable and an additional 3 deaths for which the addressability was unknown) may be addressable by removing the bumper, or a ban on all bumpers and similar products that install along the sides of a crib. This total corresponds to an average of about 0.46 deaths per year during the approximate 26-year timeframe examined by staff, or roughly one death every 2 years.²⁹

²⁹This estimate of 0.46 addressable deaths per year, combined with an estimate of about 5.3 million crib bumpers in use, suggests an annual rate of about 0.087 deaths per million crib bumpers in use. This rate of death compares with

CPSC staff also reviewed reported nonfatal injuries that occurred in cribs equipped with bumpers over the same 26-year period. EPHA staff noted that, of the approximately 110 injuries reported, 25 were reported through NEISS; the small NEISS sample did not meet the criteria to serve as a basis for a national estimate of injuries. Of the 25 reported cases, only one involved a near-suffocation (anoxia), and the role of the bumper was undetermined. From the limited data available, the annual number of injuries, although unknown, is probably very small.

If each of the estimated 12 deaths since 1990 that may have been prevented by removing the bumper was assigned a cost of \$8.7 million, based on current estimates of the value of statistical life in the empirical literature, the average annual societal costs associated with these deaths would be about \$4 million, in 2014 dollars. This estimate excludes societal costs associated with the unknown, but probably small, number of nonfatal injuries. Thus, the total annual societal costs associated with bumper deaths and injuries may be somewhat greater than the \$4 million estimate.

If approximately 5.3 million bumpers were in use in 2013, and annual societal costs attributed to bumper suffocations were approximately \$4 million, then the annual societal costs may have been about \$0.75 per crib bumper in use. If bumpers have an expected average useful life of 1 to 2 years, the lifetime present value of the societal costs would be about \$0.75 to \$1.44 per bumper pad. This range represents an estimate of the maximum value of potential benefits per unit that could be achieved by remedial action that is 100 percent effective—that is, one that eliminated the risk and prevented all deaths.³⁰ This estimate could be slightly higher if all deaths have not been reported to the CPSC, or if nonfatal injuries attributable to bumpers have not been quantified. On the other hand, the estimate does not take into account any unquantifiable safety benefits, if any, that might be attributable to the bumpers.

VII. CPSC REQUEST FOR INFORMATION

On February 16, 2016, the Commission published a Request for Information (RFI) in the *Federal Register* that sought information from stakeholders related to performance requirements for, and the safety benefits of, crib bumpers to supplement the information, standards, and data currently available to CPSC staff (81 FR 7765). In particular, staff was interested in obtaining data regarding the safety risks and benefits associated with various types of crib bumpers, and the empirical basis for, and effectiveness of, existing safety standards.

The public comment period for the RFI closed on April 18, 2016, and CPSC received 10 comments. These comments can be found in the docket for this petition, here:

<https://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dt=PS;D=CPSC-2012-0034>.

Summaries of the comments appear below.

about 4.5 deaths per million cribs in use and suggests that crib bumpers account for only a small proportion of crib-related deaths.

³⁰ By way of comparison, if half of the 26 “unknown” cases contributed to the child deaths, about 22 deaths potentially would have been attributable to the bumpers, or about 0.85 deaths per year. Under this scenario, the lifetime present value of the societal cost would range from about \$1.40 to about \$2.68 per bumper pad. If the remedial action prevented only about half of the deaths, the benefits would amount to about \$0.70 to \$1.34 per unit.

A. HAZARDOUS BUMPER FEATURES

CPSC staff sought information pertaining to specific crib bumper features and characteristics that might contribute to the risk of mechanical suffocation, or smothering, and performance requirements and tests that might be used to assess this risk. Staff also inquired about evidence that support claims that bumpers present a risk of suffocation from the “rebreathing” of CO.

Some comments made general assertions about the riskiness of bumpers, but did not include supporting test data. Some comments suggested that the AS/NZS 8811:2013 test device and procedure could screen out excessively soft bumpers, but did not provide any data or support for this claim. One comment referred to two proprietary tests by Intertek to measure suffocation and carbon dioxide (CO₂) rebreathing, but did not provide specifics about the procedures. Some comments asserted that rebreathing is relevant to crib bumpers, but did not provide or cite any specific test data or evidence to support this claim. One comment asserted that only an “infant breathing model” could assess breathing obstruction or rebreathing of CO₂.

B. SAFETY BENEFITS OF BUMPERS

CPSC staff sought information about the possible benefits of crib bumpers. Some commenters stated that bumpers offer no safety benefits at all, but some specific benefits cited by commenters include the following:

- preventing minor bumps, bruises, contusions, and similar injuries, sometimes specific to the head, from impacts with the side of a crib;
- preventing arm and leg entrapments within the spaces between crib slats;
- offering improved quality of life, as a result of fewer sleep interruptions from crib-side impacts or limb entrapments between slats;
- preventing the substitution of more dangerous items or products for bumpers; and
- keeping the child safe from falling out of a crib.

Although the comments identified these possible safety benefits for bumpers, some respondents stated that crib bumpers were limited in the extent to which they could realize these benefits. The respondent who mentioned that bumpers may prevent more dangerous products, such as pillows, from being placed in the crib, believes that this situation likely would be short-lived and that parents can and will learn that a bare crib is safest.

C. STANDARDS AND REQUIREMENTS FOR BUMPERS

CPSC staff sought information related to current standards and possible additional or alternative performance requirements for crib bumpers to address the risk of suffocation. The comments seemed to confirm that, aside from state or regional bans, ASTM F1917, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*, is the only known standard that contains performance requirements for crib bumpers. Commenters stated that the 2-inch thickness requirement of that standard serves to eliminate pillow-like bumpers from the marketplace; another comment suggested that this requirement has been effective, based on the lack of a “proximate causal connection” between an ASTM-compliant bumper and a fatality. In contrast, some commenters claimed that there is no support for the 2-inch thickness requirement.

One comment referred to the position of the American Academy of Pediatrics (AAP), which states that any traditional bumper is unsafe, regardless of its thickness.

Some commenters could not identify additional requirements that might address the risk of suffocation and suggested that the only alternative was a ban on crib bumpers. However, one commenter suggested a more specific ban on all bumpers that are horizontal or that secure with ties or hook-and-loop fasteners. Some commenters recommended some form of “breathability” or air permeability requirement. One suggested the use of an “infant breathing model,” and another suggested minimum air permeability requirements when tested to ASTM D737, *Standard Test Method for Air Permeability of Textile Fabrics*, except for a 1-inch trim height at the top and bottom of the product. Another comment noted that testing of its product found the product to be safer than the AAP standard of a firm crib mattress covered with a sheet.

D. “BREATHABILITY” AND BUMPER ALTERNATIVES

CPSC staff sought information on the risks associated with bumper alternatives, such as mesh liners and vertical bumpers. Several commenters asserted that “breathable” mesh or similar materials can help mitigate the risk of suffocation and CO₂ rebreathing; some comments pointed out the differences in permeability between traditional bumpers and some of these products, like mesh liners. Many comments stated that the available incident data suggest that these bumper alternatives do not pose the same suffocation risk as traditional bumpers. These commenters cited the lack of suffocations on these products within the data, or they noted that only traditional bumpers have been referenced as contributing factors in suffocation fatalities as contributing factors. The only incidents associated with these products that are cited in the comments involve one case in which a child’s head was pressed against a mesh liner, leaving red marks on the child’s face, and two cases involving limb entrapments that occurred even though a mesh liner was present and that did not result in injury requiring medical attention. However, some comments stated that even mesh or “breathable” bumpers can lead to asphyxiation. One comment discusses the various benefits of vertical bumpers over other “horizontal” products, such as mesh liners, which the commenter argues can still pose a strangulation hazard, particularly if these horizontal-oriented products rely on ties or Velcro to attach to the crib.

VIII. REGULATORY OPTIONS

In the Record of Commission Action for crib bumpers (see Tab A), the Commission directed staff to describe the regulatory options the Commission may take to address the risk of injury. Staff has identified four rulemaking paths that the Commission’s statutes provide to address the suffocation risk associated with crib bumpers:

- Promulgate a mandatory standard under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA).
- Promulgate a mandatory standard under section 7 of the CPSA.
- Promulgate a mandatory standard under section 3 of the Federal Hazardous Substances Act (FHSA)

- Ban crib bumpers under section 8 of the CPSA.

A. MANDATORY RULE UNDER CPSIA SECTION 104

If the Commission determines that crib bumpers are “durable infant or toddler products,” it could propose a rule under section 104 of the CPSIA, which 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 mandatory consumer product safety standards for durable infant and toddler products. These mandatory standards are to be “substantially the same as” applicable voluntary standards, or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. For a proposed rule under section 104 of the CPSIA, CPSC staff would assess potential impacts on small entities, consistent with the Regulatory Flexibility Act (RFA), and examine possible alternatives that may mitigate any significant impacts.

The phrase “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.” The CPSIA definition also provides examples of products that fit the definition, such as full-size cribs, toddler beds, and infant carriers. Crib bumpers and other infant bedding products are not included among the examples, but staff recognizes that the list is not intended to be exhaustive.

As EC staff discusses in Tab B, crib bumpers probably would not be considered “durable products” by existing economic and commercial definitions. Bumpers, along with apparel and other textile consumer goods, generally are classified in government statistics as non-durable goods with a useful life of less than 3 years. Although bumpers might be passed down among infants and could last more than 3 years with light use or repair, the expected life of bumpers in regular use is likely to be less than 3 years. If crib bumpers are not “durable infant or toddler products,” rulemaking under section 104 of the CPSIA is not a viable option.

B. MANDATORY RULE UNDER CPSA OR FHSA

The Commission could propose a rule under section 7 of the CPSA or section 3 of the FHSA. To issue a final rule under the CPSA, the Commission must determine that crib bumpers present an unreasonable risk of injury; to proceed under the FHSA, the Commission must determine that crib bumpers are a “hazardous substance” as defined in the FHSA, which also would involve a determination of unreasonable risk. In addition, because crib bumpers are covered under a voluntary standard, the Commission could issue a rule under section 7 of the CPSA or section 3 of the FHSA, only if the Commission finds that: (1) compliance with the voluntary standard is unlikely to eliminate or adequately reduce the risk of injury, or (2) substantial industry compliance with the voluntary standard is unlikely.

For such a proposed rule, CPSC staff would provide information on potential benefits and costs of a rule, as well as information on potential economic impacts on small businesses or other small entities. As EC staff discusses in Tab B, new performance or design requirements in a

CPSC mandatory rule may impose costs on manufacturers, importers, and other sellers of baby products. In addition, such a rule would impose costs associated with third party testing and certification, as required by the CPSIA for regulated children's products.

C. BAN UNDER CPSA

If the Commission determines that crib bumpers present an unreasonable risk of injury, but that no feasible, mandatory consumer product safety standard would adequately protect the public from this unreasonable risk of injury, then the Commission could promulgate a rule declaring bumpers a banned hazardous product under section 8 of the CPSA. As in the case of a mandatory rule under section 7 of the CPSA, CPSC staff would provide information on potential benefits and costs of a rule, as well as information on potential economic impacts on small businesses or other small entities, consistent with the RFA.

A mandatory rule that bans crib bumpers could eliminate from the market some or all existing bumper designs. A ban that defines subject bumpers as horizontal or continuous may allow existing vertical bumper designs. The definition also could be written to allow for mesh designs (*e.g.*, exhibiting some minimum air flow), similar to those identified in the Maryland ban. Under this technical approach, a ban may have impacts similar to a mandatory safety standard, depending upon which products or design features were affected by the ban.

Although most producers and importers of bumpers offer other kinds of baby products, some firms may be significantly affected by a total product ban. Any action to ban crib bumpers would need to consider whether consumers would substitute other products for bumpers and what effect that substitution might have on the risk of suffocation.

IX. STAFF CONCLUSIONS

Staff is aware of 107 fatalities, during the 26 years of incident data examined, where a crib bumper was found in the sleep environment. However, as staff has discussed in this briefing package, most fatal incidents in which a crib bumper was present (72 of 107 fatalities) are incidents in which even completely removing the crib bumper from the sleep environment seem unlikely to have prevented the fatality. Thirty-one of these cases had no evidence of bumper contact or bumper involvement in the incident at all. Other incidents involved cases of neck hyperextension or positional asphyxia, which staff concluded would likely have resulted in death, regardless of the bumper's presence, or they involved cases in which the infant's face was known or likely to be into the mattress or otherwise not into the crib bumper. In contrast, nine fatalities over the 26-year period examined by staff are fatalities for which removing the bumper likely would have prevented the death. Some portion of an additional 26 fatalities also might have been prevented by removing the bumper, but the incidents lack sufficient details to allow staff to assess these cases. If one were to allocate these "unknown" cases proportionally to the other "known" cases, then 12 fatalities might be addressable in some form by Commission action. However, given some of the uncertainties surrounding the incidents, the true number of addressable incidents may be somewhat higher or lower than this.

Regarding the nine specific fatalities for which staff concluded that removing the bumper from the sleep environment would likely have prevented the death, staff notes the following:

- Three fatalities involved use of the bumper in a toddler bed or other product for which crib bumpers are not intended. In the original Petition Briefing Package, staff considered such cases to be out of scope.
- Three fatalities involved broken cribs. If the cribs had not been broken, these fatalities most likely would not have occurred.
- Two, or possibly three, fatalities involved a child whose developmental level was beyond the point at which bumpers are supposed to be removed from the sleep environment. Current warnings already address this issue.
- One fatality occurred under very suspicious circumstances, and the child’s caregivers subsequently were charged with criminal child endangerment.

The Commission may choose to pursue regulatory action to address the suffocation risk associated with crib bumpers under section 104 of the CPSIA, if the Commission deems crib bumpers to be a “durable infant or toddler product.” However, staff has concluded that crib bumpers probably would not be considered durable products under existing economic and commercial definitions. Staff notes that the Commission is not limited to the economic definition of “durable” when determining whether crib bumpers are a “durable infant or toddler product” under Section 104. The Commission also may choose to pursue regulatory action under section 3 of the FHSA, or under sections 7 (mandatory rule) or 8 (ban) of the CPSA. If the Commission chooses to pursue rulemaking under the CPSA or FHSA, the Commission must find that crib bumpers present an “unreasonable risk of injury” or constitute a “hazardous substance.” Based on staff’s review of the incidents, making such findings would likely prove difficult. In addition, even if the Commission could make such findings, the overall impact of a mandatory rule or ban on crib bumpers on future fatalities would likely be small.

For example, CPSC staff concludes that a ban on all bumpers and similar products intended to be installed on the side of a crib would likely have prevented nine fatalities associated with crib bumpers over the 26-year period examined by staff. Replacing traditional bumpers with alternative products such as mesh liners or vertical bumpers might have prevented about three to six fatalities over the same timeframe. However, even these numbers may overstate the potential benefit of these actions because the most recent incident that staff has identified as likely to be addressable happened in 2007, which was nearly a decade ago. Thus, it is possible that none of the known fatalities after 2007, in which a crib bumper was present in the sleep environment, would have been prevented even by a ban on crib bumpers and similar products that install on the sides of an infant crib.

CPSC staff could continue to work with the ASTM Infant Bedding subcommittee to identify and implement safety improvements to ASTM F1917 that may address the risk of injury associated with bumpers. For example, the ability of an object to conform to the face is an important factor in suffocations. Thus, staff has considered the possibility of a “firmness” performance requirement and, in principle, supports the addition of such a requirement, like the requirement outlined in AS/NZS 8811.1. However, testing to the maximum thickness requirement in ASTM F1917 is highly predictive of the test results when bumpers are tested to the AS/NZS 8811.1 standard. Thus, staff is uncertain how much of an impact such an addition would make on injuries and deaths. Some revisions or additions to the warning requirements of the ASTM standard might reduce the risk somewhat, but the overall impact of such actions on the nine potentially addressable fatalities is unlikely to be high. CPSC staff also supports ongoing efforts

to inform and educate consumers about safe sleep practices, and staff believes that continued, repeated messages that emphasize the importance of keeping pillows and other loose, soft bedding items out of cribs are critical.

X. REFERENCES

- Massale, J. (2013). Explanation of Existing Voluntary Standards and Voluntary Standards Development Associated with Crib Bumpers – Petition CP 12-2. In J. Midgett, *Staff Briefing Package: Crib Bumpers Petition* (Tab B). Staff briefing package, U.S. Consumer Product Safety Commission, Bethesda, MD. Retrieved from: <http://www.cpsc.gov//Global/Newsroom/FOIA/CommissionBriefingPackages/2013/CribBumpersBriefingPackage.pdf>.
- Midgett, J. (2013). *Staff Briefing Package: Crib Bumpers Petition*. Staff briefing package, U.S. Consumer Product Safety Commission, Bethesda, MD. Retrieved from: <http://www.cpsc.gov//Global/Newsroom/FOIA/CommissionBriefingPackages/2013/CribBumpersBriefingPackage.pdf>.
- Scheers, NJ. (2013). Analysis of Crib Bumper Deaths. In J. Midgett, *Staff Briefing Package: Crib Bumpers Petition* (Tab F). Staff briefing package, U.S. Consumer Product Safety Commission, Bethesda, MD. Retrieved from: <http://www.cpsc.gov//Global/Newsroom/FOIA/CommissionBriefingPackages/2013/CribBumpersBriefingPackage.pdf>.
- Scheers, NJ, Woodard, D. W., & Thach, B. T. (2016). Crib Bumpers Continue to Cause Infant Deaths: A Need for a New Preventive Approach. *Journal of Pediatrics*, 169. 93–97.
- Schlaud, M., Dreier, M., Debertin, A. S., Jachau, K., Heide, S., Giebe, B., Sperhake, J. P., Poets, C. F., & Kleemann, W. J. (2010). The German case-control scene investigation study on SIDS: epidemiological approach and main results. *International Journal of Legal Medicine*, 124(1): 19–26.
- Wanna-Nakamura, S. (2013). Analysis of Available Records for 71 Fatalities Occurring January 1990 through October 2012 Citing Crib Bumpers. In J. Midgett, *Staff Briefing Package: Crib Bumpers Petition* (Tab E). Staff briefing package, U.S. Consumer Product Safety Commission, Bethesda, MD. Retrieved from: <http://www.cpsc.gov//Global/Newsroom/FOIA/CommissionBriefingPackages/2013/CribBumpersBriefingPackage.pdf>.

TAB A

2013 Record of Commission Action Regarding Crib Bumpers



U.S. CONSUMER PRODUCT SAFETY COMMISSION

4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814-4408

Record of Commission Action
Commissioners Voting by Ballot*

This is a DRAFT RCA.
It will be replaced by a Final RCA.

Commissioners Voting: Chairman Inez M. Tenenbaum
Commissioner Nancy A. Nord
Commissioner Robert S. Adler

ITEM:

Petition CP 12-2; Request for Commission Action Regarding Crib Bumpers
(Briefing Package dated May 15, 2013, OS No. 5665)

DECISION:

Petition CP 12-2, from the Juvenile Products Manufacturers Association, requested that the Commission initiate rulemaking to distinguish and regulate “hazardous pillow-like” crib bumpers from “non-hazardous traditional” crib bumpers under sections 7 and 9 of the Consumer Product Safety Act. The Commission voted unanimously (3-0) to grant the petition and directed staff to initiate rulemaking to address the risk of injury associated with the use of crib bumpers. However, the Commission rejected the JPMA’s framework because it is too narrow in scope. The Commission would like to explore all available rulemaking options, not just those under sections 7 and 9 of the Consumer Product Safety Act. The Commission would also like to assess other types of crib bumpers, in addition to the two types specified by the JPMA. Furthermore, the Commission included two directions to CPSC staff. First, CPSC staff is to provide the Commission with a briefing package that describes the possible regulatory options the Commission may take to address the risk of injury associated with crib bumpers, including a staff assessment of the effectiveness of any related voluntary consumer product safety standard, as well as an assessment of whether a more stringent standard would further reduce the risk of injury associated with crib bumpers. Second, CPSC staff is to explore and, as possible, develop performance requirements and test methods that identify which types of crib bumpers have characteristics that present safety hazards. The staff has also been directed to assess whether crib bumpers provide any safety benefit. The assessment should include a review of representative samples of crib bumpers and should include an assessment of mesh bumpers and bumpers that individually cover crib slats (also known as vertical bumpers). Chairman Tenenbaum submitted the attached statement regarding the issue.

For the Commission:

Todd A. Stevenson
Secretary

* Ballot vote due May 24, 2013

(Commissioner Adler extended the vote due date from May 21, 2013.)

Attachment: Statement of Chairman Tenenbaum



**U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814**

CHAIRMAN INEZ M. TENENBAUM

**STATEMENT OF CHAIRMAN INEZ M. TENENBAUM ON THE COMMISSION DECISION
TO GRANT THE PETITION REQUESTING RULEMAKING
TO ESTABLISH A PERFORMANCE STANDARD FOR CRIB BUMPERS**

June 3, 2013

On May 9, 2012, the Juvenile Products Manufacturers Association (JPMA or Petitioner) filed a petition requesting that the U.S. Consumer Product Safety Commission (CPSC or the Commission) initiate rulemaking to establish a performance standard for crib bumpers that distinguishes between, as Petitioner characterizes them, “hazardous pillow-like” and “nonhazardous traditional” products. On May 24, 2013, the Commission voted unanimously to grant JPMA’s petition. The accompanying direction we provided to CPSC staff as it commences rulemaking on crib bumpers, however, is even more important than the vote to grant the petition itself.

Crib bumpers are typically, although not universally, padded fabric panels with ties, intended to line the sides of an infant’s crib. Crib bumpers have been a staple in crib sales marketing, and in many American nurseries, for years. Their utility and safety benefits, however, are certainly up for debate. Tragically, many infant deaths have been linked to the use of crib bumpers. The extent of any association between crib bumpers and infant deaths is at the core of the ongoing debate.

With my strong support, CPSC staff initiated a new review of the incident data involving the role of crib bumpers in infant deaths. That review can be found in the staff briefing package.¹ In addition, individuals and organizations outside the agency have conducted reviews in prior years. The results of the reviews, both from CPSC staff and from outside the agency, have varied. Because we—and, more importantly, families with babies—desperately need clarity, we directed our staff to commence rulemaking on crib bumpers, but in a broader, more comprehensive—and, I believe, more effective—fashion than the Petitioner requested.

Petitioner’s Request and the Commission Vote

The JPMA petition requested that the Commission initiate rulemaking to distinguish between what JPMA deems to be hazardous and nonhazardous bumpers. As an initial matter, the Commission voted not to limit the rulemaking to the Petitioner’s specific request. The Commission found this approach too narrow.

¹ The staff briefing package, dated May 15, 2013, can be found here:
www.cpsc.gov/Global/Newsroom/FOIA/CommissionBriefingPackages/2013/CribBumpersBriefingPackage.pdf

Rather, we provided a two-part direction to CPSC staff. First, we directed staff to assess any voluntary consumer product safety standard that addresses the risk of injury associated with crib bumpers, as well as to assess whether a more stringent standard would further reduce the risk of injury associated with the product. We have found this approach extremely effective and efficient when promulgating mandatory standards for products covered under Section 104 of the Consumer Product Safety Improvement Act of 2008, known as the “Danny Keysar Child Product Safety Notification Act.”

Second, the Commission directed CPSC staff to explore and, as possible, develop performance requirements and test methods that identify which types of crib bumpers have characteristics that present a safety hazard. Related to this work, we also directed CPSC staff to assess whether crib bumpers are associated with any safety benefits, such as prevention of limb entrapment in crib slats. The assessment should include a review of all types of crib bumpers, including mesh bumpers and vertical bumpers. I believe it is important to include this specific direction to ensure we have as illuminating a set of scientifically driven data as possible. While existing analyses of incident data are helpful and should play a role in the rulemaking process, we must also review and consider scientific data that measures objectively, for instance, the airflow in and around an infant’s face when different types of crib bumpers are used.

Looking Forward

The death of an infant is a devastating and life-changing event for a family. The staff package contains new and valuable research, indicating a connection between infant deaths and crib bumpers, which I find deeply concerning. I want to extend my condolences to each family who has lost a child under these circumstances. I remain personally invested, each and every day, in doing everything possible to prevent such tragedies from occurring.

We all share the common goal of protecting children and families from dangerous products, and we are especially sensitive to concerns regarding products that are intended to be part of an infant’s sleep environment. Our vote marks the next step in a complicated and resource-intensive process to assess crib bumpers scientifically and objectively. It is my hope and intention that this process will enable us to state definitively whether crib bumpers are an unnecessary hazard in cribs. Families deserve nothing less than this.

In the meantime, I continue to advise parents and caregivers to remember that when it comes to your baby’s sleep environment, “Bare is best!” NEVER add pillows, quilts, sleep positioners, comforters, or cushions to your baby’s crib, bassinet, and play yard. For more advice on safe sleep environments, please visit our Crib Safety Guide at: www.cpsc.gov/en/Safety-Education/Safety-Guides/Kids-and-Babies/Cribs/.

Before you do, though, it bears repeating: Bare is best!

TAB B

EC Staff Memorandum,

“Economic Considerations Related to Crib Bumpers”



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

MEMORANDUM

Date: June 1, 2016

To : Timothy Smith
Project Manager, Crib Bumper Project
Directorate for Engineering Sciences

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

Robert Franklin
Senior Staff Coordinator
Directorate for Economic Analysis

FROM: Samantha Li and Mark Bailey
Directorate for Economic Analysis

SUBJECT: Economic Considerations Related to Crib Bumpers

In 2013, the U.S. Consumer Product Safety Commission (CPSC or “Commission”) granted a 2012 petition (CP 12-2) by the Juvenile Products Manufacturers Association (JPMA) to initiate rulemaking on crib bumpers. The Commission directed CPSC staff to investigate available regulatory options, including possible new mandatory performance requirements and possible improvements to an existing voluntary standard (ASTM F912-12). The Commission also directed staff to assess the safety benefits, if any, that bumpers may provide with respect to other risks, such as head injuries or limb entrapments.

This memorandum presents information on crib bumper usage, durability, state and local regulations, the possible safety benefits associated with bumper usage, the societal costs of deaths and injuries, and a brief discussion of remedial alternatives. CPSC staff previously provided some general market background on bumpers in connection with the JPMA petition.¹

¹ S. Li, CPSC Directorate for Economic Analysis, “Petition on Crib Bumpers: Market Information and Economic Considerations, December 18, 2012, Tab C of CPSC staff briefing package: <http://www.cpsc.gov/Global/Newsroom/FOIA/CommissionBriefingPackages/2013/CribBumpersBriefingPackage.pdf>.

I. Crib and Bumper Usage

Based on information from the 2013 CPSC Durable Nursery Products Exposure Survey of U.S. households with children under 6 years old:

- An estimated 9.2 million cribs were in use in households with young children in 2013. This represented about 73 percent of the estimated 12.6 million total cribs owned by households (*i.e.*, about 3.4 million cribs were owned, but not in use).
- Among the 9.2 million cribs in use, an estimated 5.3 million were equipped with bumpers. This represents about 55 percent of the 9.9 million total bumpers owned by households (*i.e.*, about 4.5 million bumpers were owned, but not in use).

The household use estimates may understate, somewhat, total crib and bumper usage. In addition to the products to be in use in households with young children, as estimated from the survey, cribs and bumpers are probably in use in some households without young children (*e.g.*, unsurveyed homes of older adults providing care for grandchildren). Additionally, the survey did not cover child care facilities; one childcare industry group's 2015 directory² lists more than 115,000 licensed childcare centers and more than 137,000 home daycare providers, some of which may use cribs and bumpers. Furthermore, the survey did not cover hotels or other commercial lodging establishments; the U.S. Bureau of Labor Statistics (BLS) reports that there are about 67,000 lodging establishments in the accommodation industry sector, North American Industry Classification System (NAICS) code 721.³ Based on staff's preliminary contacts with a few childcare and lodging facilities, bumper usage in such establishments is probably low. The total estimated number of crib bumpers in use, however, may be somewhat higher than the estimated 5.3 million. In 2012, CPSC staff identified 37 firms that produce or distribute crib bumpers.⁴ An additional 26 firms have been identified, for a total of 63 firms that supply or distribute crib bumpers.

II. Bumper Durability

Another aspect of bumper usage is the durability of the product. Cribs are clearly "durable products" by any recognized definition. Bumpers, by construction and usage, clearly are less durable. The following points relate to crib bumper durability:

² Child Care Centers estimate entire U.S. (2015, May 1). <http://childcarecenter.us/>.

³ U.S. Bureau of Labor Statistics, "Quarterly Census of Employment and Wages," May 2015. <http://www.bls.gov/iag/tgs/iag721.htm>.

⁴ S. Li, CPSC Directorate for Economic Analysis, "Petition on Crib Bumpers: Market Information and Economic Considerations, December 18, 2012, Tab C of CPSC staff briefing package: <http://www.cpsc.gov/Global/Newsroom/FOIA/CommissionBriefingPackages/2013/CribBumpersBriefingPackage.pdf>.

- Dictionary definitions⁵ of “durable goods” refer to goods that are not consumed or destroyed during use and can be used repeatedly over a number of years. Examples cited include appliances and machinery.

In the NAICS classification system of manufacturing and other commercial activity, the Census Bureau describes categories of “durable” and “non-durable” goods; these categories are used in data compilations and reports on a variety of national statistics and economic indicators. The BLS also studies and reports on commercial activity, using NAICS data. In these various government reports, manufactured products are generally considered to be durable if they have expected lives of at least 3 years. Non-durable products are products intended for immediate consumption (*e.g.*, food, medicines), or for short-term usage lasting less than 3 years (*e.g.*, most preserved foods, shoes, apparel and other textiles). This is consistent with the definition of “durable” developed by the U.S. Department of Commerce’s Bureau of Economic Analysis.⁶

- Crib bumpers are covered under NAICS code 314120, for “curtain and linen mills primarily engaged in production of household textile products,” including bed sets, blankets, comforters, cushions, pads, protectors, quilts, sheets, and pillowcases. This code is included among the “non-durable” categories for both domestic production and for wholesale trade (including imports).
- The working definition of “durable goods” is necessarily blurry at its edges. The governmental definitions above imply that non-durable goods are short-lived when in continuous or near-continuous use for their intended purpose. Some goods that are not usually intended to be stored or inventoried for long periods may last longer than 3 years, if used intermittently. This may apply to things like preserved foods, fashion-oriented articles like many shoes and textile products, and intermittent-use items like crib bumpers. These sometimes are referred to as “semi-durable” goods. The nature of durability, therefore, may take into consideration the expected life of a product in regular or constant service and the potential life of that product under conditions of reasonably foreseeable (including intermittent) use. It should be noted, however, that there is no official government or industry definition of “semi-durable” goods; the products mentioned above are generally included in the “non-durable” category.
- The CPSC Nursery Products survey provided no useful national data on patterns of bumper use: only four survey respondents provided additional details of bumper usage and disposition (*e.g.*, whether bumpers were acquired new or used, the length of usage time per baby, or whether people discarded bumpers after usage or passed them to other households). Anecdotal information suggests that bumpers sometimes may be used for a period of a few months and subsequently

⁵ Random House, Oxford, Merriam-Webster, and other dictionaries.

⁶ Bureau of Economic Analysis. (2015, May 1). Glossary. <http://bea.gov/glossary/glossary.cfm>.

handed down for use by successive children over a period of years, if the bumpers were not too worn or soiled; however, the survey data do not yield that level of detail.

- CPSC staff has considered consumer product durability based, in part, on a product's metal, wood, or plastic content. Although some metal-, wood-, or hard-plastic-containing products (*e.g.*, shoes) may not last 3 years, other items constructed of these materials would be sturdier and longer-lived. Crib bumpers are relatively homogeneous in terms of construction materials: most are constructed of natural (*e.g.*, cotton), synthetic (*e.g.*, polyester), or blended-fiber fabrics and soft upholstery fillings like cotton or polyester batting or flexible polyurethane foam. Although some bumpers may incorporate metal or plastic zippers, buttons, or other trim, bumpers generally are not constructed of metal, wood, or hard plastic.
- Another issue to consider in assessing durability is the existence of secondary markets for used items, and the availability of repair services or supplies for products that may otherwise become unusable. These factors can apply to crib bumpers; used bumpers can be found at yard sales and in online marketplaces; and damaged bumpers can be re-stuffed or sewn back together, thereby extending their service lives and their residual value to consumers.
- One industry representative involved in ASTM subcommittee activities opined to CPSC staff that, if consumers followed label instructions and removed bumpers from a crib when the child was old enough to sit up or pull up to a standing position, then the bumpers his company markets could be used for a second or third child, and could last for up to 5 years. This representative stated that he knew of no industry or other consensus description of durability that was widely accepted among firms in the juvenile products industry.

From an economic perspective crib bumpers do not clearly fit within the technical descriptions of the term "durable goods." Certainly, some bumpers could last longer than 3 years with light usage or repair; however, like other articles of bedding or apparel, regular or continuous usage would result in a shorter useful life.

III. Safety Benefits of Bumpers

The Commission asked staff to assess crib bumpers' safety benefits to users. A perception of safety is clearly an element of bumper marketing and usage. JPMA's petition and public comments, as well as some advertising messages and online consumer reviews, refer to traditional, continuous, padded bumpers as protective against limb entrapments and head impacts for active babies. The AAP Technical Report noted that

bumpers “were developed to prevent head entrapment.”⁷ However, the possible protective benefits of crib bumpers, if any, have not been quantified.

Manufacturers have recently introduced bumpers that they claim are designed as safer alternatives to traditional bumpers. These include non-continuous, vertical bumpers that wrap around one or two crib slats, and mesh bumpers that are continuous, but are designed to be more air permeable, and therefore, potentially less restrictive to breathing than traditional bumpers. Advertisements for these newer products claim that the products reduce the risk of suffocation, but still offer a level of entrapment protection, similar to what traditional bumpers afford.

IV. Preliminary Estimate of Societal Costs Associated with Deaths and Injuries

The Commission directed staff to provide a briefing package that describes the possible regulatory options the Commission may take to address the suffocation risk associated with crib bumpers. Important factors to consider when evaluating possible regulatory options include the societal costs associated with bumper pad injuries, and the likely benefits that might be derived from a product safety standard that reduces future societal costs.

CPSC staff analyzed reports of incidents in which bumpers were present in cribs or other sleep environments, including 107 infant suffocation deaths that occurred over the more than 26-year period from 1990 to early 2016 (*i.e.*, approximately four deaths per year). Staff determined that in 72 of the 107 reported fatalities, bumpers were present, but removing them from the sleep setting is unlikely to have prevented the deaths. In another 26 incidents, the role, if any, played by the bumpers could not be determined.

Out of the 107 reported fatal incidents, staff identified a total of 9 deaths in which crib bumpers, in combination with other risk factors (*e.g.*, broken or missing crib slats, the presence of soft bedding), appear to have contributed to the death.⁸ Additionally, if we allocate the 26 unknowns proportionally to the 81 knowns, then about 12 deaths, or an average of about 0.46 deaths per year (12 deaths ÷ 26 years), may be attributable to bumpers. The Directorate for Epidemiology noted that there could be some additional incidents not reported to the CPSC.⁹

⁷ American Academy of Pediatrics Technical Report: “SIDS and Other Sleep-Related Infant Deaths: Expansions of Recommendations for a safe Infant Sleeping Environment,” *Pediatrics*, V. 128, #5, November 2011, <http://pediatrics.aappublications.org/content/128/5/e1341.full.pdf+html>.

⁸ All nine cases in which the team concluded that a crib bumper appeared to have contributed to the incident occurred before 2008. Consequently, annual estimates of the rate of death involving crib bumpers might be lower, if the analysis were limited to more recent years. Additionally, because of multiple risk factors in the nine death cases, staff cannot conclude that all (or what proportion) of the deaths in which bumpers appear to have contributed would have been prevented in the absence of bumpers.

⁹ CPSC Memorandum from A. Suchy, Directorate for Epidemiology, to Tim Smith, “Overview of Crib Bumper Incident Reports From January 1, 1990 to March 31, 2016” (April 22, 2016).

As described above, there were about 5.3 million crib bumpers in use in 2013. If we assume 0.46 deaths annually, there would have been roughly 0.087 deaths annually per million bumpers in use (0.46 deaths ÷ 5.3 million). By way of comparison, there were about 9.2 million cribs in use and about 41 crib-related deaths annually during the period 2010 to 2012 (the most recent data years),¹⁰ yielding an annual fatality rate of roughly 4.5 deaths per million cribs in use (41 ÷ 9.2 million).

CPSC staff also reviewed reported nonfatal injuries that occurred in cribs equipped with bumpers over the same 26-year period. The Directorate for Epidemiology noted that, of the approximately 110 injuries reported, 25 were reported through NEISS; the small NEISS sample did not meet the criteria to serve as a basis for a national estimate of injuries. Of the 25 reported cases, only one involved a near-suffocation (anoxia), and the role of the bumper was undetermined. From the limited available data, it appears that the annual number of injuries, while unknown, is probably very small.

If each of the estimated 12 deaths since 1990 that may be prevented by removing the bumpers was assigned a cost of \$8.7 million,¹¹ then the average annual societal costs associated with these deaths would amount to about \$4 million (0.46 deaths per year x \$8.7 million) in 2014 dollars. This excludes societal costs associated with the unknown, but probably small, number of nonfatal injuries; thus, total annual societal costs associated with bumper deaths and injuries may be somewhat greater than the \$4 million estimate.

If there were approximately 5.3 million bumpers in use in 2013, and annual societal costs attributed to bumper suffocations were approximately \$4 million, then societal costs may have been about \$0.75 (\$4 million ÷ 5.3 million bumpers) per crib bumper in use per year. If bumpers have an expected average useful life of *one to two* years, the lifetime present value of the societal costs per unit (discounted at 3 percent) would be about \$0.75 to \$1.44. This number is useful because it represents an estimate of the maximum value of potential benefits per unit that could be achieved by a 100 percent effective remedial action that prevented all deaths attributable to bumpers.^{12,13} This estimate could be

¹⁰ R. Chowdhury, CPSC Directorate for Health Sciences, "Injuries and deaths Associated with Nursery Products Among Children Younger than Age Five," December 2015, <http://www.cpsc.gov/Global/Research-and-Statistics/Injury-Statistics/Toys/NurseryProductsAnnualReport2015.pdf>.

¹¹ The \$8.7 million estimate is the value of statistical (VSL) in 2014 dollars. For a further discussion of the \$8.7 million societal cost assigned to fatal injuries, see the preliminary regulatory analysis in the CPSC's notice of proposed rulemaking on recreational off-highway vehicles (ROVs) at:

<https://www.federalregister.gov/articles/2014/11/19/2014-26500/safety-standard-for-recreational-off-highway-vehicles-rovs>. The dollar value has been adjusted to 2014 dollars using the Consumer Price Index.

¹² The benefits of a remedial action that was not 100 percent effective would be less. For example, the benefits of a rule that prevented only half the deaths attributable to crib bumpers would be approximately \$0.375 to \$0.72 per bumper.

¹³ In the unlikely scenario that half of the 26 "unknown" cases contributed to the child deaths, there would have been about 22 deaths potentially attributable to the bumpers, or about 0.85 bumper deaths per year. Under this scenario, the lifetime present value of the societal cost would have ranged from about \$1.40 to

slightly higher, if all deaths have not been reported to the CPSC, or if nonfatal injuries attributable to bumpers have not been quantified. On the other hand, the estimate does not take into account any unquantifiable safety benefits, if any, that might be attributable to the bumpers.

V. Potential Economic Impacts of Remedial Action Alternatives

The Commission could pursue four basic alternative remedies to address the potential suffocation risk associated with crib bumpers:

- take no action, and continue outreach efforts;
- work with ASTM to strengthen the voluntary standard;
- promulgate a mandatory standard under section 7 of the Consumer Product Safety Act (CPSA), section 3 of the Federal Hazardous Substances Act (FHSA), or section 104 of the Consumer Product Safety Improvement Act (CPSIA); or
- ban crib bumpers under section 8 of the CPSA.

a. No Action

CPSC staff could enhance its ongoing efforts to inform and educate consumers about safe sleep practices, including stressing the importance of keeping loose, soft bedding and other items out of cribs. No product changes would be necessary, and no costs would be imposed, other than costs to the government associated with the information and education program.¹⁴

b. Voluntary Standard

CPSC staff could work with the ASTM subcommittee to identify and implement improvements to the performance requirements and test methodologies in the voluntary standard. These improvements may confer safety benefits to consumers and impose costs associated with product modifications. The cost associated with a voluntary standard would be lower than the cost associated with a mandatory standard because of the absence of a third party testing requirement that would be triggered by a rule.

c. Mandatory Safety Rule

As with enhancements to the voluntary standard, new performance or design requirements in a CPSC mandatory rule could confer safety benefits to consumers, but they also would impose costs on manufacturers, importers, and other sellers of baby products. Furthermore, a safety rule would impose added costs associated with third party

about \$2.68 per bumper pad. If the remedial action prevented only about half of the deaths, the benefits would amount to about \$0.70 to \$1.34 per unit.

¹⁴ The government information program “Bare is Best,” conducted by CPSC, is an example of ongoing efforts to inform and educate consumers about safe sleep practices.

testing and certification, as required by the CPSIA for regulated children's products. At this time, CPSC staff is uncertain about what would be required in a standard to address the potential risk, or the extent to which the risk of death could be addressed, by a performance standard.

d. Ban of Crib Bumpers

A mandatory rule banning crib bumpers from the market would eliminate some or all existing bumper designs. A ban that defines bumpers as horizontal or continuous may allow existing vertical bumper designs; the definition could also allow mesh designs (*e.g.*, exhibiting some minimum air flow). A ban may have impacts similar to a safety standard's impacts, depending on which products or design features were affected by the ban. A ban of all bumper designs would impose costs on society in the form of lost consumer and producer surplus (*i.e.*, the difference between the total value that consumers place on crib bumpers and the cost of producing the bumpers). The net safety benefits of a ban could potentially be reduced, if consumers substituted other potentially hazardous items for bumpers.

VI. Conclusions

Preliminary information available to CPSC staff indicates the following:

- About 5.3 million cribs with bumpers are in use in U.S. households with children under the age of 6; the total number in use may be slightly higher. CPSC survey data suggest that a little more than half of all cribs in household use are bumper-equipped cribs.
- By existing economic and commercial definitions, bumpers probably would not be considered "durable products." Bumpers, along with apparel and other textile consumer goods, are generally classified in government statistics as non-durable goods with a useful life of less than 3 years. Although bumpers may sometimes be passed down among babies and can last more than 3 years with light use or repair, the expected life of bumpers in regular use is likely less than 3 years.
- Staff's review of fatal incident reports indicates that bumpers appear to have contributed to an average of about one suffocation death every other year; bumper use may also result in a small number of nonfatal injuries annually. The societal costs that might be addressed by a regulatory action amount to approximately \$0.75 to \$1.44 per bumper over its expected product life. It is also possible that bumpers prevent some injuries involving limb entrapment or crib-structure impact that otherwise would have occurred, but the extent of this benefit is unquantified.
- Remedial action alternatives may confer varying levels of safety benefits to consumers, and may impose a range of potential costs. Such costs may vary depending on the product modifications that could be required under any

voluntary standard upgrade or CPSC mandatory safety standard. A ban that allows some existing designs could have impacts similar to those of a standard. If a ban of all bumper designs led consumers to substitute soft bedding or other potentially hazardous items for bumpers in cribs, the potential benefits of a ban could be reduced.

TAB C

EPHA Staff Memorandum,

“Overview of Crib Bumper Incidents Reported from January 1, 1990 to March 31, 2016”



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

MEMORANDUM

Date: April 22, 2016

TO: Tim Smith, Project Manager, Crib Bumpers Project
Division of Human Factors, Directorate for Engineering Sciences

THROUGH: Kathleen Stralka, Associate Executive Director,
Directorate for Epidemiology

Stephen Hanway, Division Director
Division of Hazard Analysis

FROM: Adam Suchy, Mathematical Statistician,
Division of Hazard Analysis

SUBJECT: Overview of Crib Bumper Incidents Reported from January 1, 1990 to
March 31, 2016

I. Introduction

In May 2012, the Juvenile Products Manufacturers Association (JPMA) petitioned the Consumer Product Safety Commission (CPSC) to initiate rulemaking to define and distinguish “soft” pillow-like crib bumpers from traditional crib bumpers. Of particular concern to JPMA was a test to measure the thickness of the product, so as not to exceed 2 inches. This memorandum characterizes the number of incidents or concerns reported to CPSC staff, and the hazard patterns associated with bumper pad incidents that were reported between January 1, 1990 and March 31, 2016. The incidents are based on reports received by CPSC staff that mention a bumper pad in the environment. As such, these incidents might include cases in which a bumper pad was present, but not involved in the incident.

II. Incident Data¹

Staff searched the DTHS (Death Certificates), INDP (In Depth Investigations (IDIs)), IPII (Injury and Potential Injury Incidents) and NEISS (National Electronic Injury Surveillance System) databases for incidents or concerns involving bumper pads reported to CPSC. The incidents were reported to have occurred between January 1, 1990 and March 31, 2016. Because there is no product code strictly for bumper pads, CPSC staff performed multiple searches, consisting of a combination of product codes and narrative

¹ Incidents presented in this memo should be considered a minimum number that have occurred. There may be additional incidents not reported to CPSC in which crib bumpers were present.

keyword searches, to find all of the bumper pad incidents. The first data search included the product codes for *portable cribs* (NEISS code 1529), *baby mattresses or pads* (1542), *cribs (excluding portable cribs)* (1543) and *cribs (not specified)* (1545) that have “bump” or “pad” (or both) in the narrative field. The second data search included any incident that contains both “bumper” and “pad” in the narrative field, with no restriction on the product code. Upon careful review of the data from these two searches, the final in-scope set of data was selected. The incidents were characterized as fatal or nonfatal. Other than pictures from investigations and the occasional information about the manufacturer or model, the incidents did not include sufficient detail for staff to determine the thickness of the bumpers, as requested by the petitioner.

From these searches, CPSC staff found 107 fatal and 282 nonfatal incidents. Of the 107 fatal incidents, all but eight involved a crib bumper pad inside a crib. Of the eight fatal incidents involving bumper pads outside a crib, two occurred in a toddler bed, three in a bassinet, one in a play pen, one in a day bed, and one on a mattress on the floor. CPSC staff, through group consensus, categorized three of the eight fatalities as “incidental,” with no evidence of involvement of the bumper pad in the fatality. CPSC staff also received a letter from a state’s Department of Social Services that simply stated their awareness of four fatalities “within the last year” associated with “unsafe crib bedding,” which generally includes bumper pads. However, there is no further information about the four fatalities mentioned in the letter. As such, the four fatalities are not included among the 107 fatalities in the tables below. It is also quite possible that one or all of the four fatalities have already been included among the 107 deaths staff considered.

Table 1: Incidents Reported When a Bumper Pad Was Present and Injury Status
January 1, 1990 - March 31, 2016

Fatalities²	Injury	No Injury	Unknown	Total
107	110	161	11	389

Source: DTHS, INDP, IPII and NEISS databases,

Reporting is ongoing for these databases and the reported number of incidents may change in the future.

Of the nonfatal incidents, 57 percent (161 out of 282) were coded as having “no injury.” These non-injury incidents ranged from a concern about a bumper pad not fitting properly, to a near-death incident that, without intervention by a caregiver, might have resulted in a fatality. Incidents in which injury was coded as “unknown” consisted of a wide range of situations, such as bumper pad entanglements, slat entrapments, and wedge entrapments.

² These fatal incidents reported to CPSC do not constitute a statistical sample of known probability and do not necessarily include all fatalities from January 1, 1990 to March 31, 2016, where a bumper pad was present in the sleeping environment. However, the reported fatalities do provide at least a minimum number of fatalities during the time period.

Table 2: Incidents Reported When a Bumper Pad Was Present and Injury Status by Age
January 1, 1990 - March 31, 2016

Age	Fatalities	Injuries	No Injury	Injury Status Unknown	Total
1 to 4 months	67	25	31	3	126
5 to 8 months	25	27	44	1	97
9 to 11 months	6	16	16	0	38
12 to 23 months	5	28	14	4	51
2 years and older	4	2	2	0	8
Unknown	0	12	54	3	69
Total	107	110	161	11	389

Source: DTHS, INDP, IPII and NEISS databases

Reporting is ongoing for these databases and the reported number of incidents may change in the future.

Of all the reported fatalities, 92 percent (98 out of 107) were infants under 12 months old, and 63 percent (67 out of 107) of fatalities were infants 4 months old and younger. There were only four fatalities involving children older than the age of 23 months; they were two 2-year-olds, one 3-year-old, and one 5-year-old. One child had health issues and one was developmentally delayed. Of the children whose ages were known and who were involved in the nonfatal incidents, a majority were under 12 months of age.

The following table provides incident and fatality statistics for each 5-year period since 1990. CPSC staff has received more reports on bumper pad incidents since 2000, and more than half of the fatalities of which CPSC staff is aware thus far reportedly occurred since 2005. Staff does not know why there has been an apparent increase in incidents during more recent reporting periods.

Table 3: Incidents Reported When a Bumper Pad Was Present and Injury Status by Period
January 1, 1990 - March 31, 2016

Period	Fatalities	Injuries	No Injury	Injury Status Unknown	Total
1990 to 1994	12	8	10	1	31
1995 to 1999	12	11	12	0	35
2000 to 2004	16	19	53	1	89
2005 to 2009	26	29	46	4	105
2010 to Mar 31, 2016	41	43	40	5	129
Total	107	110	161	11	389

Source: DTHS, INDP, IPII and NEISS databases

Reporting is ongoing for these databases, and the reported number of incidents may change in the future.

**Table 4: Incidents Reported When a Bumper Pad Was Present and Injury Status by Age and Gender
January 1, 1990- March 31, 2016**

Age	Fatalities		Injuries			Total
	Male	Female	Male	Female	Unknown	
1 to 6 months	46	33	24	17	0	120
7 to 11 months	10	9	8	18	1	46
1 year and older	4	5	18	12	0	39
Unknown	0	0	2	6	4	12
Total	60	47	52	53	5	217

Source: DTHS, INDP, IPII and NEISS databases

Reporting is ongoing for these databases, and the reported number of incidents may change in the future.

Table does not include No Injury or Injury Status Unknown.

Comparing gender and age, there do not appear to be any meaningful differences in the fatality counts.

III. NEISS Data

There were 25 NEISS cases between January 1, 1990 and March 31, 2016, found to involve a bumper pad. Because the data did not meet the minimum criteria for computing an estimate,³ staff of the Directorate for Epidemiology could not provide an estimate of emergency department-treated injuries to children (through NEISS) between January 1, 1990 and March 31, 2016, who had interacted with bumper pads. However, the 25 NEISS injuries were included with the rest of the incident data described earlier.

IV. Hazard Patterns

None of the reported fatal incidents was witnessed; consequently, the cause of death in each case involved some degree of speculation. Often, details were vague about how the child was positioned when initially found; a second- or third-hand account was all the evidence available about the fatality; additional items in the crib environment may have been a contributing cause of the fatality; or, there were conflicting reports from multiple sources describing the details of the fatality.

Generally, the causes of death in reports for the fatal incidents were stated as asphyxia, suffocation, or SIDS. A number of reports indicated that in addition to a crib bumper being present, the sleeping environment contained multiple additional items, such as pillows, blankets, and stuffed dolls. In many of these incidents, it is unclear whether the crib bumper played a primary, secondary, or any role in the death of the child; therefore, the hazard pattern becomes more speculative than conclusive. CPSC staff, through group

³ A minimum NEISS estimate of 1,200 is required to report a national estimate.

consensus, categorized the fatalities into hazard scenarios, based on the best available account information about the position of the child when found, and the cause of death determined by the medical examiner. Table 5 shows the distribution of the 107 reported fatalities by hazard scenarios.

**Table 5: Incidents Reported When a Bumper Pad Was Present Fatal Incidents by Hazard Scenario
January 1, 1990 - March 31, 2016**

Hazard	Reported Fatalities
Incidental	31
Contact Outside Crib	5
Entrapment/Wedging	41
<i>Against Object in Crib</i>	23
<i>In Perimeter of Crib</i>	12
<i>Other</i>	6
Contact Without Entrapment/Wedging	23
Contact With Possible Entrapment/Wedging	7
Total	107

Source: DTHS, INDP, IPII and NEISS databases

Reporting is ongoing for these databases, and the reported number of incidents may change in the future.

1. Incidental: For 29 percent (31 out of 107 fatalities) of the reported fatalities, a bumper pad was present in the crib, but there was no evidence of the bumper pad’s involvement in the fatality. In three of these fatalities, the cause of death was known to have been exclusively medical in nature, and therefore, unrelated to the crib bumper. Aside from the few fatalities exclusively due to medical causes, fatalities were not classified as *incidental*, if the victim was in contact with the bumper pad at the time of the incident.

2. Contact Outside Crib: Five percent (5 out of 107 fatalities) of the reported fatalities were cases in which the bumper pad was outside a crib, and the child was found in contact with a crib bumper pad in a way in which the bumper pad may have contributed to the fatality. There were three other incidents in which the bumper pad was found outside a crib; but in those incidents, there was no evidence to link the involvement of the bumper pad in the fatality. Thus, these three fatalities were ruled *incidental*.

3. Entrapment/Wedging: In 38 percent (41 out of 107 fatalities) of the reported fatalities, the child was found wedged or entrapped against the bumper. This category was divided into three scenarios in which the child was found wedged or entrapped.

a. Against Object in Crib: In 21 percent (23 out of 107 fatalities) of the reported fatalities, the child was entrapped or wedged between a bumper pad and another object in the crib, such as a bed pillow, an infant recliner, or a cushion.

b. In Perimeter of Crib: In 11 percent (12 out of 107 fatalities) of the reported fatalities, the child was found entrapped between the mattress and the side of the crib.

c. **Other:** Six percent (6 out of 107 fatalities) of the reported fatalities involved entrapment against a bumper pad in some scenario not covered by the other Entrapment/Wedging hazard patterns described previously. An example would be a child found wedged under the bumper pad.

4. Contact Without Entrapment/Wedging: In 21 percent (23 out of 107 fatalities) of the reported fatalities, the child was reportedly in contact with the bumper pad, but without an issue of entrapment or wedging.

5. Contact with Possible Entrapment/Wedging: In 7 percent (7 out of 107 fatalities) of the reported fatalities, the child was found to be in contact with the bumper pad, but the incident scenario lacked sufficient details for CPSC staff to determine whether the child was entrapped or wedged against the bumper pad. These fatalities typically described the child as being found with his or her face between the mattress and the bumper pad. The incident descriptions often used the phrase “wedged between” to describe the position of the child when found. The incident details were such that staff was unable to conclude whether the face of the child was truly entrapped in this space or if the term “wedged” was being used to describe the orientation of the face relative to the two surfaces.

Table 6 summarizes fatal incidents by time period and hazard scenario. The category *Contact Inside Crib* in Table 6 combines the two categories: (1) *Contact Without Entrapment/Wedging*, and (2) *Contact With Possible Entrapment/Wedging* from Table 5.

**Table 6: Incidents Reported When a Bumper Pad Was Present
Fatal Incidents by Period and Hazard Scenario
January 1, 1990 - March 31, 2016**

Period	Incidental	Contact Outside Crib	Entrapment/Wedging	Contact Inside Crib	Total
1990 to 1994	1	0	6	5	12
1995 to 1999	4	2	4	2	12
2000 to 2004	2	1	7	6	16
2005 to 2009	7	1	8	10	26
2010 to Mar 31, 2016	17	1	16	7	41
Total	31	5	41	30	107

Source: DTHS, INDP, IPII and NEISS databases

Reporting is ongoing for these databases, and the reported number of incidents may change in the future.

Despite an overall increase in reported fatalities in recent years, more than half of the increase in reported fatalities between 2009 and March 2016 appeared in the *Incidental* category. The remainder of the increase in fatality reports in recent years involved *Entrapment/Wedging* incidents. Staff does not know why there has been an increase in reported fatalities during this time period.

Table 7 summarizes the nonfatal incidents and reports in which a bumper pad was present. In some incidents, multiple hazards were mentioned, and the more primary hazard was used.

**Table 7: Incidents Reported When a Bumper Pad Was Present
Non-fatal Incidents or Concerns by Hazard Pattern
January 1, 1990 - March 31, 2016**

Hazard	Incidents/Complaints
Near-Suffocation	23
Head Entrapments	40
Wedge Entrapments	11
Slat Entrapments	57
Near Strangulation or Entanglements	28
Choking or Ingestion of Small Parts	33
Climb Outs	10
Concerns	37
Other	43
Total	282

Source: INDP, IPII and NEISS databases

Reporting is ongoing for these databases and the reported number of incidents may change in the future.

1. Near-Suffocation: In eight percent (23 out of 282 non-fatalities) of reported nonfatal incidents, the child’s face was found pressed against the crib bumper pad. Suffocation incidents may be a result of the child becoming wedged between two items in some way, of which one of the two items in wedging incidents is often a crib bumper. Suffocations with only the face in an item can occur without wedging. In three incidents, a child was in a sleep positioner that flipped over, causing the face of the child to be pressed into the bumper pad.

2. Head Entrapments: In 14 percent (40 out of 282 non-fatalities) of reported nonfatal incidents, the head of the baby was found under or between the bumper pad and another object, such as the crib rail or the mattress, but the report did not specify further the primary injury circumstance. In situations where the head of the baby was found under the bumper, the face was often obstructed, or the neck/other body part was found lying over the bumper pad ties, or the tie was found in the mouth of the baby, posing a choking hazard.

3. Wedge Entrapments: Four percent (11 out of 282 non-fatalities) of reported nonfatal incidents mentioned that the infant was found wedged, caught under, or trapped under the bumper pad, without any mention of the head or face.

4. Slat Entrapments: Twenty percent (57 out of 282 non-fatalities) of reported nonfatal incidents involve arm or leg entrapments in between the slats of the crib, even though a bumper pad was present.

5. Near-Strangulation or Entanglements: Ten percent (28 out of 282 non-fatalities) of reported nonfatal incidents usually resulted from a bumper pad tie becoming loose and

wrapping around the neck, limb, or digit of the child. Other near-strangulations or entanglements occurred as threading or stitched-on patterns from the bumper pad unraveled. About half of strangulation or entanglement category incidents specifically mention the head, mouth, or neck being wrapped up by a piece of a bumper pad.

6. Choking or Ingestion of Small Parts: Twelve percent (33 out of 282 non-fatalities) of reported nonfatal incidents involved choking or ingestions. Most of the choking or ingestion of small parts incidents involved a child putting a piece of the bumper pad, such as decorative stitched-on patterns or the stuffing from inside the bumper pad, in their mouth.

7. Climb-Outs: Four percent (10 out of 282 non-fatalities) of reported nonfatal incidents occurred when a child, old enough to stand up, used the bumper pad as a step, to climb over the edge of the crib. The child often fell back into the crib, or fell out of the crib. The youngest children in these climb-out incidents were two 7-month-olds, two 9-month-olds, one 10-month-old, and one 11-month-old child.

8. Concerns: In 13 percent (37 out of 282 non-fatalities) of reported nonfatal incidents, the reports did not indicate that a child was involved; but instead, were generally, bumper pad-related problems foreseen by the parent or complainant. Many reported installation problems or ill-fitting bumper pads. Common examples of concerns with bumper pads were: the bumper did not fit the crib, the bumper was too thick, the bumper sagged, or there was a gap between the bumper and the slats or the mattress.

9. Other: In 15 percent (43 out of 282 non-fatalities) of reported nonfatal incidents included: contusions/abrasions caused by contact with rough or prickly bumper pads, non-breathable material of the bumper pad, needles found in the pad, crib rails or slats breaking and the bumper either protecting the child from further injury or the bumper pad causing the child to become entrapped, paint coming off the bumper pad, and an incident in which a bed sheet was used in the place of a bumper pad when a bumper was not available.

TAB D

Tables of Fatal Incidents

Hazard Pattern: Incidental (31 Reported Fatalities)

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
5	1992	2 Mo. Female	A 2 month old female was found dead in a crib. Her face was turned to the side. A distance of 6 inches separated the victim's face and the crib bumper pad.	Nothing was near the child's face, and the bumper was about 6 inches away.	Unlikely
16	1997	10 Mo. Male	A 10 month old male died of positional asphyxia, wedged between his crib railing and a dresser six inches away. He apparently stood on the crib bumper pad and climbed over the crib railing.	The victim climbed or fell out of the crib and became wedged in a 6-inch space between the outside of the crib railing and the adjacent dresser. A bumper was present, but there is no evidence of its involvement in this incident aside from speculation by the investigator that the child probably stood on the bumper to climb over the side. In addition, the difference between the height of the bumper and the top of the crib railing is small (12 inches versus 15 inches), and the child was a 10-month-old who was "very large" for his age, so the child could have climbed out without using the bumper.	Unlikely
18	1998	11 Mo. Male	The victim was and 11 month old infant boy with a history of severe asthma attacks. He went to sleep at night in a full-size crib with a bumper pad. The victim was later found lifeless in the crib with the loose bumper pad around his waist. The coroner's investigation and autopsy reports revealed this death was "natural" due to an asthma attack causing cardiac arrest. The bumper pad was determined not to be the cause of the victim's death.	The cause of death was identified as a severe asthma attack, which caused cardiac arrest. The victim had history of severe asthma attacks, and had one the night before. The bumper was specifically determined not to be the cause of death.	Unlikely
20	1998	1 Mo. Female	A girl, 6 weeks old, was placed on her stomach in a crib along with a comforter set, bumper pads, toys and blankets. Two hours later, she was found not breathing. The cause of death was sids.	The victim was found prone, and the cause of death was SIDS. Although a bumper was present, blankets reportedly covered all sides of crib. None of the documents mention bumper contact or involvement.	Unlikely
24	1999	7 Mo. Female	A 7 month old female died of sids and was found unresponsive by her sister, on a mattress on floor with bumper pads and pillows. 5847	The victim was found on a mattress on the floor, with bumpers and pillows. There is no mention of bumper contact or involvement in this incident.	Unlikely

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
31	2002	7 Mo. Female	A seven month old female was found unresponsive in her crib by her mother. The victim was placed on her back in the crib, which did not have a mattress. The make shift mattress consisted of a thick blanket wrapped in a sheet, several pillows and a crib bumper not secured to the crib. The victim was found with her face against the crib bumper and pillow. Cause of death was asphyxiation.	The victim reportedly was found on her back with her head extended backwards, below her shoulders, into a gap between an uninstalled bumper and a pillow, with her face against the bumper and pillow. The incident occurred in a crib with a "make shift" mattress consisting of a "very thick blanket wrapped in a sheet," which formed a 10-inch gap between the blanket and pillows. A pillow was used as headboard. The autopsy refers to an "overstuffed bumper," but the police referred to them as pillows and the police report stated that the head was between a pillow that was used as a mattress and a pillow that was used as a headboard. The only bumper visible in the report photos appears to be inaccessible because it is covered by pillows. Evidence suggests that the Investigator/ME misidentified a pillow as a bumper, and that the bumper was not involved.	Unlikely
38	2003	3 Mo. Female	Decedent lying prone in a crib with a full size pillow & bumper pads - positional asphyxia - autopsy yes.	The victim was found prone below a full-size pillow with her head turned to the side. Bumpers were present, but there is no mention of their involvement or of contact with the bumpers.	Unlikely
52	2007	2 Mo. Male	A 2 month old infant was put to bed in a crib along with his monozygotic twin. Both twins awakened for feedings at approximately 1 am and 4:30 am the next morning. Both twins were placed in "baby back nappers." these devices consist of two triangular foam pillows attached to one another by cloth straps, they are intended to keep an infant who is placed between them on his or her back. At some point the victim's shoulder and face dropped to the right and his nose and mouth contacted the back napper. He was found dead at approximately 11:30 am the next morning.	The victim was found turned within foam wedge positioners, with his face pressed against right-hand side of a cloth-covered sleep positioner. His nose and mouth were almost "buried" into the pillow or wedge, and no other pieces of bedding were near his face. Bumpers are visible in the incident report photos, but they are not mentioned in the reports and the victim never contacted them.	Unlikely
53	2008	2 Yr. Female	Pt found at home face down in crib between pillow & bumper, cold, stiff & not breathing, sm amount of blood found in crib; death cause unknown	The victim was found face down between a pillow and a bumper. However, the cause of death was found to be cardiorespiratory arrest due to seizure activity. The victim had a history of seizures.	Unlikely
56	2008	2 Mo. Female	Within six hours of being fed and placed in her crib, a two-month-old female was discovered unresponsive. The crib had a small foam mattress, covered by a thick pink, floral comforter. A pink floral crib bumper was securely tied to the corners of the crib. A small brownish, orange stain was observed on the comforter. The cause of death is listed as an acute cerebral anoxia in the brain.	The victim was found face down on a mattress that was covered by a soft comforter. The head was reported as having been turned to the side originally, suggesting that, when the child was found, the face was literally face down. The bumper was mentioned as being present and securely tied, but there is no mention of its relevance to this incident.	Unlikely

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
58	2009	1 Mo. Female	A one-month-old female suffocated in the soft bedding of a non-full size crib, after she managed to turn over onto her stomach, while sleeping in a sleep positioner. Days prior to incident, the mother of the victim witnessed her daughter turn herself over and thought the sleep positioner would prevent her from turning over. Once turned over, the victim suffocated in the numerous blankets, pillow and sheets which were doubled over onto the mattress pad. The mother added the blankets because she thought the crib pad was too hard.	The victim was found face down in a sleep positioner with her arms down by her side. She reportedly suffocated in the blankets, pillow, and sheets that were doubled-over onto the mattress pad. A bumper was present but the victim was not near or in contact with the bumper.	Unlikely
60	2009	2 Mo. Female	A two month-old female was discovered dead in a bassinet. The infant was last seen alive eight hours earlier when her mother fed her infant formula from a bottle. The infant was then placed to sleep on her stomach on top of an adult-sized pillow inside of the bassinet. Also in the bassinet with the infant were bumper pads around the perimeter of the bassinet, two blankets, and a stuffed animal. Cause of death was determined to be asphyxiation due to soft bedding.	The victim was found prone with her head turned to the right and her face pressed down into a pillow, which was used to pad the floor of the bassinet and curved up the sides of the bassinet. The victim's face was "completely buried" or "embedded" into the pillow, with the mouth and nose area "stuck" to the pillow. The report mentions that the top of the victim's head was touching a bumper. However, the reported contents of the scene refer to a bassinet cover, not a bumper. Thus, it sounds as if a bumper might not have been present, and even if one was, the evidence suggests it did not play any role in the death.	Unlikely
62	2009	7 Mo. Female	A father placed his seven-month-old daughter supine in a full size crib with four blankets that included a quilt and bumper pad. The child was found unresponsive with the quilt wrapped around her neck. The child was transported to a local hospital where she was pronounced. An autopsy revealed the manner of death was an accident with asphyxia as the cause of death.	The victim was found prone, face-down with a quilt wrapped around her neck. The quilt reportedly was "very constricting." A bumper was present but was not mentioned as being relevant, in contact with child, or otherwise playing a role in the incident.	Unlikely
66	2009	2 Mo. Male	2months 11 days old male decedent found lying face down in a portable playpen. Inside the playpen was one standard size crib bumper pad that had been folded to accommodate the smaller size of the playpen. There were 3 standard sized blankets folded.	The victim was found face down in a playpen. A bumper was mentioned as being present, and was folded to accommodate the playpen size, but there was no indication that it was relevant, in contact with the child, or otherwise involved in the incident.	Unlikely
68	2010	3 Mo. Male	A 3 month-old boy died from positional asphyxia after he was discovered not breathing in his crib by his grandmother. The boy was reportedly found face-down on top of a decorative crib quilt that was spread out over the mattress. It is noted the crib was also fitted with bumper pads and a second blanket was also in the crib. The boy had previously been placed in the crib on his stomach for a nap.	The victim was found prone and face-down on top of decorative quilt that was spread over the mattress. Bumpers were installed, but the report explicitly states there was "no indication that ... bumper pads were found near the victim's face."	Unlikely

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
77	2011	2 Mo. Male	2 mom died after he was put in the crib against the bumper pad on the pillow. He was found unresponsive lying supine in the crib.	The victim was found face down on a pillow. He had been placed in the crib with his right side next to the bumper, but there is nothing to suggest that the child was in contact with bumper at time of incident. A blood stain was found near the corner of the pillow. Regardless, the cause of death was reported to be lymphohistiocytic myocarditis. There is no evidence that the bumper played a role in the death.	Unlikely
78	2011	3 Mo. Male	A three month old male infant was found unresponsive in a drop side crib with bumper pads after being put down for a nap on his stomach. He was found by his mother three hours later unresponsive. The crib had other items inside with the infant including a cigarette lighter, pillow, blankets, a stuffed animal and a rag. Cause & manner undetermined.	The victim reportedly was found prone in same position as he had been placed to sleep. Bumpers are mentioned as being present, but there is no indication that they were relevant, in contact with the child, or otherwise played a role in the death.	Unlikely
79	2011	2 Mo. Female	A two-month-old female suffocated while sleeping in a crib at her home. She was found on her stomach in the corner of the crib, with a knit blanket wrapped around her shoulder and back and pressed between her face and the crib mat. There were no other injuries in this incident.	The victim was found prone with a blanket pressed between her face and a "crib mat." The incident report refers to the distance between the "crib mat" and the top of the crib as being 28 inches, which matches the "inner side rail height" and is almost same as headboard and footboard height (29.5 inches), so the "crib mat" is referring to the mattress. Suffocation was on the blanket. Bumpers were installed, but there is no evidence that they were involved in the incident.	Unlikely
82	2012	4 Mo. Male	A-4-month-old male was found unresponsive in his crib after his head was found under a u-shaped pillow and stuffed animals. Prior to his death, the decedent had respiratory issues and fussiness with possible cold like symptoms. The cause of death was classified as asphyxia.	The victim was found on his back with a nursing pillow and a large stuffed animal over his face. A crib bumper was installed, but there is no mention of its involvement or of contact between it and the victim.	Unlikely
89	2012	5 Mo. Male	A 5 month old male infant sleeping alone in a crib, died from rebreathing suffocation. The infant was discovered in a prone position with his face and mouth down on a thick foam pillow. The crib contained additional soft bedding materials such as a blanket, a folded quilt, bumper pads, and a foam mattress. The crib itself was not deemed to be a factor in this death.	The victim was found prone with his face/mouth down on the center of a thick foam pillow. A bumper was mentioned as being present in crib, but there is no evidence suggesting that it was relevant, in contact with the child, or otherwise played a role in the death.	Unlikely
90	2012	2 Mo. Male	2 mom decedent was placed in crib along with twin. They were propped up by baby pillow with bottles. Their mother discovered the decedent face down in soft bedding inside wooden crib with baby pillows, soft blankets, stuffed animals, and bumper around edges. Cod: asphyxia	The victim was found face down in soft bedding. He had been on a nursing pillow. A bumper was installed but there is no mention of its relevance, contact with the child, or having otherwise played a role in the death.	Unlikely

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
91	2012	3 Mo. Male	<p>Subject is a 16 week old male. He has no known medical history. Parents report he was an uncomplicated pregnancy. Mother had prenatal care from 3 months on and estimated 10 - 12 visits. She reports only taking prenatal vitamins. Mother denies smoking, ETOH or drugs during pregnancy. Subject was a third child of the mother. He was a vaginal delivery without complication and was discharged 24 hours after delivery. Subject had no illness or other complications in his first week of life. Subject was having regular doctor visits and was up to date on immunizations. Mother could not remember when the last MD visit was. However she reported he was scheduled 11-7-12 for another appointment and immunizations. Parents denied any recent injury and deny use if CDS, ETOH or smoking in the apartment. Subject reportedly had a runny nose two days ago, but was fine yesterday. Subject was breast feeding in the evenings and fed "[REDACTED]" formula during the day. The most recent bottle from feeding collected.</p> <p>The mother repo [end of narrative]</p>	The victim was found prone with his face into the mattress. The report mentions that a crib bumper was installed, but there is no mention of its relevance, contact with the child, or having otherwise played a role in the death.	Unlikely
92	2013	3 Mo. Female	A three-month-old girl was found by her mother unresponsive in her crib and was pronounced dead at the hospital. Police reported the crib contained blankets, a pillow, and it had bumpers.	The victim was found prone with her face into bedding. A small blanket was to the left of her face, but her face was turned to the right. The report mentions that bumpers were present, but there is no mention of their involvement, contact with the victim, or having otherwise played a role in the death.	Unlikely
93	2013	6 Mo. Male	6 months & 18 days old male decedent was found in corner of crib with bedding over his face. Crib had stuffed animals, blanket, & soft bumpers within it. Cod: suffocation by bedding	The victim was found in the corner of the crib with bedding over his face. Bumpers mentioned as being present, but there is no indication that the bumpers are the "bedding" referred to in the incident.	Unlikely
94	2013	1 Mo. Male	The 28 day old infant was found face down in his crib on 10/4/13. The infant had been placed down in the crib in a left lateral position and was propped up with bedding. The crib contained an what appeared to be the original mattress. Bumper pads lined the inside of the lower portion of the crib and a thick folded comforter was placed on top of the mattress. The infant had been placed on top of the comforter and covered with a small baby blanket. When the mother returned to the crib several hours later she found the infant face down into the comforter. She picked the infant up and found that he was unresponsive and not breathing. He was pronounced dead at the scene upon arrival of emergency perosnnel	The victim was found face down into a comforter. Bumpers are mentioned as being present, but there is no indication that they were involved or in contact with child.	Unlikely

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
95	2013	1 Mo. Male	A 28 day old boy was found unresponsive in his crib by his mother. The boy was found in the crib with three blankets inside and a crib bumper installed. The boy was pronounced deceased at the scene and the cause of death was ruled to be asphyxia due to adverse sleep environment. Addendum added 11/25/2014.	The victim was found unresponsive in the crib. It is unclear whether he was found face down or on his back. A bumper is mentioned as being present, but there is no mention of it playing a role or being in contact with infant.	Unlikely
96	2013	2 Mo. Female	A two-month-old girl was found by her mother in her crib with blood and foam around her nose and mouth. She was pronounced dead at the hospital. The crib contained several sheets, blankets, and a pillow.	The victim was found on his back with blood and foam around her nose and mouth. There is no indication that anything was near her, let alone a bumper. A bumper is never mentioned in the report. An installed bumper is barely visible in the incident report photos, but they are essentially inaccessible and covered by other blankets and bedding.	Unlikely
97	2014	2 Mo. Male	A 2-month-old boy was found unresponsive in his crib. The child died of positional asphyxia. The child had recently been to the doctor for congestion. The child's mother reported she had place a pillow in his crib to ease his congestion. Several blankets were also found in the crib and it was also fitted with a bumper pad.	The victim was found on his back with his face turned to the right. There was an indentation and fluid in the center of the pillowcase. A bumper is mentioned as being present, but there is no mention of its relevance, being in contact with child, or otherwise playing a role in the death.	Unlikely
103	2014	5 Mo. Male	The 5-month-old male victim was found unresponsive in his crib on top of a small blanket. The victim was partially on his side and partially on his stomach when found. The victim was pronounced deceased at the scene. The cause of death was determined to be positional asphyxia due to sleeping in the prone position on soft bedding.	The victim was found partially prone and partially on his right side on top of a blanket in a crib. The cause of death was determined to be positional asphyxia due to sleeping prone on soft bedding. He was found by his father, who stated that nothing was obstructing the victim's nose or mouth. There is no evidence of bumper contact or involvement.	Unlikely
104	2014	3 Mo. Female	A 3 month old female died from positional asphyxia while sleeping in her wooden crib. The child was discovered face down in the crib by her father. 911 and CPR were started on the infant. She was taken to a hospital where she was pronounced deceased. The coroner stated that the bedding and pillows were the contributing factor which likely caused this death.	The victim was found face down "with blankets and pillows" in a crib by the father. Lots of bedding was in the crib, and bedding and pillows were specifically identified as contributing factors to the death. The child had a history of being found face down in the crib. There is no mention of bumper contact or involvement.	Unlikely

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
105	2015	8 Mo. Male	<p>The 8-month old male victim died as a result of compression and positional asphyxia after it is believed he fell head first out of his crib at home while attempting to climb out of it. The boy became wedged between a 5 inch gap between the crib and his mother's bed. There was also a full-body pillow stuffed in the gap where the victim became lodged. It is noted the mattress position in the crib was raised to it's highest setting. It is also noted the crib had bumper pads installed that could also have been used for additional height and leverage by the victim.</p>	<p>The victim was found wedged upside-down in a 5-inch gap between the outside of the crib and the mother's bed, along with full-body pillow stuffed into gap. His face was into crib side, and he apparently fell out of the crib while attempting to climb out. There was speculation about possibility that the child "could have used" the installed bumpers to climb out, but there is no reported evidence of this. In addition, the crib mattress had been raised to highest position, which would put mattress-top to crib-top distance at about 12 ¼ inches, which is less than half the child's height of 26 inches. Child was known to be able to pull himself to a standing position.</p>	Unlikely

Hazard Pattern: Contact Outside Crib (5 Reported Fatalities)

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
17	1997	5 Yr. Male	A developmentally slow boy, age 5, died of positional asphyxia after he pushed himself into the corner of his toddler bed, with his face down between bumper pads.	The victim was found face down between bumpers in the corner of a toddler bed. The victim was a developmentally delayed 5-year-old.	Likely
19	1998	4 Mo. Male	This incident involved the death of a four month old infant due to positional asphyxia. The infant was found unresponsive by his mother, lying on his stomach with his face into the padding which surrounded his bassinet.	The victim was found prone in the corner of a rocking bassinet with his nose and mouth pressed into bumpers that were installed around the interior side wall of the bassinet. HS concluded that the bassinet likely stopped in a tilted position, and suffocation was likely due to the associated positional asphyxia, not the bumper.	Unlikely
29	2001	11 Mo. Female	An 11 month old female slid off a day bed mattress at the open side/foot end of the day bed with her lower body under a crib bumper pad. The top edge of the crib bumper pad is believed to have become caught around the victims neck and as she slid forward, was unable to breathe and suffocated. The cause of death is mechanical asphyxia. The manner of death is considered accidental.	The victim was found seated, leaning forward, on the floor next to a small daybed (likely a toddler bed) with a bumper around her neck. Her lower body slid through the open side of the bed, under the installed bumper, and bumper caught around neck. The cause of death was mechanical asphyxiation from entanglement.	Likely
48	2007	21 Mo. Male	A 21-month-old male victim died of asphyxia due to compression of the neck when he became entrapped and suspended in the ties to a bumper pad that was affixed to his bed in his home. The victim was in a convertible crib that had been set up as a toddler bed. The bumper pad was tied at the top to the side slats of the bed. The victim had been put to bed by his mother at night and was found partially hanging out of the bed and unresponsive by his mother the next morning.	The victim was found partially hanging out of a toddler bed with his knees close to floor and the back of his head under a bumper, which was installed on the side rails of the toddler bed. He was entangled in the lower ties, which were not secured and were wrapped around his neck. The cause of death was asphyxia due to neck compression, secondary to entrapment and suspension in the bumper.	Likely
102	2014	2 Mo. Male	A two-month-old infant was found unresponsive in his crib. The child was lying face down. The child had been placed to bed on his stomach and several items including a padded bumper pad, a blanket and packages of diapers were in the crib where the child was found. The cause of death was probable positional asphyxia.	The victim was found prone and face-down into the mattress in the upper left corner of the sleep product. Although the incident report identified the sleep product as a crib, the photos show that the product actually was a bassinet. A bumper was installed, so given the child's position his head presumably was in contact with the bumper. HS staff notes that the bassinet likely stopped in a tilted position and that well-developed lividity on the face and body indicate a face-down prone position. Blankets also were reportedly in the same corner of the bassinet.	Unlikely

Hazard Pattern: Entrapment/Wedging Against Object in Crib (23 Reported Fatalities)

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
6	1992	2 Mo. Female	A 2 month old female died sleeping on cushions (bumper pads & crib mattress) in her crib.	The victim was trapped face down between the side rail and a thick homemade cushion in the crib. The report states that there was sufficient space between the mattress and crib to force a "bump pad," and hand-written notes refer to the victim being wedged between the cushion, bumper, and mattress. The ME concluded that suffocation was against the mattress.	Unlikely
10	1993	1 Mo. Male	Found unresponsive wedged between pillow and bumper pad. Positional asphyxia - autopsy yes	The victim was found lying face down, wedged between a blanket-covered pillow and a thick bumper on side of crib. The victim had blanket-pattern markings on his face, suggesting that his face was either straight down into the thick blanket that was used as a mattress pad, or pointed toward the pillow.	Unlikely
13	1996	2 Mo. Female	Baby's head went between pillow and padded crib wall, face down in soft bedding - asphyxia; suffocation-face down in soft bedding - autopsy yes	The victim was found prone with her head and neck in a 4-inch space between the bumper and a pillow, and her "full face was into the mattress." The victim was placed prone on the pillow, and her torso and legs were still on the pillow. The infant was described as a "sick child," with VSD, breathing problems, poor weight gain, and a chronic cough.	Unlikely
27	2000	3 Mo. Female	Father went to check on pt to find pt in middle of large pillow and small pillow -face in bumper railing of crib. D:s/p cpr, cardio resp	The victim was found wedged face-down between the bumper and a pillow, with a blanket over or in her mouth.	Unlikely
30	2001	3 Mo. Female	A female infant, age 3 month, who was found wedged between adult pillows and crib bumper on an adult bed died from asphyxia.	The victim was found prone, wedged between adult pillows and a bumper. The Narrative states she was on an adult bed, but the report states that she was in her crib.	Unknown
32	2002	4 Mo. Male	A male infant, age 4 month, placed for a nap in a crib with twin sister was found wedged between the bumper pad & his sister. Cause of death asphyxia due to positional crib accident.	The victim was found prone, wedged with his head face-down between the bumper and his sibling. He was 4 months old, but was 3 months premature.	Unlikely
47	2007	1 Mo. Female	A 1 month old female was found unresponsive after being placed in a prone position on an infant positional sleeper with her head drooping down. Cause of death: positional asphyxia. 2007-4041	The victim was found slumped face-down over an infant positioning pillow, with her head drooping downward. The reenactment photo shows the back of her head against the installed bumper, but the report never mentions the bumper as being present or relevant.	Unlikely

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
51	2007	22 Mo. Male	Face became pressed against crib bumper pad while sleeping - asphyxia; suffocation - - autopsy yes.	The victim was found on his left side at end of crib, between a bumper and an infant positioner under a sheet in the crib, with his face pressed against the bumper. However, the reenactment photos show the victim positioned with his face pointed away from the bumper. The victim was a 22-month-old with "severe" cerebral palsy, who had little muscle control and could not turn over.	Unknown
54	2008	2 Mo. Female	The two month old female was placed face up in the unknown model of crib on top of a sofa cushion with her head slightly elevated. Numerous other items and pillows were in the crib. The infant was found deceased the next morning by the father wedged between a pillow and the bumper pad.	The victim was found lying prone on a sofa cushion within the crib, with her face partially wedged face-down between the pillow/cushion and the bumper. Chronic interstitial pneumonitis reportedly contributed to this incident.	Unlikely
55	2008	3 Mo. Female	Wedged between bumper guard and pillow. Positional asphyxia. Autopsy-yes.	The victim was found on her side with her face wedged between a pillow and the bumper-installed crib railing. The right side of her face was down into the mattress and pillow and the left side of her face was partially touching the "rails," so her face was likely pointed into the mattress or slightly into the bumper.	Unlikely
69	2010	1 Mo. Male	A seven-week-old male victim died when he rolled out of a sleep positioner and became stuck at the corner of the bumper pad. The victim was put to bed about 11:30 p.M. And the parents found the child the following morning at approximately 6:15 a.M. The victim was found by his father turned on his stomach with his face against the bumper pad and mattress. The victim's father screamed for his wife and removed the victim from the crib. The victim's father initiated cpr on him and called 9-1-1. When ems arrived, the victim was pronounced dead.	The victim was found prone between a sleep positioner and a bumper, with his face where the bumper meets or intersects with the mattress. He recently was diagnosed with infant asthma.	Unknown
70	2010	6 Mo. Female	A six-month-old female victim was found unresponsive in her crib, lying between a nursery product and a bumper pad. Victim was transported to the hospital where she was pronounced dead shortly after her arrival. The autopsy listed diagnosis as probable positional asphyxia. Manner of death listed as accidental.	The victim was found wedged or lodged between an infant recliner and a bumper. She reportedly was lying on her back, perpendicular to the recliner, with her head tilted back off the edge of the recliner and her face into the bumper.	Unlikely
71	2010	1 Mo. Male	1-month-old male decedent was placed on top of an adult pillow on a crib. He was wedged between the pillow and bumper pad.	The victim was found with his face wedged between a pillow and the bumper. He had been sleeping on the pillow and apparently rolled off, so his actual face position is unclear. Purge on both the pillow and bumper suggest that his face might have been straight down.	Unknown

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
72	2010	3 Mo. Male	A 3-month-old male was sleeping in his full size crib on his stomach when his father found him face down on the corner of a regular size pillow with his head leaning against the bumper pad. He died of positional asphyxia.	The victim was found face down in the corner of an adult pillow, with his head against the bumper. The victim apparently "turned his head and suffocated on the edge of the pillow."	Unlikely
74	2010	1 Mo. Female	A five week old female, victim, was placed in a baby bouncer inside her crib to sleep. The bouncer had been propped up on the bottom with a pillow to level it so that it would be horizontal rather than on an incline. The harness on the bouncer was not used to secure victim into it but a blanket was placed on top of the bouncer and another blanket was used to cover her. Victim died of suffocation when she was found on the side of her crib mattress at the bottom of the bouncer wedged between the crib bumper pad and the pillow holding the bouncer chair.	The victim was found lying partially prone on her side, wedged between the bumper and a pillow, which was propping up an infant bouncer that was in the crib. The victim's head was toward the bed's headboard, and her face was toward the bumper. The victim was 5 weeks old and "not that mobile."	Unknown
75	2010	4 Mo. Female	A 4-month-old female infant was placed to sleep in a harnessed infant seat which was placed in a crib with bumper pads. When the victim's father checked the video monitor he did not see the victim in the infant seat. He went into the bedroom and found the victim not breathing, still harnessed in the infant seat with her head hanging off and tilted back with the neck hyper-extended and her face in the bumper pad of the crib. The victim was transported to the hospital where she was pronounced dead. The cause of death was position/compression asphyxia.	The victim was found halfway out of an infant recliner, with her head hanging off and tilted back so her face was into the bumper. Her head was entrapped between the recliner and the bumper. HS staff concluded that this was a case of neck hyperextension.	Unlikely
76	2010	4 Mo. Male	A four-month-old male died from positional asphyxia when he was found face down wedged between a nursing/feeding pillow and the crib bumper pad.	The victim was found face down with his head tilted to the left, wedged between a nursing pillow and the bumper. Based on the reenactment photos, his face appears to be into the pillow.	Unknown
80	2011	4 Mo. Male	A 4 month-old male was found unresponsive, lying perpendicular to and on top of a foam baby recliner installed in his crib, into which he had been placed to sleep the evening prior. When found the victim's head was hanging off the recliner and his face was pressed against a crib bumper affixed to the side of the crib. The victim was transported to a local hospital where he was pronounced dead. The postmortem report listed sids as the cause of death and the manner of death as natural. Addendum added 1/27/2012. Addendum received 2/17/2012. Addendum added 3/30/2012. Addendum added 9/25/2012.	The victim was found lying on his back in an infant recliner. He was turned perpendicular to the recliner, with his head hanging off and his entire face pressed into the bumper. The very top of his head was resting on the mattress. The ME insisted that the cause of death was SIDS, not asphyxia. HS staff concluded that this was a case of neck hyperextension.	Unlikely

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
84	2012	7 Mo. Male	A seven-month-old male was placed in a reclining infant sleeper with the cover and the harness missing. The reclining sleeper was also placed inside a full size crib with a bumper pad. The last time the victim was seen alive was approximately 4:00 a.M. At approximately 6:15 a.M. The victim's mother came in and found the victim unresponsive. The victim was in a prone position with his head entrapped between the top wall of the reclining sleeper and the crib wall and/or the top of the bumper pad. Cause of death listed as sids.	The victim was found prone with his head entrapped between side of an infant recliner and the bumper-installed crib side.	Unlikely
86	2012	1 Mo. Male	I mom decedent was found unresponsive by his father wedged between crib pads & full size, adult pillow. Paramedics & law enforcement attempted to revive child, but couldn't. Cause of death: suffocation by bedding	The victim was found wedged between the bumper and an adult pillow.	Unknown
98	2014	3 Mo. Male	The parents checked on the 3 month old male victim at approximately 0945 hours on the date of the incident. It appears he was wedged between a full size pillow and the bumper pads face down. He was transported to the hospital where he was declared.	The victim was found lying prone and partially on his right side, with his face between a full-size pillow and the bumper. The autopsy report says his face was between the bumper and mattress.	Unknown
99	2014	8 Mo. Female	An eight month old female died from asphyxia due to obstruction of her airway after her 31 year old father found her partially leaned over onto her right side with her head up against the crib bumper pad and with her lower part of her body on her portable infant recliner cushion in her crib. The victim's left leg was still strapped into the harness/restraint system of the infant recliner cushion.	The victim was found partially turned to her right side and arched over the side of an infant recliner. Her head and right shoulder were pinned between the infant recliner and bumper, with her face into the bumper.	Unlikely
107	2016	5 Mo. Male	A 5-month old male infant was positioned in a car seat (product) whereby such product was situated overnight on top of a crib mattress. The infant was not buckled into or strapped to the product. The product flipped over entrapping the infant between the canopy and handle. He did not survive. The mattress did not contribute to the entrapment. The deputy coroner theorizes the infant's own movement at some point in time caused the product to flip over.	The victim was found in a hand-held infant carrier that had been placed in the crib and flipped or tipped over. He reportedly was found prone, with his knees in the seat pan and his face and neck entrapped between the carrier canopy and the top of the seat back. The child had not been buckled or strapped into the carrier. A bumper is not mentioned at all, but reenactment photos using a doll show one present and in contact with the doll's head. Staff cannot tell whether the child actually was in contact with a bumper since one was never mentioned, even when describing what was in the crib. The bumpers in the photos look like they are sagging, but staff cannot be certain whether this was the case at the time of the incident.	Unlikely

Hazard Pattern: Entrapment/Wedging in Perimeter of Crib (12 Reported Fatalities)

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
8	1992	7 Mo. Female	7 month old girl was placed in her crib for nap after being fed by her mother. Child was found later in her crib with her head wedged between the mattress and the bumper pad attached to side slats. Child was pronounced dead on arrival at the hospital.	The victim was found with her head "wedged between the side of the mattress and the bumper pad," but the position of her face is unknown.	Unknown
11	1993	9 Mo. Female	A 9 month old female was found deceased in her crib by her 21 year old mother on July 12, 1993. The infant's death was ruled as accidental suffocation due to entrapment between the crib mattress and the crib's railing. Police and coroner's reports state that two side rail slats were missing from the crib, creating a 7" space that the victim's body slipped through. The victim was found hanging from the crib with her chin and neck suspended by a bumper guard.	The victim was found hanging on the outside of the crib near the wall, between the mattress and crib railing, with her chin and neck suspended by the bumper along inside railing. She was facing the wall, with the back of her head against the mattress, and the bumper covering her nose and mouth. Two slats were missing from the crib, creating a 7-inch space through which her body slipped feet-first.	Likely
15	1997	2 Mo. Male	A 2-1/2 month old male died due to probable suffocation. According to an investigator with the sheriff's department, the infant's mother found him face down in his crib. The investigator stated the baby's head got caught between a baby blanket and the bumper pad in his crib. He was pronounced dead at the scene.	The victim was found face down in crib. According to the Sheriff's office, his head was caught between a blanket and the bumper, but according to the autopsy report the child was entrapped between side of crib and edge of mattress.	Unknown
21	1998	7 Mo. Male	Baby became wedged between mattress and bed rails - acute asphyxia; chest compression baby bed between mattress and rails - autopsy yes	The victim was trapped between the crib side rail and the mattress, with only his head "sticking up." His chin was on the mattress and back of his head was wedged against the side rail slats. The crib was assembled from components of different crib manufacturers, with the side rail mounted upside down with L brackets and with missing hardware. The left side rail was falling away from the top of one end rail, and the right side rail was pushed away at the bottom. The cause of death was asphyxia from chest compression.	Unlikely
22	1998	6 Mo. Female	A 6 month old girl was found dead in her infant crib. Her body was wedged between the bumper pad and side rail of the crib with her legs outside the crib and her face against the bumper pad and mattress.	Nine of 17 slats on the crib side rail came loose and separated from the top or bottom rails. The bumper was installed and that side of the crib turned toward the wall to try to "solve the problem." The victim slipped through one of the openings feet-first and became trapped upright between the wall and the mattress, with her face pressed against the mattress or bumper.	Unlikely

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
26	2000	7 Mo. Male	A 7-month-old infant boy died of suffocation when he was found trapped between the mattress and the side of the crib. It was an older style crib, leaving a gap between the mattress and the bed frame.	The victim slipped through and wedged into a 3- to 4-inch gap between the mattress and the foot panel of the crib. The victim's head and upper torso were between the side of crib and the mattress, with his face between the mattress and crib or bumper. His feet were protruding from the gap between the mattress and the crib side. The cause of death was compression asphyxia.	Unlikely
28	2001	8 Mo. Female	An 8 month-old girl slipped between a mattress in a baby crib and the side of the baby crib, pinning her head between that mattress and the side of that baby crib. She was alone for about 15 to 20 minutes when the incident occurred. She was transported to a local hospital where she was pronounced dead from asphyxiation.	The victim reportedly stood on the edge of the mattress, and slipped and pinned her head between the mattress and crib side. Her feet were suspended straight down, and her face was against the bumper that was installed along the frame. The crib was missing slats, and the mattress support system had come loose, causing the mattress to sag.	Unlikely
33	2003	10 Mo. Male	Slid between mattress & crib rail/wall - asphyxia; consistent with positional asphyxiation; compression between mattress & crib rail/wall - autopsy yes.	The victim slid feet-first into an opening between the crib side rail, which came loose from the end of the crib, and the mattress, causing his chest and head to become trapped or pinned. His feet were down toward the floor, and his head was at the level of the mattress. The bumper was completely below the mattress line.	Unlikely
36	2003	12 Mo. Female	Child found hanging by crib pad after falling out of crib - asphyxiation - autopsy no.	The victim was found hanging outside crib, by her neck and chest, from a bumper. Her body was trapped in a 6- to 8-inch space between the crib side and the wall, with her feet hanging. Her arm was caught between the slats, and her neck and chest were caught under the bottom of the crib side rail, with the bumper tight against her neck. The crib side rail had separated from the crib at one corner.	Likely
45	2007	9 Mo. Male	Trapped between mattress and lift gate of crib - compressional asphyxia; autopsy yes.	The victim was trapped and suspended upright between the mattress and the crib's drop side, which detached from the rail and swung outward. The resulting 5-inch gap permitted the passage of his torso but not his head. The victim's back was against the drop side, and his chest was against the mattress side. His head, neck, and throat were between the top-side surface of mattress and the crib side, with his neck entrapped against the edge of the mattress. Nothing was wrapped around or obstructing his nose or mouth. The cause of death was compression asphyxia.	Unlikely

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
59	2009	7 Mo. Male	A 28 year old mother placed her 7 month old son down on his back in the middle of his crib & covered him with a light blanket. She then left the room & took a nap. At some point the child moved around in the crib. He ended up with his head between the crib mattress and either the head board of the crib or a bumper pad. The child's face was against the mattress. He died from positional asphyxia. Police identified the crib as being in good condition with no structural problems & said the mattress was a good fit.	The victim was found prone and face down with his head stuck between the mattress and headboard. His throat was against the mattress, and his nose was into the mattress. The bumper may not have been tied or installed at the headboard.	Unlikely
106	2015	5 Mo. Male	Was called to a home in our county where baby died after being put to bed in a drop-side crib which had the bottom portion of the rail not attached to the crib and the top portion of the rail attached to the crib. Mom had purchased crib at a flea market and had actually sent away for a kit to "fix" the crib, but had not yet done the fix. Drop side of crib was against the wall, crib was in far corner of room with bedding, bumper pads and a mobile attached. Baby was found trapped between the bumper pad and the inside of the drop side rail which had tilted out, entrapping the 6 month-old infant in an almost standing position with the baby's face and neck trapped against the bumper and mattress, the right hand and arm were caught in an upward position in one of the crib slats and the baby's chest was pinned against the mattress. There were actual crib slat marks against the back of the baby's head and right arm when found. It is estimated baby had been found 1-3 hours after death. Mom and other family members wer [end of narrative]	The victim was found trapped and suspended upright between the bumper and the inside of drop-side crib rail, which had tilted out. The child's face and neck were trapped against the bumper and mattress, and the back of his head was against the crib slats (i.e., the head was trapped between the mattress and crib slats, but the bumper was between the front of the face and the mattress). The child's chest also reportedly was pinned against mattress. His right arm caught in crib slat. The crib apparently was purchased already broken at flea market or yard sale.	Unlikely

Hazard Pattern: Entrapment/Wedging, Other (6 Reported Fatalities)

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
4	1991	4 Mo. Male	A 4 month old male died sleeping in his crib wedged between the mattress and frame and bumper pads in a tilted position.	The victim was found face down in the rear-headboard corner of the crib, which dropped down after crib supports broke, causing the frame and mattress to tilt. The victim was wedged against the bumper, but the position of his face is unknown.	Unknown
7	1992	5 Mo. Male	Child put head through slats in crib & died - asphyxia; hyperextension of neck associated with crib bumper resting on anterior neck - autopsy yes	The victim was found on his back, wedged with his head between the side rail slats and the mattress. The victim's body was perpendicular to the side rail, with the left side of his head against the rail and the right side of face against mattress. Other information in the incident reports state that the victim's head was wedged between the slats. A bumper was installed and was pressing onto the neck; however, the cause of death was reported as asphyxia from neck hyperextension.	Unlikely
41	2005	4 Mo. Female	A four month old female died from asphyxiation when she was found unconscious by her father in her crib with her head compressed against the crib bumper located in her home. The cause was asphyxia according to the me's report.	The victim was found face down, with her arm wedged between the crib and mattress. A bumper was present, and the autopsy report identified the cause of death as "asphyxia due to compression of head against crib bumper."	Unlikely
50	2007	2 Mo. Female	A two-month-old female died of suffocation when her face and body were pressed against the bumper pad inside the crib. Her arm was caught between the bumper pad and the side rails, so she could not push her self up to breath. There were several other items in the crib that may have contributed to the incident.	The victim was found with her face and body pressed against a bumper. Her arm was under the bumper and caught between the bumper and crib side rails. Other items in the crib reportedly might have contributed to the fatality.	Unknown
81	2011	5 Mo. Male	A 5-month old male was found unresponsive in a crib at his residence. The child was found lying on his stomach with his legs protruding from between the crib slats. The medical examiner concluded that the child died as a result of wedging in conjunction with suffocation.	The victim was found prone with both legs protruding through the crib slats, under an installed bumper, to his upper thighs. The orientation of his face is unknown, but it clearly was not into the bumper. The child could "almost crawl."	Unlikely
101	2014	2 Mo. Male	A father placed his 2-month-old son (the victim) into his crib to sleep. The victim was placed face-down on his stomach. Approximately 10 hours later the victim's mother went to check on him and discovered that he was unresponsive. He was found in a face-down position with his face wedged between the crib mattress and a crib bumper pad. His left arm was trapped underneath the bumper pad and between the vertical slats of the side rail of the crib. The cause of death was suffocation.	The victim was found prone and against the bumper, with his face wedged between the mattress and the bumper. His left arm was under the bumper and trapped either between the vertical crib slats or between the "bed and rails." A pattern on the face indicates that both nostrils and the mouth were occluded.	Unknown

Hazard Pattern: Contact Without Entrapment/Wedging (23 Reported Fatalities)

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
1	1990	2 Mo. Male	2 month old preemie presents with cardiac arrest,mom went in to check baby in crib found him with face against plastic bumper.	The victim's face was in contact with a bumper. However, details are limited and the reference to a "plastic" bumper raises some questions about whether this was a crib bumper or some other type of bumper (e.g., part of the apnea monitor that was present).	Unknown
2	1991	3 Mo. Male	This investigation involved a 3 month old male infant which was found by his father dead. The coroner indicates that the cause of death is sudden infant death syndrome. The victim was healthy and appeared to be growing normally. There had been a bumper pad in use in the infant's crib. The bumper pad was filled with 100% polyester quilting and had a polyester and cotton outer casing.	The victim was found prone with the head toward the left side of the crib, which had a bumper installed. The bumper reportedly was in contact with the victim, but the mother claimed that the face was not "completely covered" by it.	Unknown
3	1991	8 Mo. Female	An 8 month old female was found in her crib unresponsive. Cpr and mouth-to-mouth respiration were conducted. She was not revived. The crib contained a waterbed mattress. The crib was designed specifically for the weight of the mattress. Crib bumper pads were in the crib, as well as stuffed toys and a loose blanket.	The victim was found face-down on a comforter-covered waterbed mattress, "next to" the bumper. According to the IDI, the victim was "not trapped" against the bumper, but was "pushed up tight" against it.	Unlikely
9	1992	2 Mo. Male	A 2 month old male was found dead in his crib. He was laying on his stomach with his face straight down into a quilt which was under the infant.	The victim was found prone with his face straight down into a padded quilt, with his head pressed toward his chest and the top of his head pressed into the corner of the crib. The top of his head reportedly might have been covered by the fringe of the quilt. The report specifically states that the bumper was not near the face.	Unlikely
12	1994	4 Mo. Male	A 4 month old male died of sids sleeping with his face down between the mattress and bumped pad of his crib.	The circumstances surrounding the death are unreadable in the incident report. A Neuropathology report states: "The partial loss of neurons from Sommer's sector of the hippocampus raises the possibility of a seizure disorder relating to the perinatal germinal matrix hemorrhage."	Unknown
14	1996	14 Mo. Male	A 14 month old baby boy died sleeping in a crib with his face pressed firmly against a bumper pad. Baby was treated weeks ago for a head and chest cold with extensive breathing treatment.	The victim was found "face down on stomach" with his face pressed against bumper. The police report states that the child was prone on the left side of his face, with his face "in between" the mattress pad and bumper. He had reportedly been sick and had been placed on a breathing machine. During CPR it was reported that he sounded "very congested and not getting any air in his lungs." He reportedly had reactive airways and distinct wheezing episodes.	Unknown
23	1998	7 Mo. Male	A coroner determined a 7 month male infant died in a crib due to positional asphyxiation - face in corner of crib against bumper pad.	The victim was found on his back with his head turned to the right and his face into the corner of the bumper.	Unknown

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
25	2000	4 Mo. Male	On february 14, 2000. A four- month-old-male was found dead in his crib at home. Reports indicated that the victim became wedged between the mattress and the bumper pad of his crib. The death was declared an accident; cause of death was listed as asphyxia by suffocation.	The victim reportedly was found prone with his head slightly to the left and his face into or against the bumper. Staff cannot tell whether the face was truly into the bumper or in the area where the bumper and mattress intersect. However, HS staff determined that blanching and lividity reflect a prone, face-down position.	Unlikely
34	2003	2 Mo. Male	A male infant, age 10 weeks, was found deceased against the bumper pad in his crib with his face down in mattress.	The victim was found face down into the mattress along the edge of the crib, against the bumper. There is no indication that anything else was in the crib and the victim's face was not pointed toward the bumper.	Unlikely
35	2003	2 Mo. Female	Baby suffocated at home in the corner of the crib against the crib bumper. Suffocation - accidental. Autopsy - yes.	The victim was found with her head in the corner of the crib and her face "into" the bumper, which was "sagging inward."	Likely
37	2003	2 Mo. Male	A male infant, age 2 months, died after he was found with his face against a bumper pad in his crib at home by his mother.	The victim was found with his neck extended and face buried into a bumper. His nose and mouth were completely blocked by the bumper. The crib was missing most of its hardware.	Likely
40	2004	4 Mo. Female	A 4 month old female was found unresponsive by her parents in a crib at her home. The parents received the crib from a relative who purchased it from a thrift store. The crib was missing the mattress support so they went to a hardware store and had five pieces of wood cut. They realized the pieces of wood were too long and put them on an angle allowing the corner of the mattress to depress. The crib contained a bumper pad, toys, a quilt and a blanket. The victim was found face down in an area that was depressed. The victim's cause of death is pending.	The victim was found face down on a quilt, with the top of her head in contact with the bumper. The crib had makeshift mattress supports installed at angle, which allowed the corner of the mattress to "depress." The victim was found in this "depressed" area.	Unlikely
42	2006	5 Mo. Female	Trapped face-down against padding in the corner of the crib - pending, position asphyxia - autopsy yes.	The victim was trapped face down against the padding in the corner of the crib. The face also reportedly was against the bumper. It is unclear whether the face was pointing into the area where the mattress and crib side intersect, but HS staff concluded that the face was likely into the mattress.	Unlikely
44	2007	3 Yr. Female	A three year old female was found in a crib with a crib bumper wrapped around her head and neck. She died as a result of this incident.	The victim was found with a bumper wrapped around her head and neck. She was 3 years old, 7 months premature, emaciated, had cerebral palsy, and was on heavy narcotics to control seizures.	Likely

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
46	2007	4 Mo. Female	4 month old female decedent suffered positional asphyxia when she was discovered with her head between the railing and round mat. There was a bumper pad around the inside of the crib.	The victim was found prone with her face in the corner of the crib, toward a round "mat" in crib. The so-called "mat" might be a bumper, which is known to have been present. A stain near the bumper and the assertion that nothing was removed from the crib seems to support this. The victim reportedly was not "face down" on the blanket, and was found with her "cheeks abutting mattress/blanket and bumper pad."	Unknown
49	2007	5 Mo. Male	The boy was smothered while sleeping face down and up against a bumper padding inside a crib at his mother's cousin's home. The babysitter gave him a 4 oz bottle at 5 a.M. And at 7:10 a.M. She found him unresponsive, bluish-purple and cold to the touch. His body was face down with his face on a bumper pad that was pulled down like he was snuggling with it. Autopsy determined he died of "positional asphyxia while laying face down in thick soft crib bumper pad bedding at the corner of the crib."	The victim was found prone with his mouth and nose straight down into a bumper that was pulled down. His arms were extended over his head.	Likely
64	2009	4 Mo. Female	A 4 month old female was found unresponsive in her crib on her side with her forehead pressed against the bumper pad. The infant was sleeping on a mattress that was very soft and pliable.	The victim was found by her sibling with her face reportedly against the crib railing. About an hour earlier, the mother saw the victim partially on her side with her forehead pressed into, and nose and mouth "lightly touching" the bumper. The police concluded that the victim probably died before mother awoke, so her more detailed recounting of the head position was probably the position in which child died.	Unknown
65	2009	2 Mo. Male	A two-month old male was fatally injured (suffocated) at his residence when he was found unresponsive in a crib with his face against a crib bumper.	The victim was found prone with his head against the side of the bumper-covered crib, but his exact position is unclear because the person who found him was not wearing his glasses. From the available evidence, including emesis stains on mattress, HS staff concluded the face was likely into the mattress.	Unlikely
67	2010	6 Mo. Male	A six-month-old male victim suffered fatal suffocation while taking a mid-day nap in his crib. The victim's mother reported her son was placed in the middle of his crib, laying on his back for a nap. When she returned two hours later he was up against the crib's bumper pad, in the corner of the crib, unconscious with a light blue color. Cpr was performed but failed to revive the victim. He was pronounced dead the following day at a local children's hospital. Toys and blankets were also in the crib at the time of the incident.	The victim was found prone or on his right side against a bumper in the corner of the crib. His head was angled down in the corner and his left arm was over the top of the bumper. His face was wedged between the mattress and bumper or was pressed into the bumper. A blanket was on the mattress that was under the child.	Unknown

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
73	2010	2 Mo. Female	A 2 mof infant decedent in prone position with face against crib bumper at home. Positional asphyxia. Autopsy- yes.	The victim was found prone with her face against the mattress. The coroner and sheriff reports state that the face was against the bumper, but the coroner states that this is incorrect and that the face was actually into the mattress. One of the victim's arms was over the top of the installed bumper and between two crib slats. The coroner stated that the positional asphyxia "was not due to the crib bumper, and that the crib bumper was not involved in any way other than the victim having her arm over top of it." The arm was not trapped or impeded from removal while between slats.	Unlikely
83	2012	3 Mo. Male	A three month-old infant was found dead in his crib by his father. The infant was found face-down against a bumper pad that was attached to his crib. The father attempted cpr on the baby but was unsuccessful. The infant was declared deceased at the scene. The official cause of death is listed as "probable asphyxia".	The victim was found prone in corner of the crib with his face "down" (per the data record sheet) and against the installed bumper.	Unlikely
85	2012	2 Mo. Female	A two-month-old female was found unresponsive in her crib by her mother. After not waking up for her morning feeding, the mother went to check on her daughter and found her face down against the crib bumper pad. There was also a crib size comforter type of blanket underneath the victim. The coroner found the death to be an accidental asphyxia due to obstruction of the external airways by soft bedding.	The victim was found prone on a comforter-covered mattress with her face turned to the right into a bumper-installed crib side. She reportedly was lying "diagonal" with her face "turned into" the bumper; however, her chin also reportedly was tilted downward "closer to her chest." Given her body and chin positions, the victim's face must have been pointed in the direction of the bumper, but not actually pushed into the bumper.	Unlikely
87	2012	1 Mo. Male	1 mom decedent was found with his face into bumper. He died d/t suffocation in standard wooden crib. Couple of baby blankets was in crib. Bumper was attached properly. Cod: idiopathic cardiomegaly, suffocation.	The victim was found with his head face-down and next to the bumper. He was 7 weeks old and had an enlarged heart and heart arrhythmias. The ME could not determine whether the sleep environment was the sole cause of death.	Unknown

Hazard Pattern: Contact with Possible Entrapment/Wedging (7 Reported Fatalities)

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
39	2004	19 Mo. Female	Found unresponsive in crib with face wedged between mattress and bumper; transported to hospital - asphyxia due to suffocation by obstruction of nose and mouth; chronic anoxic encephalopathy due to meconium aspiration at birth - autopsy yes.	The victim was found with her face "wedged between the crib bumper and the crib mattress." The cause of death was suffocation by "obstruction of nose and mouth."	Unknown
43	2006	4 Mo. Male	A male infant, age 4 months, died when he was found unresponsive in his crib by his mother. His face was up against the crib's bumper pad when found. Cause of death: sids.	The victim was found prone with "the right side of his face" against the bumper. He had been put to sleep on a pillow, so he might have been wedged between it and the bumper.	Unlikely
57	2008	2 Mo. Male	A 10 week old male infant was placed in a full sized crib to take a nap. He was found lying with his face wedged against the bumper pad and mattress lying on his side. He was unresponsive. He was taken to the hospital and pronounced dead due to asphyxia due to obstruction of the nose and mouth.	The victim was found lying on his side with his face wedged between or against the comforter-covered mattress and the bumper. His mouth reportedly was up against the bumper and "almost" wedged between it and mattress. A nursing/positioning pillow was close to where child was found, but there is no mention of contact with the pillow.	Unknown
61	2009	2 Mo. Female	A two-month-old female was found unresponsive wedged in between the mattress and the crib or between the bed and a baby bumper. She was rushed to the emergency room and then to a larger hospital where she was put on life support. She died 16 days later after she was taken off life support.	The victim was found "wedged in between" the mattress and a bumper-covered crib side.	Unknown
63	2009	2 Mo. Female	A three-month-old infant was placed to sleep on her stomach in her crib. Her mother placed a blanket over her as well. When her mother found her the next morning, approximately 12 hours later, she was turned in the opposite direction with her face down between the mattress and crib bumper. The victim was unresponsive and purple in color. Paramedics transported her to the hospital where she was pronounced dead.	The victim was found with her face wedged down between mattress and bumper, facing the bumper and with the top of her head resting against a "womb bear" (stuffed toy). Other parts of the report claim that the face was "face down" when the victim was found. HS staff concluded that lividity was consistent with a face-down position. A comforter was under the victim.	Unlikely
88	2012	2 Mo. Female	A 2 months and 26 days old female infants head wedged between crib bumper and mattress. Positional asphyxiation with head wedged between crib bumper and mattress. Bed sharing with twin sibling in crib. Autopsy-yes.	The victim was found wedged between the bumper and the mattress.	Unknown

Record	Year	Age & Sex	Incident Narrative (Copied Verbatim)	Notes from Team Review	Addressability
100	2013	2 Yr. Female	A 2 year old female was found by her grandmother with her face wedged between the crib bumper and the mattress. She was transported to the local hospital for treatment. She survived the incident but suffered multiple health issues. A year after the initial incident, she went into cardiac arrest and was transported to the local hospital where she was pronounced deceased. The cause of death was determined as hypoxic/ischemic encephalopathy which stemmed from the initial incident.	The victim suffered cardiac arrest about one year after being found with her face wedged between a bumper and mattress. She had gone into cardiac arrest during prior incident, and experienced other medical issues since that time; however the child also had medical issues since birth. No additional details are available about the original bumper-related incident. HS staff concluded that the death likely stemmed from the known congenital encephalopathy and was not likely a consequence of the earlier reported incident involving a bumper.	Unlikely

TAB E

HS Staff Memorandum,

“Analysis of Deaths Citing Crib Bumpers Reported from January 1, 1990 to March 31, 2016”



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
ROCKVILLE, MD 20850

MEMORANDUM

June 22, 2016

TO: Tim Smith, Human Factors Engineer, Crib Bumpers Project Manager
Division of Human Factors
Directorate for Engineering Sciences

THROUGH: Alice Thaler, D.V.M., M.S., Bioethics
Associate Executive Director
Directorate for Health Sciences

Jacqueline Ferrante, Ph.D., Division Director
Division of Pharmacology and Physiology
Directorate for Health Sciences

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

SUBJECT: Analysis of Deaths Citing Crib Bumpers Reported from January 1, 1990 to March 31, 2016

Introduction

In May 2013, the Consumer Product Safety Commission (CPSC or “Commission”) granted a petition (CP 12-2) from the Juvenile Products Manufacturers Association (JPMA) to initiate rulemaking regarding crib bumpers.¹ The JPMA requested the CPSC to adopt standards to distinguish “traditional” crib bumpers from “hazardous pillow-like” crib bumpers and develop a performance standard to address the risks associated with the latter. The CPSC granted this petition, but opted to pursue a broader framework than requested by the JPMA. The Commission directed CPSC staff to investigate available regulatory options, including possible new mandatory performance requirements and possible improvements to an existing voluntary standard (ASTM F1917-12).

Crib bumpers are cushioned linings intended for use around the inside perimeter of a baby’s crib to protect an infant’s head from bumping into the hard crib slats, and also to serve as a barrier preventing an infant’s limbs from getting caught between the slats. Bumpers also can serve a decorative purpose. Traditional bumpers are secured to the crib

by ties located at regular intervals along the length of the crib bumper. Crib bumpers are subject to a voluntary standard, ASTM F1917-12 *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*. Bumper guards are listed in section 3.1.4 of this standard as one of the items defined to be *infant bedding and related accessories*.² This section also includes a variety of other bedding items intended for use in a nursery.

This memorandum provides an analysis of 107 fatal incidents reported to CPSC from January 1, 1990 to March 31, 2016, and also includes a comparison with other incident reviews in the published literature. The analysis includes discussions of the likely effectiveness of: (1) the current voluntary standard; (2) more stringent requirements related to mechanical suffocation, breathability/airflow, and rebreathing; and (3) other products (*e.g.*, mesh liners and vertical bumpers), in addressing suffocation, limb entrapments, and impact injuries.

I. Incident Review and Analysis

CPSC's Division of Hazard Analysis (EPHA) staff conducted searches of all available reports of incidents, injuries, and deaths mentioning crib bumpers in the immediate sleep area that were reported to CPSC from January 1, 1990 to March 31, 2016, using the methodology described in Tab C. Because there is no specific product code for crib bumpers, EPHA staff relied upon a broad range of product codes for infant sleep products with which crib bumper pads might be used or associated. Searches were also carried out looking for the keywords, "bumper," "bump," and "pad" appearing in the report narratives and model name fields, with no restriction on the product code, as a means of capturing any incident where the presence of a crib bumper was observed. The search involved four CPSC databases: the Injury and Potential Injury Incidents (IPII) files, Death Certificates (DTHS), the National Electronic Injury Surveillance System (NEISS), and the In Depth Investigation (INDP) files.

The search identified 107 fatal and 282 nonfatal incidents in which the incident report identified the presence of a crib bumper in the infant's sleep area. The 107 reported fatal incidents included 68 of the 71 incidents previously discussed in the 2013 Bumper Pad Briefing package (Suchy, Tab F). Sixty-five fatalities involved infants aged ≤ 4 months, a critical developmental period that puts this age group at risk for suffocation and Sudden Infant Death Syndrome (SIDS). Notably, in a significant number of the 107 fatal cases, the infant was found in a prone position.⁴⁸ The placement of an infant to sleep in a prone position, particularly on top of infant positioners and on/or a soft object, such as a pillow or a folded quilt, poses a high risk of entrapment and suffocation.^{3, 4, 5, 6, 7, 8, 9, 10, & 11}

In most of the reported fatal incidents, the cause of death was determined by the Medical Examiner (ME) to be asphyxia, positional asphyxia, suffocation, or SIDS. There were

⁴⁸ In 71, or 89 percent, of the 80 reported fatalities where the position was stated and relevant (*i.e.*, the infant was not on a seat or trapped in the side), the infant was found in a prone position. Among non-"Incidental" cases (see definition of "Incidental" later in this memorandum), this value is 91 percent (51 of 56 reported fatalities).

cases where the ME report/autopsy identified medical issues that may have been a contributory factor in the fatality. A number of the incidents also reported the presence of additional bedding in the crib or an overall cluttered sleep environment that included items such as pillows, blankets, quilts, and large stuffed animals. Pillows can be hazardous when placed under or beside a sleeping infant. For example, a search of three CPSC databases (IPII, DTHS, and INDP) for the period 1992 to 2010, *showed 690 deaths on pillows* for children aged ≤ 12 months.⁵

Brief summaries of the 107 fatal incidents are provided in Tab D, organized by hazard pattern classification. The multi-disciplinary Crib Bumper project team categorized these cases into the following groups: (1) Incidental; (2) Contact outside a crib; (3) Entrapment or wedging; (4) Contact without entrapment or wedging; and (5) Contact with possible entrapment or wedging. The team also determined the likely addressability of these incidents by assessing whether removing the bumper would have prevented the fatality. Health Sciences (HS) physiologists conducted a thorough and systematic analysis of available records for all 107 fatal incidents that included death scene investigations, autopsy reports, caregiver reports, police reports, and death certificates (DTHS). The primary objective of the analysis was to identify the factors directly contributing to the fatal scenario, and, in particular, the role that may have been played by a crib bumper. The staff further assessed whether improvements to existing voluntary standards (ASTM F912-12) or implementation of new standards would address identified hazards. Below is a more detailed discussion, with examples of cases in each category. See the 2013 Crib Bumper Petition for a detailed analysis of fatalities from January 1990 through October 2012 (Tab E, Table 1 and Appendix A, Table A).¹

The challenge in determining whether a crib bumper played a role in a fatality, or whether its presence was incidental to the fatality, is that the incidents were not witnessed. In many instances, information came from second or third hand parties or could have been based on speculation. Although death certificates and autopsy reports may state the cause of death, it is unlikely, in most cases, that the medical examiners or pathologists witnessed the child in the sleep environment where the fatality occurred or had sufficient on-site information to make a determination that the cause of death was suffocation, because there are no clear markers for suffocation in autopsy reports. The ME cause of death determination based on information from death scene investigation may not necessarily be determinative. Nevertheless, HS staff evaluated all the evidence available for each case and applied consistent scientific reasoning, including weighing the credibility of witness statements that appeared to be implausible. The HS staff analysis was based on applying sound science to the information provided, and when the cause of death was unknown, staff did not make presumptions on the cause of infant death based on very limited, unsubstantiated, or unconfirmed information.

1. Incidental (31 Fatalities):

Staff defined “Incidental” as a bumper was present in the sleep environment, but there was no evidence of bumper contact or involvement in the fatality. In 31 cases (29%), there was no evidence of involvement of a crib bumper in the fatality. In three cases, the ME ruled the cause of death to be exclusively due to a preexisting medical condition:

cardiac arrest due to severe asthma attack (#18), cardiorespiratory arrest due to seizure (#53), and lymphohistiocytic myocarditis (#77). While there are no clear markers at autopsy for suffocation there are identifiers for these three cases based on medical history and autopsy findings.

In the remaining 28 cases (#s 5, 16, 18, 20, 24, 31, 38, 52, 53, 56, 58, 60, 62, 66, 68, 77, 78, 79, 82, 89-97, 103, 104, & 105), the bumper did not contact the infant, nor was it involved in the fatality. Three examples of these cases are illustrated in Figure 1.



Figure 1: *On-site police photographs of incidents where there was no evidence of involvement of a crib bumper in the fatality, with examples from case #s 52, 58, & 96.*

In three of the 28 cases, the bumper was used outside a crib in a setting where a crib bumper is not intended to be used and was considered incidental in involvement because there was no contact or mention of the bumper involvement in the incidents. In incident #24, the 7-month-old victim was found on a mattress on the floor, with bumpers and pillows. There was no mention of bumper contact or involvement in this incident. In incident # 60, a 2-month-old girl was found in a bassinet with her head “completely buried” or embedded into the pillow, with her mouth and nose area “stuck” to the pillow. The report also mentions that the top of the victim’s head was touching the bumper. However, the reported contents of the scene refer to a bassinet cover, not a bumper. Thus, it sounds as if a bumper might not have been present, and even if one was present, the evidence suggests that it did not play any role in the death. In incident # 66, the 2-month-old boy was found face down in a playpen. A bumper was mentioned as being present, and was folded to accommodate the playpen size; but there was no indication that the bumper was relevant, in contact with the child, or otherwise involved in the incident.

Two cases (#s 16 and 105) involved children climbing out of their crib, falling and becoming entrapped between the crib and an adjacent piece of furniture. Staff believes that the bumpers appear to be irrelevant to the falls, because in both cases, the mattress was set in the uppermost position, which made it easy for the child to climb out and fall. In incident # 16, the victim climbed out or fell out of the crib and became wedged in a 6-inch space between the outside of the crib railing and the adjacent dresser. A bumper was present, but staff found no evidence of its involvement in the incident, aside from speculation by the investigator that the child probably stood on the bumper to climb over the side. Staff also notes that the difference between the height of the bumper and the top of the railing in the incident report is small (12 inches versus 15 inches), and the child was a 10-month-old who was reported to be “very large” for his age. Thus, there is no

evidence in this incident that the child contacted or used the bumper in the manner hypothesized by the investigator. In incident # 105, the infant was found wedged upside-down and face into the crib side in a 5-inch gap between the crib and the mother's bed. A full-body pillow was stuffed into the gap. The child apparently fell out of the crib while attempting to climb out. While there was speculation about the possibility that the child "could have used" the installed bumpers to climb out, there was no reported evidence of this. In addition, the crib mattress had been raised to its highest position, which would put the mattress-top to crib-top distance at about 12 ½ inches. The child was 26 inches tall and was known to be able to pull himself to a standing position. Given the lack of evidence that the bumper was used to climb out, and because staff believes that the child could easily have climbed out of the crib without the use of the bumper under these circumstances, staff determined that the bumper's presence was inconsequential and found that the bumper was unlikely to have played a role in the incident.

2. Contact Outside Crib (5 Fatalities):

Staff defined "Contact Outside Crib" as the child was in contact with a crib bumper outside an infant crib. Five fatalities involved contact with a bumper outside a crib, in a sleep setting for which the crib bumper was not intended. Although staff notes that the bumper pads were used in a sleep setting for which they were not intended, staff did not consider this as a factor in assessing addressability because this could be considered foreseeable misuse of the product. These cases involved a toddler bed (#s 17 & 48), bassinet (#s 19 & 102), and daybed (# 29). One of the toddler bed cases involved the death of a 5-year-old boy with developmental delays, found with his face between two bumper pad sections that adjoined in a corner of the crib.

In the 2013 analysis for the original Petition Briefing Package, fatal incident cases involving a bumper used outside a sleep setting, for which bumper use was not intended, were considered out of scope.¹ This included the use of bumpers in a bassinet, toddler bed, play pen, daybed, or a mattress on the floor. The current analysis takes into account foreseeable misuse of the bumper and includes all incidents where the presence of a bumper was reported, regardless of whether the bumper was inside or outside of an infant crib. Three of the five cases (#s 17, 29, & 48) would likely be addressable (removing the bumper would have prevented the fatality), whereas, the remaining two cases (#s 19 & 102), are unlikely to be addressable. These five cases are discussed in more detail below.

Case # 17: IPII MECAP Doc # X985332A: A 5-year-old boy with developmental delays "died of positional asphyxia after he pushed himself into the corner of his toddler bed with his face between the bumper pads." This incident is considered addressable because the fatality may have been prevented had the bumper been absent. The determination is made with a high degree of uncertainty because it is based solely on the limited information in the MECAP summary (quoted above in full content), which seemed to implicate the bumper pad in the child's death.

Two (#19 and #102) of the five incidents involved a rocking bassinet or cradle. These cases are described below.

Case # 19: (IDI 990315HCC2319): An at-risk 4-month-old twin boy, who was born 3 months premature, was sleeping with his twin brother in a rocking wooden bassinet, in which a full-size cloth bumper was wrapped 1½ times around the perimeter. The twins were placed in prone positions at opposite ends of the rocking bassinet. The next morning, the mother removed one twin for a feeding and found the victim unresponsive with his face against the bassinet side wall, in an area where the bumper overlapped. The ME ruled that the death was due to “positional asphyxia,” noting that the baby “had crawled face first into the corner of his crib with his nose and mouth pressed against the protective bumper.” Based on physiological changes noted in the autopsy report indicating the presence of “livor mortis in the anterior portion of the body with blanching on forehead and nostrils,” which are indicative of positional asphyxia, HS staff notes that a more probable scenario is that the rocking bassinet came to a halt in a fixed, tilted position from the uneven weight distribution of the two occupants, resulting in the victim's face being forcefully maintained against the bumper. HS staff notes that positional asphyxia can occur in any rocking-type bassinet/cradle that comes to rest in a fixed, tilted position; and HS staff believes that this incident involved positional asphyxia due to the tilting bassinet, rather than mechanical asphyxiation due to the bumper.^{12, 13, 16, 17} Positional asphyxia is a pathophysiological term referring to breathing insufficiency due to complete airway obstruction by an object or because of abnormal head/neck positions when the baby's head is tilted too far forward, too far back (hyperextension), or too far to the side. These positions make it too hard for infants to breathe, leading to inadequate supply of oxygen. Although contact with the bumper pad may have accelerated the infant's death, removing the bumper is unlikely to have prevented the fatality. Had the bumper not been present, it is conceivable, although unlikely, that a caregiver could have discovered the infant and intervened before positional asphyxia (head tilted forward) led to death. Staff considers this unlikely because this scenario is dependent on several factors, including the intended sleep duration (*e.g.*, nap vs. overnight) and how often the sleeping child is monitored by a parent.

Case # 102: IDI # 150701CCC2646: A 2-month-old infant died sleeping on his stomach in the corner of a rocking cradle facedown with a sheet over him. The cradle contained a padded bumper pad, a blanket, and a package of diapers (circled items in Figure 2). The infant was found prone, facedown into the mattress, near the corner of the of the crib in full rigor mortis, and well-developed lividity was observed on the face and body indicating that the baby was in a facedown prone position. According to the report, the infant was found “face down in the crib with face near the corner of crib that contained multiple items including padded bumpers and blankets.” The report states that bumper pad and other items in the crib were removed by the father, but the exact location of the head, with respect to the bumper, and the relative position of the other items with respect to the bumper or infant's head, were not stated. The ME reported that the cause of death was “probable positional asphyxia.”



Figure 2. Case #102 Photograph of the crib. The circled items were in the crib when the baby was found unresponsive and were removed when the police arrived.

Staff notes that positional asphyxia can occur in any rocking-type bassinet/cradle that comes to rest in a fixed tilted position, at an angle greater than 5 degrees with the horizontal axis, regardless of style (fabric, mesh or wood slats). The tilt can cause a potentially lethal sleep environment should the infant slide in the direction of the tilt and his/her head becomes wedged in the corner.^{15, 16, 17} Developmental delays in the respiratory system and an infant's inability to raise or turn his/her head against gravity to maintain airflow, are cofactors that put him/her at risk for positional asphyxia. One study noted that 10 positional asphyxia deaths occurred in suspended rocking-type bassinets or cradles when they came to rest in a fixed tilted position.¹⁵ In addition, five of the 10 reported fatal incidents were in mesh-sided cradles, suggesting that a mesh bumper will not be effective in protecting the infants in this hazard scenario. To address this tilt-related suffocation hazard, the mandatory bassinet standard, 16 C.F.R. part 1218 (which incorporates by reference ASTM F2194 – 13, with modifications),¹³ requires rocking cradles to come to rest at an angle not exceeding 5 degrees. Because of the tilt-related hazard in these two incidents, it is unlikely that removing the bumper pad would have changed the outcome. HS staff concludes that the bumper likely did not contribute to the fatality and is unlikely to be addressable by removing the bumper because the infant was found prone, facedown into the mattress.

The remaining two incidents in this hazard pattern, case #48 and #29, involved children hanging or becoming suspended on bumpers that were installed on a toddler bed or small day bed. Staff's assessment for these two incidents is that the bumper likely contributed to the risk of injury and that removing the bumper would likely have changed the outcome.

Case # 48: IDI # 009713HCC3744: A 21-month-old boy died of asphyxia due to compression of the neck when he became entrapped and suspended in the ties of a crib bumper that were tied to the top of the footboard and side railing of a toddler bed. The ME report indicates the child "apparently slipped between the bed and some form of railing and was found dead in the morning by his mother" (IDI p. 5 Exhibit B). Staff

concludes that this death might be addressable by the removing the bumper, because removing the bumper would eliminate the strangulation hazard.

Case #29: IDI # 010417CNE6292: An 11-month-old girl, put to sleep in what was described as a daybed, and died when her lower body slid through a gap in the side of the bed frame and her neck was caught by the top edge of the crib bumper (Figure 3). The ME listed the cause of death as mechanical asphyxiation. The crib bumper had been used as a means to keep the infant from sliding off the mattress.

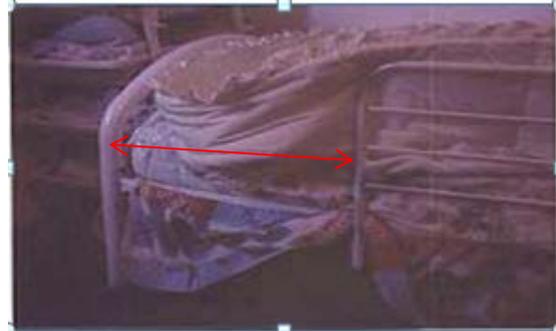


Figure 3. View of the entrapment site (case #29), image source IDI # showing area where the child was found

The entrapment scenarios for case #s 29 and 48 are likely to be addressable because removing the bumper would eliminate the strangulation/hanging hazard.

Section Summary: Of the five cases discussed in this section, two of the entrapment scenarios likely involved the bassinet or cradle coming to rest in a tilted position and are unlikely to be addressable by removing the bumper because the deaths were due to positional asphyxia (#19) or the victim was found prone face down in the corner the bassinet (#102). The remaining three would be potentially addressable because removing the bumper might have prevented the two strangulation/hanging cases (#s 29 & 48) and the corner entrapment suffocation of the 5-year-old boy with disabilities (#17).

3. Entrapment/Wedging:

Staff defined “Entrapment/Wedging” as the child was entrapped or wedged against the crib bumper. This category includes 41 cases where a bumper was involved in a wedging or entrapment incident. The analysis of a number of these cases was confounded by limitations in the reporting, and particularly information on items in the crib and exact placement of the victim relative to such objects. Any extraneous item that clutters the sleep space of an infant presents a potential entrapment and/or suffocation hazard. The placement of objects such as pillows, infant positioners, cushions, siblings, large soft toys, and thick bedding or quilts in the crib provides an additional surface other than the side of the crib, and can create a wedge-entrapment scenario, even in the absence of a crib bumper.^{3,4,5,6,7} Additionally, in a number of the cases it was unclear whether the victim’s face was into the bumper or another object.

Fatalities can also result from other mechanisms, apart from blockage of oxygen intake. Entrapment that causes prolonged restricted head or body movement can lead to positional asphyxia. The repeated attempts by the infant to free their head from between two fixed objects (crib side and object in the crib), especially when the whole body is entrapped in a prone position, can lead to exhaustion and respiratory stress. This is particularly true for infants under 3 months of age when placed in a prone position, because this age group does not have sufficient muscle control and strength to keep

lifting their head and are physically unable to extricate themselves from this position. The inability of infants to extract themselves from such a position is not dependent on 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.

This category was further subdivided into three separate hazard patterns: (1) against an object in the crib; (2) in the perimeter of the crib; and (3) other. Examples from each of the subcategories are provided below.

- ***Against Object in Crib (23 fatalities):***

Staff defined "Against Object in a Crib" as the child was entrapped or wedged between the bumper and another object in the crib, such as a bed pillow, infant recliner, or cushion. Staff identified 23 incidents in which a child was reported to have been entrapped between the bumper pad and another object in the crib. These objects included specialized infant products, such as: infant recliners (#s 70, 75, 80, 84 & 99); a thick homemade cushion (#6); sofa cushions (#s 54, and 74), one of which was used to prop up an infant bounce seat (#74); adult-sized pillows (#s 10, 13, 27, 30, 55, 71, 72, 86 & 98); C-shaped nursing and infant positioning pillows (#s 47 & 76) (Figure 4); infant sleep positioners (#s 51 & 69); a handheld infant carrier or car seat (#107) (Figure 4); and a sibling (#32).

Five incidents (#s 70, 75, 80, 84, & 99) involved entrapment between a bumper-covered crib side and an infant recliner (a product not intended for use in a crib), in which the infants were either loosely strapped or unharnessed. Babies can slide down or partially rotate in a seat when not properly buckled, and they can get into a position in which their airways are compromised or blocked. One of these cases (#84) would not be addressable by removing the bumper because the infant was discovered by his mother face down in a prone position with his head entrapped between the side of the recliner and the bumper-installed crib side. If the bumper was not present, the entrapment still would have happened based on the position of the seat and its proximity to the crib side. In the other four cases (#s 70, 75, 80 & 99), the infants were found with their heads hanging off the infant recliner with their upper torsos tilted backward, their necks hyperextended beyond the edge of the infant recliner, and their faces into the bumpers.

Positional asphyxia is a pathophysiological term referring to breathing insufficiency, due to either complete airway obstruction by an object or abnormal head/neck positions when the baby's head is tilted too far forward, too far back (hyperextension), or too far to the side. These positions make it too hard for infants to breathe, leading to inadequate supply of oxygen. Infants 4 months old and younger are especially susceptible to positional asphyxia because of the combination of a heavy head, weak neck muscles, and delayed respiratory and neurological function. Babies in recliners or sleep positioners can slide when not buckled and can get into these positions. However, staff acknowledges that death by positional asphyxia would take more time than suffocation by nose and mouth occlusion, so the presence of the bumper may have hastened or accelerated the infant's death. Thus, had a crib bumper not been present, it is conceivable, although unlikely, that

a caregiver could have discovered the child and intervened before the positional asphyxia led to the fatality. This extended time could allow an opportunity for intervention, but it would depend on several factors, including the intended sleep duration (e.g., nap vs overnight) and how often the sleeping child is monitored by a parent. HS staff believes that the hyperextension of the neck was likely the cause of the deaths, because sustained neck hyperextension, when an infant's unsupported head is tilted backwards and downwards below the level of their heart, can result in death.^{14,15,16,17,18,19,20, 21} Thus, staff believes that these deaths are unlikely to be addressable by removing the bumper.

Two deaths involved a nursing or positioning pillow (#s 76 & 47). In one case, a 4-month-old boy reportedly was placed to sleep in a supine position in a crib, propped up against a C-shaped nursing pillow, and was later found by his mother unresponsive and facedown, wedged between the bumper and the pillow (#76). He had moved into a prone position and appeared to have crawled part way over the nursing pillow with his head tilted downward and became wedged in the gap between the pillow and the bumper-covered crib sides. In the reenactment photo (Figure 4) using a doll, it is not clear whether the face (nose and mouth) was pressed against the nursing pillow or bumper. Because of limited and conflicting information on the position of the face, it is unknown whether this case would be addressable by removing the bumper.



Figure 4. Image of reenactments of child entrapment on a body positioning pillow, a nursing pillow, and car seat or handheld carrier (for case #s 47, 76, & 107), respectively.

In the other case (#47), a 1-month-old girl, placed to sleep prone on an infant positioning pillow, was found slumped facedown over the infant positioning pillow with her head drooping downward. The reenactment photo shows the back of her head tilted downward and against the installed bumper. A 1-month-old infant would be physically unable to extricate herself from the position found, and likely died because of external blockage of the airways by the pillow, even if the bumper was not against the back of the head. The reenactment photo shows the back of her head against the installed bumper, but the report never mentions the bumper being present or relevant. The cause of death was identified as positional asphyxia.

Staff concludes that this death (#47) is likely not addressable by removing the bumper because staff assesses that it was not the bumper that held the infant in the compromising position, but instead, it was the infant's general inability developmentally to extract him or herself from that situation. Even if the bumper is removed, the infant would likely be

unable to get out of the compromising position, so that the back of the head would still be positioned against the crib side with the face against the pillow.

A 5-month old boy was found slumped over a car seat, with his face and neck entrapped between the car seat and canopy (#107). According to the report, the child's face was entrapped against the carrier. Although reenactment photos show the head in contact with the bumper, the report never mentions the bumper's presence or relevance, if any. The cause of death was identified as positional asphyxia because the infant would have been physically unable to extricate himself from the position found, which was facedown with his head and neck entrapped under the canopy that ultimately caused the death. Staff concludes that this death would likely have occurred with or without the bumper.

HS staff concludes that these latter two deaths (#s 107 & 47) are unlikely to be addressable by removing the bumper because staff believes that it was likely not the bumper that held the infant in the compromising position, but instead, the death was due to the infant's general inability developmentally to extract him or herself from that situation. Even if the bumper were removed, the infant would likely be unable to get out of these compromising positions.

Another case, involving a sleep positioner (#69), is described below.

Case #69: *IDI # 10081HWE2299:* A 7-week-old boy with significant medical issues, recently diagnosed with infant asthma and flu-like symptoms, and who had been put to sleep on his side with an inclined sleep positioning device, was found dead in the morning, wedged facedown between the bumper-covered crib sides and the outer edge of the positioner. The ME's autopsy report describes his death as: "Probably asphyxia, a) found prone with face wedged between bumper pad and mattress, b) use of sleep positioner." The case reports do not specify whether the baby's face was pressed against a comforter that was between him and the mattress, or against the crib bumper. Thus, staff cannot tell whether this fatality would be addressable by removing the bumper, and therefore, classified this case as "unknown." However, the use of infant sleep positioning devices in a crib is now recognized as an entrapment hazard that can cause positional asphyxia/suffocation death,²² regardless of the presence of a bumper.

In 12 incidents, infants suffocated as a result of entrapment between a pillow and the bumper-covered crib side. The pillows/cushions involved in these incidents included adult-size pillows, sofa cushions, and homemade pillows. In most incidents, the child was found in a prone position, face-down into the mattress between the bumper and a pillow. The age range of the infants was 1 month to 3 months. Several of the pillow-related fatalities lacked detailed reports. Below are several examples of these types of cases.

Case # 13: (*Docs X12C0726A &9612104372*): A 2-month-old girl was found with her head between a pillow and the padded crib wall, and described as: "Face down in soft bedding Asphyxia: suffocation, face down in soft bedding." The baby reportedly had been "placed prone" on a full-size pillow, with her head on its left side; and the report states: "her torso and her legs still on the pillow, but her head and neck were between the crib bumper pad and the pillow in a four inch area. Her full face was into the mattress." It

was noted that she was 3 weeks premature and had been sickly since birth, with a congenital heart defect and a chronic cough. This incident is considered unlikely to be addressable by removing the bumper because the infant was found face down into the mattress, not the bumper. Body entrapment in a prone position between a pillow and a crib side can restrict body movement for certain age groups, and limit the ability of the infant to turn the head to free the airways. Thus, this fatality most likely would have occurred despite the presence of the bumper. The inability of a 2-month-old infant to extract herself from this type of entrapment between two fixed objects, and the continuous effort made to lift the head to free the airways to breathe or change position, can cause respiratory stress, which results in positional asphyxia. Moreover, prone sleeping alone, with no body restrictions, is a high-risk factor for suffocation.

Case # 54: (*Docs # 0812049146, IDI # 4090901HCC1016*): A 2-month-old girl was found lifeless by her father. She reportedly was placed to sleep supine in her crib with her head elevated by pillows, and was found lying prone 180 degrees from the original position with her head “partially wedged” and “face-down” between a pillow and the bumper pad. Numerous items cluttered the crib, including two adult pillows, a square sofa cushion, toys, blanket, and a jewelry box. The ME’s autopsy report ruled the cause of death to be “positional asphyxia,” but lists “chronic interstitial pneumonitis” as a contributing factor. The victim had been on antibiotics for a stuffy nose for several days. Like case #13, this is also a case where the entrapment and death was due to the infant’s being prone, face-down position on the mattress. The inability of a 2-month-old infant to extract herself from this type of entrapment between two fixed objects, and the continuous effort to lift the head and free the airways to breathe or change position can cause respiratory stress, which results in positional asphyxia. Therefore, it is unlikely that removing the bumper would have changed the outcome. In addition, as mentioned earlier, prone sleeping, alone, is a high-risk factor for SIDS and suffocation, even without body restrictions.

Case #74: (*IDI #120217HCC3389 & Doc: 1048069877*): A 1-month-old girl who had been placed to sleep in an infant bouncy seat fell out of the seat and was found dead in the crib at the base of the bouncer, wedged between the bouncy seat, pillow, and bumper-covered crib frame. The parents had set up a reclined bouncy seat covered with blankets to position the unharnessed baby, and a pillow was used as a seat-propping device. The harness on the bouncer was not used to secure the victim. The crib mattress had been raised to the height of the parent’s mattress, and the crib side rail had been removed (Figure 5). HS staff concludes that, although the bumper may have contributed to the risk of injury in this incident, removing the bumper pad covering the crib frame would have not likely have changed the fatal outcome because of all the other multiple hazards present in a very unsafe sleep setting.



Figure 5 Photo of sleep environment with arrows pointing to the parent's bed, pillows, folded blankets, and baby bouncer. The crib was placed next to the parent's bed "rigged" so that the side rail was removed and the crib mattress was raised near the height/ level of the adult bed to facilitate night time breast feeding.

The presence of extraneous objects in these cases constitutes a compromised sleep setting in the crib and presents the same positional asphyxia hazard, regardless of bumper type or presence. Entrapment that results in restricted body or head movement can lead to death by suffocation, especially when an infant is placed to sleep on his or her stomach, as occurred in most of the cases.

Subcategory Summary: Of the 23 cases discussed in this section, 15 of the entrapment scenarios are unlikely to be addressable by removing the bumper because the child's face was either found facing into a mattress or pillow, or their head was found suspended off the side or edge of a specialized infant product (#s 6, 10, 13, 27, 32, 47, 54, 55, 70, 72, 75, 80, 84, 99, 107). The inability of infants to extract themselves from compromising positions depends on the age of the infant. Continuous effort made by an infant to lift his or her head to free the airways to breathe or change position can cause respiratory stress, which results in positional asphyxia, and as a result, these cases are not addressable by removing the bumper. It is unknown whether the remaining eight cases would be addressable because of limited or conflicting information on the position of the infant's face (#s 30, 51, 69, 71, 74, 76, 86, & 98).

- ***In Perimeter of Crib (12 fatalities)***

Staff defined "In Perimeter of Crib" as 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. There were 12 incidents where the child was found entrapped in the perimeter of the crib, between the mattress and the crib side. These cases consistently involved cribs that had broken slats or missing hardware (Figure 6) or older cribs that probably did not meet the federal standard at the time of the incident (#s 8, 11, 15, 21, 22, 26, 28, 33, 36, 45, 59, & 106). These conditions can result in excessive gaps between the mattress and crib frame, which is a well-known entrapment hazard.

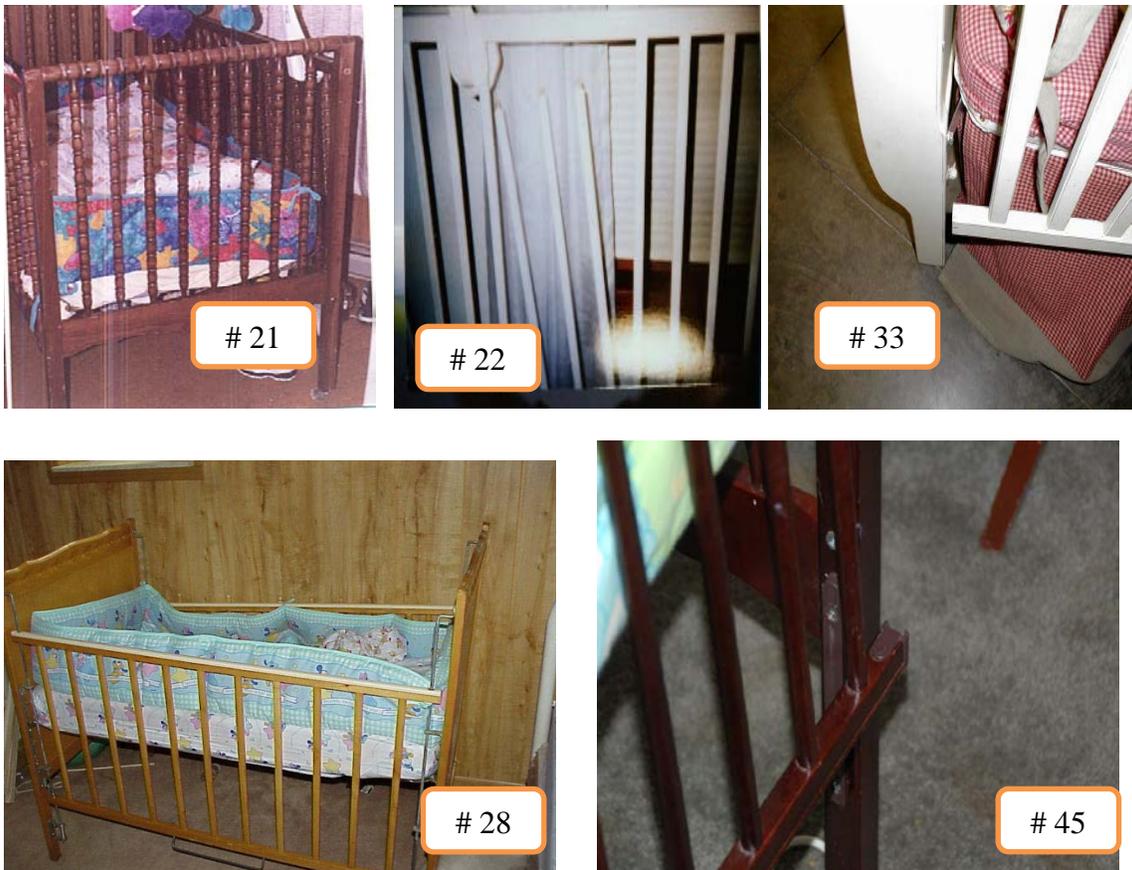


Figure 6. Photographs of broken cribs/components. Image source: IDIs for cases # 21, 22, 28, 33 &45.

In eight of the 12 cases (#s 21, 22, 26, 28, 33, 45, 59, & 106), the cribs had missing or broken slats, missing hardware, or other crib failures, resulting in separation between the crib sides and the mattress. In each case, staff concluded that body entrapment between rigid components occurred. As noted above, body entrapment between two rigid components of a crib may result in death by positional asphyxia/suffocation, regardless of whether a crib bumper is present. Thus, these eight cases would likely have resulted in death, regardless of the bumper's presence. Staff determined that there were two likely addressable cases (#s 11 & 36) in this category, because removing the bumper would likely have prevented the strangulation/hanging hazard that resulted in the fatalities. These two cases, and an example of a case that is unlikely to be addressable (#59), are described below.

Case #11: (IDI # 940818HCC2202 & Doc # X9474925A): A 9-month-old girl was found hanging, with a crib bumper around her neck, through a gap in a defective crib railing that was missing two crib slats. The missing slats formed a gap wide enough for the infant's body to slip through. The ME ruled the death accidental "suffocation due to being trapped between a crib mattress and the crib railing." Although the primary cause of death was the defective crib, which allowed the child to slip through the railings, this case is likely addressable because removing the bumper might have changed the outcome.

Case # 36: (IDI #130107CCC3287, Docs X12C0732A & 0331011150): A 12-month-old girl fell out of her crib and died from hanging asphyxiation (strangulation) in a broken crib, as a result of separation of the crib frame at a corner, creating a hazardous gap. The baby fell through the gap. Her body was trapped in a 6-inch to 8-inch area between the crib side and the wall; her arm was caught between the slats, and her neck and chest were caught under the bottom of the crib side rail and was strangled on the crib bumper. The policeman responding to the scene noted: “the rear guard rail of the crib, which is supposed to be fixed in place, was broken or had been taken apart. The upper right and rear corner of the crib side and the guardrail were not connected. The lower portion of this corner was still affixed. I observed that the crib bumper pad was hanging down in the middle and the ties had been broken away from the bumper itself.” Staff determined that this case likely would be addressable because removing the bumper might have prevented the strangulation.

Case # 59: (IDI # 1101HCC3323, Doc # 0949000490): A 7 ½-month-old boy was reportedly found “face down, his head stuck between the head of the crib and the mattress with the infant's head against the mattress.” The autopsy concluded that the death was due to *accidental positional asphyxia*, and noted: the “nose was into the mattress.” Police and ME descriptions of the baby's position when found, suggest to staff that a crib structural integrity issue existed, involving an excessive gap between the mattress and the crib headboard. Moreover, death scene photos show a toy broom wedged between the crib side rail and the mattress, indicating a gap (Figure 7). The greatest hazard leading to the death was the defective crib. Staff categorized this case as likely not addressable because the child's face was pressed into the mattress, rather than the crib bumper; so removing the bumper would likely not have prevented the fatality.



Figure 7. Case #59: An overview of crib content and space between the crib side and mattress.

Subcategory Summary: Of the 12 cases in this hazard pattern, eight are unlikely to be addressable by removing the bumper (#s 21, 22, 26, 28, 33, 45, 59 & 106) because they involved entrapment between two rigid components of the crib, and these types of entrapments can result in body or head compression leading to death, regardless of the presence of a bumper. Because of limited information on the position of the face, staff is unable to determine whether removing the bumper would have made a difference in the outcomes in case #s 8 and 15. The remaining two cases (#s 11 & 36) are likely to be addressable by removing the bumper. Notably, the outcome of cases involving gaps created by missing slats or a broken crib may vary, depending on the size of the opening

and the child's anthropometric measurements of head/torso (either the entire child will pass through the gap and fall to the floor or the body will pass through the gap while the head gets stuck resulting in a strangulation death).

- ***Other (6 fatalities):***

Staff defined "Other" as 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. Six fatalities involved entrapment scenarios not covered by the two other categories (*i.e.*, against an object in the crib or in the perimeter of the crib). In three cases (#s 7, 41, and 81), the entrapment occurred under the bumper. One incident (# 7) involved a 5-month-old boy entrapped in a broken crib with wider-than-usual slats (crib reported to be 15 years old at the time of the incident in 1992). The infant was found on his back, wedged with his head between the side rail slats and the mattress. The victim's body was perpendicular to the side rail, with the left side of his head against the rail and the right side of his face against the mattress. The cause of death was asphyxia from neck hyperextension. In another incident, a 5-month-old child was *found face down* with her arm wedged in a space between the mattress and the side of the crib. Although the specific position of the bumper with respect to the child's face was not reported by the ME, the parent's statement in the police report was that infant was found face down on the mattress. The cause of death was reported in the death certificate as "head compressed against crib bumper with arm wedged between crib and mattress" (# 41). Although the specific object contacting the baby's face is not specified, staff considers an excessive side gap crib issue likely is involved, due to the report of the baby's arm being wedged between the crib and mattress. This can limit upper torso body movement and lead to death by positional asphyxia because the wedging probably held the infant in a facedown position and restricted breathing. An excessive side gap is a recognized entrapment hazard that can cause death by positional asphyxia/suffocation, regardless of the presence of a crib bumper.

In the third case (# 81), the child was found lying prone with both legs sticking out through the space between two adjacent slats (Figure 8), while the lower body of the infant was under a seemingly thin bumper. The entrapment was actually due to the legs hanging out of the crib. These three cases are unlikely to be addressable because the outcome would be unchanged by removing the bumper.



Figure 8. *Reenactment photograph for case # 81, showing the position in which the child was found.*

It is unknown whether removing the bumper would have changed the outcome in the remaining three cases in this hazard pattern. One of the three remaining cases involved a 2-month-old found with his arm caught between the bumper and the rail (# 50), and the position of other items found in the crib (*e.g.*, pillows, baby bear, comforter, baby clothes, etc.) is unclear. In case #101, the victim’s arm was reported to have been caught under the bumper, but it is not clear whether the arm was trapped between the crib slats or between the crib slats and crib mattress. The last death (#4) was caused by a break in the mattress support system, causing a tilt in the mattress. The 4-month-old was found wedged between the mattress and frame, and the position of the face with respect to the bumper was not known.

Subcategory Summary: Three cases in this section (#s 7, 41, & 81) are unlikely to be addressable because they would have occurred with or without the presence of a bumper. Because of limited and conflicting information on the position of the face and other products in the crib, staff is unable to determine whether removing the bumper would have had a different outcome in the three remaining incidents (#s 4, 50, &101).

4. Contact without Entrapment/Wedging (23 fatalities):

Staff defined “Contact without Entrapment/Wedging” as the child was in contact with the crib bumper, but there was no indication of entrapment or wedging against the bumper. Staff identified 23 cases involving contact with the bumper, but without entrapment or wedging. Staff believes that four of these cases would likely be addressable by removing the bumper because the child was described as being found with their face “into” the bumper (#s 35, 37, 44, and 49). Although staff classified incident (#44) as “likely,” this assessment was made with a high degree of uncertainty because of the suspicious circumstances surrounding the incident. Staff concluded that 10 of the 23 fatalities likely would not be addressable by removing the bumper (#s 3, 9, 25, 34, 40, 42, 65, 73, 83, and 85), because, the child reportedly was found with some part of the body other than the face was in contact with the bumper, or the bumper reportedly was in contact with the top or back of the head. Because the face was not into the bumper in these cases, and the

child was not wedged or entrapped, removing the bumper is unlikely to have prevented these fatalities. Staff concluded that the addressability of nine cases (#s 1, 2, 12, 14, 23, 46, 64, 67, & 87) is unknown, because the precise orientation of the face relative to the bumper was not stated. Three of these “unknown” cases reported that the face was pointing in the space between the mattress and bumper (#s 12, 14, and 46), and two cases reported that the child was contacting or facing bumper with unknown orientation (#s 1, 2). See examples below.

Case # 12: (*Docs. X94C0721A, X12C0888A*): A 4-month-old boy was found dead in a prone position with his face down between the mattress and the bumper pad of his crib. The circumstances surrounding the death are largely unreadable in the incident report, the boy's exact position when found, and what his face was touching, are not clear; moreover, the presence of a crib bumper is not mentioned in the ME report. The infant had been born premature at 27 weeks of gestation, and the autopsy found significant brain pathology, including an asymmetrical ventricular system, white matter cavity, consistent with a perinatal hemorrhage, partial loss of neurons from Sommer's sector of the hippocampus, and possible seizure disorder (p 8-9/10). The ME attributed death to SIDS; and the infant's preexisting medical conditions and abnormal brain are clear risk factors for SIDS. Because the ME attributed the death to the medical history (abnormality in the brain) by calling it SIDS, it is unknown whether removing the bumper would have made a difference in the outcome.

Case #23: (*IDI# 981118HCC2075, 9829025725 X12C0729A*): A 7-month-old boy was found unresponsive in his crib by his babysitter. According to the IDI, the boy was found lying on his back with his face turned to the right side and his face was “up into the corner of the bumper pad.” Police responders noted that they had difficulty attempting artificial respiration because the baby's airways appeared to be blocked and his jaws were locked. Paramedics transported the baby to the ER, where he was pronounced dead. Contrary to the DTHS EPIR narrative, the police report states that an autopsy was conducted in their presence. The police report contains an officer's notes on the autopsy, indicating that the pathologist did not rule on the cause of death at that time, but noted that he found bilateral lung hemorrhages of an unclear basis, possibly pneumonia or asphyxia. The baby had a respiratory infection and had been on antibiotic treatment for 5 days. The pathologist further advised police that SIDS deaths rarely had complete hemorrhaging throughout the lungs, and that further tests were needed. There is no official autopsy report in the IDI file, and there are no notes on microscopic findings or lab culture tests. There is no explanation why the DTHS, signed more than 3 months later, ruled the cause of death to be “positional asphyxia” as a result of “infant's face in corner of crib.” The document was signed by a nonmedical coroner (funeral home employee) and contains conflicting information about whether an autopsy was done. Normally, a 7-month-old child is developmentally capable of moving his head while lying supine, if his face becomes obstructed. Thus, it is unknown whether the bumper contributed to the risk and whether removing the bumper might have changed the outcome.

Case # 35: (*DTHS Doc. # 0318019177, & X12C0890A*): According to the death certificate, a 2-month-old girl died from accidental suffocation “in the corner of the crib

against the bumper pad.” According to information in the IDI, which included a very detailed child death review of this case, a number of confounding factors in the death raised questions about the role of the crib bumper. The infant was a premature baby born 2 months early, who was sleeping in the same crib with her twin. The incident report noted that the crib contained a bumper pad, padded comforter, crocheted afghan, and a blanket over the crib mattress on which the twins slept. The bumper pad apparently was sagging inward. The vulnerability of premature infants, as well as the dangers of co-sleeping with another child, plus the presence of extraneous soft bedding, all constitute known factors that can increase the risk of suffocation. However, because of the reported position of the infant when found face down into a sagging bumper in the corner of the crib, staff believes that the bumper likely contributed to the risk of harm and concluded that removing the bumper from the environment likely would have prevented the fatality.

Case # 37: (IPII Doc. # X03B5090A, X12C0722A, 0326061992): A 2-month-old boy was found unresponsive in his crib by his mother with his face against a crib bumper. The ME's autopsy report implicates suffocation in the crib bumper as the immediate cause of death, but the report also noted that the secondhand wooden crib “had most of its hardware missing.” A photo of the incident crib (Figure 9 A) and a reenactment photo with a doll (Figure 8B) show that the crib was separated at the side and end, creating a hazardous gap in the corner where the doll's head is located. Although the broken crib was likely the immediate cause of death, staff believes that removing the bumper from the crib likely would have prevented this particular fatality

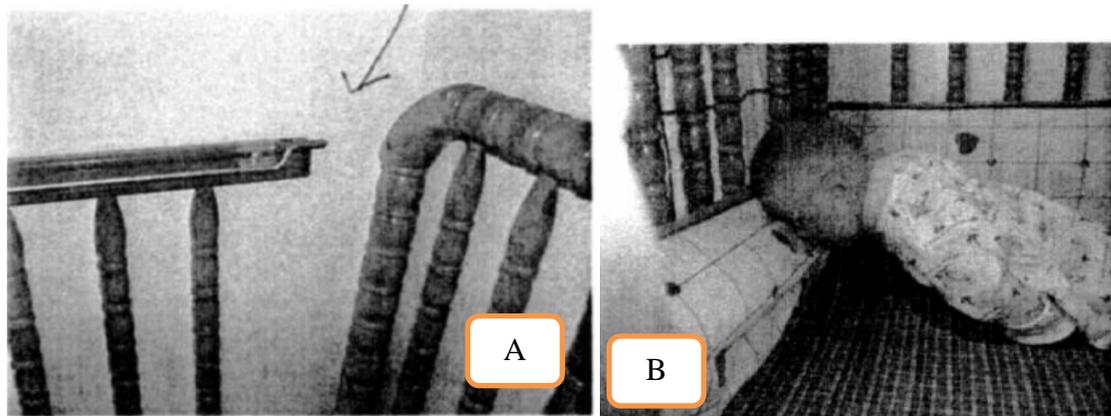


Figure 9 A. Picture of the incident crib showing the detached crib sides. B. Death scene reenactment using a doll in the corner of the crib directly below the detachment where the child was found. Case # 37

Case #44: (Docs #s 081006HCC2015, 0728001038): A 3.5-year-old girl, suffering from several serious medical conditions, died under suspicious circumstances. She was a premature twin with cerebral palsy, who had spinal meningitis at 2 months of age, a hydrocephalus condition necessitating brain shunts, and took prescription barbiturates for seizure control. At the time of death, the girl weighed only 17 pounds. (equivalent to an average 7-month-old infant). The sheriff's report stated that the mother placed the girl in the crib, and 14 hours later, the mother's boyfriend reported finding her lifeless body

lying prone with the crib bumper wrapped around the neck. The police reported finding blood on the crib railing and the crib bumper near the contact positions with the girl's face and feet. The autopsy report noted dried blood in the victim's mouth, and multiple acute traumatic abrasions on her scalp, head, face, and hand. Theoretically, removing the bumper would likely have made a difference in the outcome, but *the determination is made with a high degree of uncertainty*, considering that the victim in this case had multiple serious health issues and was underweight for her age. Furthermore, the ME regarded her death as suspicious, and her caregivers were subsequently charged with criminal child endangerment.

Case# 49: (IDI# 091021HCC2091 & Doc 0717054853): A 5-month-old boy was found blue and unresponsive in the prone position, with his face buried in a thick, soft crib bumper padding in the corner of the crib. He was pronounced dead at the scene, and the sheriff and state police conducted a death scene investigation. The autopsy reported a red, superficial, circular impression a half-inch in diameter on the left side of the boy's head, evidence of pulmonary congestion and edema, but no obvious signs of trauma. The ME ruled the death to be "Accidental: Positional asphyxia while lying face down in crib bumper." In addition to the bumper, photos of the death scene show the crib to be cluttered with a variety of items, including a comforter, heavy and light blankets, two plush medium-size toys, and a large stuffed toy keyboard that stretched nearly the width of the crib (Figure 10 A, B, & C). Although reenactment photos suggested that the baby's chin might have become caught in the improperly secured corner area of the crib bumper, all the other items that were present at the time of the incident are not shown in the reenactment photo. Therefore, the possible role of these items cannot be determined. Nonetheless, if the child was found in the position depicted in the reenactment photos, staff believes that this incident is likely addressable by removing the bumper.



Figure 10 Case 49. Police incident crib scene photos showing a cluttered crib, including thick bedding and large stuffed toys and two music toys attached to the long sides of the crib (images A & B). In contrast, the death scene reenactment photo (image C) shows a crib with nothing inside.

Case # 40: (Doc # 040827CCN0935; Docs G0480262A, X0494794A & 426061031): A 4-month-old girl was placed to sleep in a prone position in a crib and was found the next morning unresponsive in the corner of the crib, where the mattress had sunk because of a lack of mattress support (Figure 11). According to the IPII-MECAP report, the baby was

found “face straight down into a quilt,” which had been laid on top of the mattress, and bumper pads were present in the corner “partly obstructing the baby from raising her head off the quilt out of the depressed corner.” The crib was obtained as a CSPC sample. The crib had been purchased from a thrift store and was missing the original mattress support. The attempted fix by the parents was inadequate and failed to fully support the mattress, allowing one corner to sink down. The baby was found face-down in a quilt in this corner. In this-scenario, with the infant’s face tilted downward into the depression, and with the baby’s body weight pushing her head further into the corner, the child would not be able to lift her head or move her body from the compromising position. The situation would have been fatal, regardless of the presence of the bumper, even though the bumper might have restricted the baby’s movement further. Although the autopsy report noted the baby’s “face buried in a quilt and bumper pads,” the ME’s photo reenactment shows only the quilt beneath the prone baby’s face. The bumper pad is touching the sides and perhaps back of the infant’s head, but not her face. HS staff agrees with the final death certificate addendum that lists the cause of death as “positional asphyxia found unresponsive in a defective crib.” Because the baby’s face was not into the bumper, and given the specific circumstances surrounding this incident, removing the bumper would likely not have made a difference in the outcome. In this scenario, it is the forces generated by the body weight on the head/neck in a downward tilted position in the corner of the crib, not the bumper, which kept the infant from moving her head.



Figure 11 Case # 40 Image showing the makeshift mattress platform, and doll reenactment

Case # 25: (IDI# 001018HCC2040 & Doc X0073156A): A 4-month-old boy was found by his father lying in a prone position in his crib with “arms up and his face into the soft padding.” Contrary to the MECAP report, there is no mention of any kind of wedging in the police report or the father’s report, which simply notes “an apparent indentation in the soft padding where the baby’s face was” (Figure 12). The police photos taken at the scene of the incident show an indentation in the crib bumper. These also show a sagging crib bumper along with thick blankets and a pillow in the crib. This case is confounded by the inconsistency between the ME and police reports regarding “wedging,” the infant’s prone position, and the thick blankets in the crib. According to the initial IPII and autopsy report, the death of this 4-month-old boy was the result of “asphyxia by suffocation, accidental” associated with “a history of being found wedged in bed clothing (crib bumper).” In contrast to later police supposition that the depression in the mattress was caused by the boy’s face, the father’s statement to the police (only 3 hours after the boy

was discovered) reported that “the color around his mouth and nose was white and the rest of his face was red.” It is HS staff’s opinion that the father’s description is likely indicative of unfixed lividity and pressure point blanching. This blanching and lividity clearly reflects a prone, facedown death position, which suggests that the bumper would have to have been on the horizontal (mattress) surface and below the child, for the boy’s face to have been pressed into it. It is unknown to staff how the bumper attached to the crib side could have been beneath the prone boy’s face. The blanching indicates strong pressure, indicating occlusion of the mouth and nose, causing mechanical asphyxia. Given the likely position of the boy’s face relative to the bumper, and because the physical evidence at autopsy—lividity and pressure point blanching—are considered reliable evidence of the infant position, the apparent depression in the soft padding is likely incidental. Thus, removing the bumper would not likely have made a difference in the outcome.

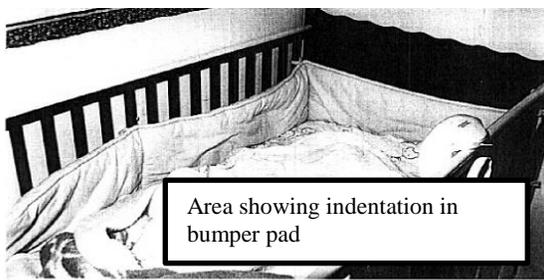


Figure 12 Case # 25 Crib view showing a sagging bumper and multiple bedding items, including heavy blankets and a pillow.

Section Summary: Of the 23 incidents in this scenario, 12 are unlikely to be addressable by removing the bumper (#s 3, 9, 25, 34, 40, 42, 65, 83, 85& 87), because each child was found with their face into the mattress or pointing away from the bumper. Four are likely addressable (#s 35, 37, 44 & 49) by removing the bumper. In the remaining seven cases, there was contact with the bumper, but precise information on the orientation of the face with respect to the bumper is unknown or ambiguous, where it was reported that the face was in the area between the mattress and the bumper (#s 12, 14, 23, 46, 64, 67, & 87), or was contacting or facing the bumper with unknown orientation (#s 1, 2)

5. Contact with Possible Entrapment/Wedging (7 fatalities)

Staff defined “Contact with Possible Entrapment/Wedging” as the child was in contact with the bumper, but staff could not determine whether the child was entrapped or wedged against the bumper. Staff identified seven cases (#s 39, 43, 57, 61, 63, 88, & 100) that involved contact with a crib bumper. However, staff was unable to assess whether the child was entrapped or wedged against the bumper because the incident reports lacked sufficient details. Staff considered three cases (#s 43, 63, & 100) unlikely to be addressable by removing the bumper. Two of these cases involved the child prone with their face into the mattress (#s 43 & 63), and one involved the death of a child 1-year after a bumper-related incident, reportedly from medical complications related to that incident (#100).

Case # 43: (*Doc # X0760223A*): A 4-month-old boy who was born 6 weeks early was found unresponsive in his crib, with his face up against the bumper pad. He had been placed to sleep lying prone on top of an adult pillow. He somehow "had scooted up on the mattress and the right side of his face was up against the side of the crib pad," where he was found dead. The ME attributed the death to SIDS. The pillow apparently trapped him in this position.

Case 63: (*IDI # 110914CCC2938 & DTHS 0926041921*): A 2-month-old girl reportedly was found face down on the mattress. This case contained inconsistent information from official sources about the position of the infant's face with respect to the bumper pad. According to the SUID, a comforter was under the victim, who was described as "face down, next to bumper pad, top of head resting against a "womb bear" stuffed toy, with "comforter under child." In the "found" position depicted in photos and sketches, the top of the head is resting on the bumper. In the IDI autopsy report, the ME opines that the infant "died of positional asphyxia," and was "found in a crib facing the mattress bumper." It is not clear what the ME meant by "facing the mattress bumper," or handwritten notes that indicate that the infant was found face down with lividity on the right side of the face and body. The ME report differs greatly from the DTHS records, which ruled suffocation SIDS face-down in the crib. One law enforcement officer reported that the baby was found face down between the mattress and crib bumper.

The reported lividity patterns on the right side of the baby's face and body are most consistent with a face down position.

Case # 100: (*IDI # 150521CCC1575 & X1551060A*): This investigation was initiated through the receipt of a MECAP reporting the death of a 2-year-old girl due to an incident a year beforehand involving a crib bumper. According to the Medical Examiner's report, sometime in March 2013 (exact date unknown), the victim was found in her crib with her face wedged between the crib bumper and the mattress. During that incident, the victim went into cardiac arrest. She survived the incident, and subsequently suffered a second cardiac arrest while at the local hospital (date unknown) and a third cardiac arrest on December 29, 2014, while at home in the care of her grandmother. The Medical Examiner's report indicates that, due to the incident, the victim suffered from cerebral palsy and seizures and died a year later. The medical records also show that the child was diagnosed at birth with congenital hydrocephalus, a buildup of excess cerebrospinal fluid (CSF) in the brain, which can cause increased pressure in the brain and lead to brain damage with mental and physical complications.

The child was transported to the local hospital for treatment; staff does not have her medical records or the police report related to the 2013 incident. Attempts to obtain additional information from the victim's family were not successful. Thus, the circumstances surrounding the case are not clear. The incident occurred in 2013, and the IDI was completed in 2015. HS staff notes that the congenital encephalopathy was not a consequence of the incident, as stated on page 2 of the IDI. Regarding the medical hypoxic/ischemic encephalopathy finding, HS staff believes that the death and the hypoxic/ischemic evidence stems from the congenital encephalopathy and was not likely

a consequence of the previous incident the year before. HS staff believes that the bumper likely did not play a role in the death of the infant a year after the incident.

In the remaining four cases in this hazard pattern, it was not known whether removing the bumper would have changed the outcome (#s 39, 57, 61, & 88) because the reports of the incidents lacked details or contained conflicting or inconsistent information (# 57). An example is provided below.

Case #57, (IDI # 090611HCC2690 & 0827026623): A 2-month-old boy was found by his father unresponsive and lying on his side, having somehow “flipped over, crawled up over the nursing pillow and his face was against the padded bumper and mattress.” The police report indicates: “mouth up against the bumper *almost* wedged between the mattress and the bumper” (emphasis added). Police photos show a cluttered crib that includes a comforter-covered mattress, C-shaped pillow, quilts, blankets, toys, a bottle, a book, and a wall clock. The exact position of the baby’s body/head/face when found is unclear. The ME report/autopsy states: “*Probable asphyxia due to obstruction of the nose and mouth,*” and additionally notes: “*found unresponsive lying with his face wedged against the bumper of his crib and the mattress.*” The death certificate, however, names the nursing pillow as a contributing factor. Because of limited and conflicting information, it is not known whether removing the bumper would have affected the outcome.

Section Summary: Of the seven incidents, four lacked information on the position of the face relative to the bumper. Thus, it is not known whether removing the bumper would have affected the outcome (#s 39, 57, 61 & 88). In the remaining three incidents, removing the bumper would not likely have made a difference in the outcome, because in two cases (#s 43, 63), the child was found in a prone position facedown into the mattress; and in one case (#100), HS staff concludes that the bumper likely did not play a role in the death of the infant a year after the incident.

Overall, staff has determined that 72 of the 107 fatal incidents were unlikely to be prevented by removing the bumper because the fatalities were either “incidental,” or the face was not directly in contact with the bumper when the fatality occurred. Nine cases are likely or potentially addressable by removing the bumper. In the remaining 26 incidents, classified as “unknown,” staff was unable to make a determination on the effectiveness of removing the bumper because of limited or conflicting information on the position of the child’s face with respect to the bumper. A summary of the classifications for these 107 cases is provided in Table 1.

Table 1. Case Summary					
Text Section	Category/Subcategory	Unlikely Addressable	Likely Addressable	Unknown	Category Totals
1	Incidental (totals)	(31)			31
	<i>Case #s</i>	5,16, 18, 20, 24, 31, 38, 52, 53, 56, 58, 60, 62, 66, 68, 77, 78, 79, 82, 89, 90, 91, 92, 93, 94, 95, 96, 97, 103, 104, 105			
2	Contact Outside Crib	(2)	(3)		5
	<i>Case #s</i>	19, 102	17, 29, 48		
3	Entrapment/Wedging				41
	<i>Against Object in Crib(totals)</i>	(15)		(8)	23
	<i>Case #s</i>	6, 10, 13, 27, 32, 47, 54, 55, 70, 72, 75, 80, 84, 99, 107		30, 51, 69, 71, 74, 76, 86, 98	
	<i>In Perimeter of Crib(totals)</i>	(8)	(2)	(2)	12
	<i>Case #s</i>	21, 22, 26, 28, 33, 45, 59, 106	11, 36	8, 15	
	<i>Other</i>	(3)		(3)	6
<i>Case #s</i>	7, 41, &81		4, 50, 101		
4	Contact without Entrapment/Wedging (totals)	(10)	(4)	(9)	23
	<i>Case #s</i>	3, 9, 25, 34, 40, 42, 65, 73, 83, 85	35, 37, 44, 49	1, 2, 12, 14, 23, 46, 64, 67, 87	
5	Contact with Possible Entrapment/Wedging (totals)	(3)		(4)	7
	<i>Case #s</i>	43, 63, 100		39, 57, 61, 88	

II) Current and Possible Voluntary Standard Performance Requirements and Alternative Products

Voluntary Standards

Crib bumpers currently are subject to the voluntary standard, ASTM F1917-12, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*. The standard includes a performance requirement to address the suffocation hazard by limiting the maximum thickness of bumpers (Section 6.2). Bumpers that conform to this standard must be capable of sliding through an aluminum bumper-thickness test fixture

that has a slot with a thickness of 2 inches, when drawn through the test fixture with up to 5 pounds of force (detailed by LSM staff in Tab G). The rationale for the 2-inch thickness is based on existing ASTM standards for “other padded items infants interact with such as play yard pads,” which have not been known to present a hazard (ASTM F1917-12, Rationale X1.1). HS staff notes that the 2-inch surface thickness has not been known to present a suffocation hazard when used as a sleep surface in play yards.

Staff is also aware of an Australian/New Zealand standard (AS/NZS 8811.1:2103), “Methods of Testing Infant Products; Method 1: Sleep Surfaces – Test for Firmness,” which can be used to identify hazardous softness in sleep surfaces, such as infant sleep mats, bassinets, and cradles. This test is intended to assess “whether a horizontal or nearly horizontal infant sleep surface exhibits excessive compression when subjected to a constant force applied through a standard load pad.” HS staff believes that this test method may have applicability to bumpers because firmness is an important factor related to suffocation hazards. Although it is not clear whether the incorporation of this requirement would have addressed any of the incidents, HS staff believes that inclusion of the firmness test (as described in AS/NZS 8811.1:2103) in the existing voluntary standard could add a safety factor to further protect against mechanical suffocation-type deaths. Therefore, HS staff recommends that an additional mechanical suffocation firmness test (as described in AS/NZS 8811.1:2103) be considered for inclusion in the existing voluntary standard, ASTM F1917-12.

Alternative Products

The precise etiology of SIDS remains unclear; however, over the years, numerous experimental and epidemiological studies identified a number of significant risk factors. A higher incidence of SIDS has been associated with placing infants to sleep in a prone position, premature and low birth weight babies, babies with brain abnormalities, mothers lacking prenatal care and/or who smoke during pregnancy, and infants overheating due to overwrapping or excessively warm room temperatures. In particular, many U.S. and international studies provide strong evidence that the prone sleeping position puts infants at significantly higher risk of SIDS.^{23, 24, 25,26}

In 1991, a study reported that rebreathing of carbon dioxide CO₂ (hypercapnia) was the cause of multiple infant deaths on infant bean bag cushions²⁷ and hypothesized that rebreathing of CO₂ might be associated with an increased risk of SIDS. In subsequent studies, the authors applied the “CO₂ rebreathing hypothesis” to an infant crib environment and suggested that lowering or dispersing the level of CO₂ would be an effective countermeasure to reduce the risk of SIDS. Although this hypothesis is controversial within the medical community, it has led to the development of infant sleep products that manufacturers claim allow increased airflow and reduced CO₂ accumulation. These products include:

- vertical/mini bumper sets composed of multiple cushioned pads that are attached to individual crib slats;

- “breathable” mesh crib liners, unpadded products that encircle the crib perimeter like a traditional bumper; and
- bumper alternatives that look like a traditional bumper and claim to have “breathable” properties.

Like traditional bumpers, these products are intended to provide some protection against impact and/or limb entrapment with the crib side, while allowing increased airflow near an infant’s face. The implication is that infants can sleep safely in the vicinity of these products.

Regarding claims that these products reduce the risk of SIDS by preventing rebreathing of CO₂, HS staff has found no published studies demonstrating their effectiveness in reducing SIDS. Moreover, HS staff is not aware of any safety standards with performance requirements for breathability for such products.

The prone sleep position is a known high-risk factor for SIDS and suffocation, especially for infants under 6 months of age. Given the unproven role that rebreathing plays in SIDS, and the list of factors that play a major contributing role to suffocation and SIDS in the prone position, such as hyperthermia, impaired arousability altered cardiovascular control, and being unable to lift their head and escape from potentially unsafe sleep settings, any product that advertises or promotes the prone position could put an infant at increased risk. It is unknown if there is an implication that use of these “breathable” products would allow an infant to be safely put to sleep in the prone position. Finally, although these “breathable” products, by themselves, do not present an increased risk over conventional products, it is unknown if there is a consumer perception that by using “breathable” products there is a reduced need for vigilance.

HS staff agrees that in an **entrapment scenario where a baby’s face is pressed against a bumper without neck hyperextension**, these products are likely safer than traditional bumpers. However, HS staff believes that the increased safety of these products is limited to **this specific scenario** and is not due to prevention of rebreathing CO₂, but rather, is attributable to preventing smothering. As described in an authoritative forensic textbook: *“Smothering occurs when there is an external, mechanical obstruction of the nose and mouth.....Accidental smothering deaths include young infants with external airway obstruction by large, soft bedding material (example: face-down on an adult pillow).”*

HS staff also evaluated whether the nine fatalities (#s 11, 17, 29, 35, 36, 37, 44, 48, & 49) identified as likely addressable (*i.e.*, removing the bumper likely would have prevented the fatality) could be addressed by the use of an alternative product, such as a mesh liner or vertical/mini bumper. Staff determined that case #s 35, 37, 44, & 49 may be addressable by both or either of these products; case #s 29, 48, & 36 are unlikely to be addressable; and addressability was unknown for the remaining case #s 11 & 17. A more detailed summary of staff’s evaluation of these nine cases and the rationale regarding their addressability by mesh liners or vertical bumpers is in Table 2, which appears at the end of this memorandum, because of its size.

III. Reviews of Recent Published Literature on Bumpers.

In February 2016, Scheers and colleagues (referred to in this document as “authors”) published a paper titled: “Crib Bumpers Continue to Cause Infant Deaths: A Need for a New Preventive Approach.”²⁸ This publication described 42 infant deaths from 1985 to 2012, which the authors directly attribute to the presence of crib bumpers, and 6 additional fatalities that the authors consider likely related to bumpers. Notably, these were the same cases⁴⁹ discussed by the lead author, NJ Scheers, in Tab F of the 2013 CPSC staff Crib Bumper Petition (CBP) briefing package.²⁹ HS staff took a different approach to evaluating the data one staff feels is more consistent in defining scenarios and likelihood HS staff reviewed and evaluated all of the available records for each case file including first responder’s reports, medical examiner and/or coroner investigation reports, scene reenactments, autopsies, patient medical histories, and CPSC investigational findings. HS staff used the most compelling evidence in making a determination for the cause of death and cases with very limited information were categorized as unknown.

Conclusion

Of the 107 reported incidents, staff determined that 72 were unlikely to be addressable because the bumper was incidental to the fatality, the child’s face was not into the bumper, or involved other scenarios in which removing the bumper would not have prevented the fatality. Nine cases were likely or potentially addressable by removing the bumper; and a subset of these possibly addressable by using mesh or vertical bumpers. In many of the cases where staff considered a bumper made a possible or likely contribution to the deaths, the majority included extenuating or confounding circumstances. In the remaining 24 incidents, classified as “unknown,” staff was unable to make a determination on the effectiveness of removing the bumper because of limited or conflicting information on the position of the child’s face with respect to the bumper.

The Crib Bumper Team’s analysis of fatal incident data showed that in the majority of cases, other serious hazards were present in the infant’s sleep environment, regardless of the crib bumper’s presence, with only nine fatalities likely associated with crib bumpers. Other addressable hazards include:

1. Prone Sleep Position—The prone sleep position is a known high-risk factor for SIDS, and suffocation; yet, young, particularly vulnerable infants, are still placed in this position to sleep, as shown by the data staff reviewed.
2. Pillows—Pillows placed under or around an infant create hazardous suffocation and/or entrapment risks. 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.⁸

⁴⁹ Confirmed per staff verbal communication with the lead author that the 48 cases were indeed the same incidents reported in Tab F.

3. Crib Integrity Issues—Numerous incidents involved broken cribs, makeshift cribs, cribs missing hardware, or similar crib-integrity issues, all of which can create gaps that can lead to entrapment and pose suffocation and hanging strangulation risks.

4. Other Objects in the Sleep Environment—Anything that crowds the sleep environment of an infant can present a hazardous entrapment and/or suffocation hazard. This includes the presence of a sibling. The cases staff reviewed also showed many instances where the infant sleep environment was cluttered with folded quilts, comforters, large stuffed toys, and other objects. These items also create entrapment and/or suffocation hazards. The presence of specialized infant products, such as sleep-positioning devices, or recliners, or nursing pillows, are also known to pose risks when placed in an infant sleep setting.

For this briefing package, HS staff assessed whether, in each incident, the bumper played a role in the fatality and whether removing the bumper would have prevented the fatality. Through this analysis, HS staff concludes that a cluttered sleeping environment is hazardous, and an appropriate infant sleep setting is critical (*i.e.*, an infant placed on its back in a crib that meets current voluntary standards and that is equipped with a firm, properly fitting mattress, with no additional pillows or comforters placed under the infant, and no positioning devices, other occupants, or bulky items placed inside the crib environment that might crowd the limited space in a crib and create an entrapment hazard).

References:

¹<http://www.cpsc.gov//Global/Newsroom/FOIA/CommissionBriefingPackages/2013/CribBumpersBriefingPackage.pdf>.

² ASTM, Current edition approved July 1, 2012. Published August 2012. Originally approved in 1999. Last previous edition approved in 2008 as F1917 – 08. Copyright © ASTM International Barr Harbor Dr., P.O. Box C-700 West Conshohocken, PA 19428, USA.

³ Gilbert-Barnes, E, Hegstrand L Chandra S, Emery J, Barnes LA, Franciosi R, and Huntington R. Hazards of mattresses, bed and bedding in deaths of infants. *Amer J Forensic Med and Pathol* 1991; 12(1):27-32.

⁴ Smialek, JE, Smialek, PZ and Spitz, WU. Accidental bed deaths in infants due to unsafe sleeping situations. *Clinical Pediatrics* 1977; 15 (11):1031-1035.

⁵ Wanna-Nakamura, S. Hazards associated with pillows and crowded sleep spaces a look beyond the safety standards. Abstract presented at the 2010 American Academy of Pediatrics (AAP) National Conference and Exhibition to be held in San Francisco, CA, October 2-5, 2010 Section on Injury, Violence & Poison Prevention.

⁶ Wanna-Nakamura S. White Paper – Unsafe Sleep Settings: Hazards associated with the infant sleep environment and unsafe practices used by caregivers: a CPSC staff perspective.

⁷ Gilbert-Barnes, E, Hegstrand L Chandra S, Emery J, Barnes LA, Franciosi R, and Huntington R. Hazards of mattresses, bed and bedding in deaths of infants. *Amer J Forensic Med and Pathol* 1991; 12(1):27-32.

⁸ Hauck FR, Herman SM, Donovan M, et al. "Sleep Environment and the Risk of Sudden Infant Death Syndrome in an Urban Population: The Chicago Infant Mortality Study." *Pediatrics* 2003; (111): 1207-1214.

⁹ Byard RW, Beal S and Bourne AJ. Potentially dangerous sleeping environment and accidental asphyxia in infancy and early childhood. *Arch Dis Child* 1994; 71: 497-500.

¹⁰ Fleming PJ, Blair PS, Bacon C, et al. Environment of infants during sleep and risk of the sudden infant death syndrome: results of 1993-5 case-control study for confidential inquiry into stillbirths and deaths in infancy. *BMJ*. 1996;313:191-195.

¹¹ *Wanna-Nakamura, S Infant Sleep Positioning Products and Wedges, 2009*
www.cpsc.gov/pagefiles/105285/positioners09.pdf - 30k -

¹² Moore L, Bourne AJ, Beal S, Collett M, Byard RW. Unexpected infant death in association with suspended rocking cradles. *Am J Forensic Med Pathol. Am J Forensic Med Pathol*. 1995 Jun; 16(2):177-80.

¹³ 16 C.F.R. Part 1218 by reference to <https://www.astm.org/Standards/F2194.htm>

¹⁴ Wilson SL, Thach BT, Brouillette RT, Abu-Osba YK. Upper airway patency in the human infant: influence of airway pressure and posture *J Appl Physiol*. 1980 Mar;48(3):500.

¹⁵ Avery MA, O'Doherty N. Effects of body-tilting on the resting end- expiratory position of newborn infants. *Pediatrics*. 1962;29:255-260. *Arch Dis Child Fetal Neonatal Ed* 2007;92:F468–F472. doi: 0.1136/adc.2006.109488.

¹⁶ Giuseppe L, Stanescu D, Dooms G, et al. Head position modifies upper airway resistance. *J Appl Physiol*. 1988; 64:1285-1288.

¹⁷ Saternus KS, Adam G. Sudden infant death. Postmortem flow measurements in the large vessels of the neck for the demonstration of posture-dependent cerebral hypoxemia. *Dtsch Med Wochenschr*. 1985 Feb 22;110(8):297-303.

-
- ¹⁸ Waldemar A. Carlo, Aris Beoglos, Bonnie S. Siner and Richard J. Martin Neck and Body Position Effects on Pulmonary Mechanics in Infants *Pediatrics* 1989;84:670-674.
- ¹⁹ Thach BT, Stark AR. Spontaneous neck flexion and airway obstruction during apneic spells in preterm infants. *J Pediatr.* 1979;94:275-281.
- ²⁰ Suratt PM, Gal TJ, Hooe DM. Effect of head flexion on airway resistance measured in a body plethysmograph. *Br J Chest Dis.* 1981;75:204-206.
- ²¹ Reiterer F, Abbasi S, Bhutani VK. Influence of head-neck posture on airflow and pulmonary mechanics in preterm neonates. *Pediatr Pulmonol.* 1994 Mar;17(3):149-54.
- ²² Lawrence, B., Gantt G, Cummins, S., Samuels-Reid, J., Wanna-Nakamura. Suffocation Deaths Associated With Use of Infant Sleep Positioners—USA 1997-2011 *MMWR.* 2012;46:933-937.
- ²³ AAP American Academy of Pediatrics, Policy Statement (Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of All Children). Task Force on Sudden Infant Death Syndrome. The Changing Concept of Sudden Infant Death Syndrome: Diagnostic Coding Shifts, Controversies Regarding the Sleeping Environment, and New Variables to Consider in Reducing Risk. *Pediatrics.* 2005;116:1245-1255.
- ²⁴ Dwyer T, Ponsonby A-L, Blizzard L, Newman NM, Cochane JA. The contribution of changes in prevalence of prone sleeping position to the decline in sudden infant death syndrome in Tasmania. *JAMA.* 1995;273:783-789.
- ²⁵ Ponsonby AL, Dwyer T, Gibbons LE, Cochran JA, Wang Y-G. Factors potentiating the risk of sudden infant death syndrome associated with prone position. *N Engl J Med.* 1993;329:377-382.
- ²⁶ Task Force on Infant Positioning and SIDS. Positioning and infant death syndrome (SIDS): update *Arch Pediatr Adolesc Med.* 1996;150:834-837.
- ²⁷ Thach T., Rutherford G., and Harris, K. Deaths and injuries attributed to infant crib bumper pads. *The Journal of Pediatrics* 2007;151:271-4.
- ²⁸ Scheers NJ, Woodard D., and Thach B. 2015 crib bumpers continue to cause infant deaths: A need for a new preventive measure *The Journal of Pediatrics* 2015;1-6.
- ²⁹ Scheers NJ BPBP Tab. F
<http://www.cpsc.gov/Global/Newsroom/FOIA/CommissionBriefingPackages/2013/CribBumpersBriefingPackage.pdf>.

Table 2: Likely Addressability of Fatalities by Mesh Liners or Vertical/Mini Bumpers.

	Mesh Bumper Addressable?			Explanation	Vertical/Mini Bumper Addressable?			Explanation	
	Likely	Unlikely	Unknown		Likely	Unlikely	Unknown		
Cases Likely Addressable by Bumper Removal/Category									HS Case Summary
Contact Outside Crib (3)									
<i>Record # 17</i>			x	Insufficient information			x	Insufficient information	IDI narrative - A five-year-old boy, with developmental delays, died of positional asphyxia after he pushed himself into the corner of his toddler bed with his face between the bumper pads
<i>Record # 29</i>		x		Continuous mesh bumper presents same strangulation/hanging hazard as a continuous traditional bumper		x		Scenario does not apply: vertical bumpers cannot be attached to "a gap in the side of the bed frame" of a toddler bed described as a daybed bed because such products do not have slats similar to those in a crib.	An 11 month-old girl, who was able to walk and climb out of a crib, was put to sleep in a toddler bed in which a crib bumper was being misused. She died when her lower body slid below the bumper, through a gap in the side of a toddler bedframe (near foot of bed), and her neck got caught by the top edge of crib bumper. She was reportedly found sitting on the floor, in a forward leaning position, between the toddler bed and the top edge of the crib bumper. The DCRT notes the ME ruled the death an accident due to "mechanical asphyxiation" caused by her becoming "entangled with crib bumper." Staff considers that misuse of a crib bumper outside of a crib clearly caused a mechanical asphyxiation death specifically involving the partial hanging strangulation of an older child. NOTE: Although the EPIR narratives, IDI and IPII describe refer to a daybed product, this should not be interpreted as an adult daybed. The IDI photographs and reported product dimensions (frame = 48"x24") clearly show that this cases involved a metal framed toddler bed, used with a standard crib sized mattress.

	Mesh Bumper Addressable?			Explanation	Vertical/Mini Bumper Addressable?			Explanation	
	Likely	Unlikely	Unknown		Likely	Unlikely	Unknown		
Cases Likely Addressable by Bumper Removal/Category									HS Case Summary
<i>Record # 48</i>		x		Continuous mesh bumper presents same strangulation/hanging hazard as a continuous traditional bumper		x		Scenario does not apply: vertical bumpers cannot be attached to "a gap in the side of the bed frame" of a toddler bed	IDI narrative - not summarized by HS in 2013- a 21-month-old male victim died of asphyxia due to compression of the neck when he became entrapped and suspended in the ties to a bumper pad that was affixed to his bed in his home. The victim was in a convertible crib that had been set up as a toddler bed. The bumper pad was tied at the top to the side slats of the bed. The victim had been put to bed by his mother at night and was found partially hanging out of the bed and unresponsive by his mother the next morning
Entrapment/ Wedging in Perimeter of Crib (2)									
<i>Record # 11</i>		x		Continuous mesh bumper presents same strangulation/hanging hazard as a continuous traditional bumper			x	The outcome depends on the size of the gap created by the missing crib slats and the age/size of the child. Either, the entire child can pass through the gap and fall to the floor, or the body can pass through the gap, while the head gets stuck between the slats resulting in a strangulation death.	The mom put healthy 9 month-old girl down for nap at noon. She was found unresponsive ~4 hr. later, with her body hanging through a 7" gap between the crib slats (1 or 2 were missing) and neck caught in bumper. The mom tried CPR, got neighbor to drive to ER, and flagged down a police vehicle to rush them to the ER. No signs of life were apparent and the baby was pronounced dead at 17:40h. An investigation was prompted by the attending MD's concern of possible abuse due to visible marks on her buttocks/anus. Autopsy found no signs of abuse with lesions due to chronic diaper rash. In a police interview at the ER, the mom said the crib was missing 2 side slats so was pushed against a wall. This was confirmed by an on-site scene reconstruction the next day (photos in IDI pdf are not viewable). The autopsy ME opined this death was an accidental "suffocation due to being trapped between a crib mattress and the crib railing". The bumper guard around the crib was around the neck of the victim. The crib railing was defective in that two missing slats formed a gap wide enough for the infant's body to slip through. The infant was found "suspended between the crib and the wall." Staff considers this death was clearly due to the recognized hazard of a broken crib with missing slats, which resulted in fatal hanging strangulation; this death would have occurred in this scenario regardless of the presence of the bumper pad. (note In EPIR, the DCRT is not linked to this IDI but is associated with a second IDI assignment number which has no record)

	Mesh Bumper Addressable?			Explanation	Vertical/Mini Bumper Addressable?			Explanation	
	Likely	Unlikely	Unknown		Likely	Unlikely	Unknown		
Cases Likely Addressable by Bumper Removal/Category									HS Case Summary
<i>Record # 36</i>		x		Continuous mesh bumper presents same strangulation/hanging hazard as a continuous traditional bumper		x		It is unlikely that a vertical bumper will stop a child falling through a broken crib frame gap. Depending on the size of the broken frame gap either, the entire child can pass through the gap and fall to the floor, or the body can pass through the gap, while the head gets stuck between the crib frame components resulting in a strangulation death. (examples)	Limited details: the 1 page DCRT indicates this 12 month-old girl fell out her crib and died from hanging asphyxiation (strangulation) caused by the crib bumper. There are no specific details on the involved crib's integrity, but staff considers it near to impossible for a child to hang in this scenario unless the child's neck gets entangled while falling through the crib structure rather than falling over the top of the side rail. Staff considers the hanging strangulation death reported here can only occur in a broken crib in which an excessive gap exists (specific location and cause of gap cause unclear). (Staff notes the DCRT appears to be signed by local police officer, not an MD). Information in the IDI clearly supports staff's speculation that this atypical bumper strangulation death of an older 12m baby clearly occurred when the baby fell through a gap of a broken crib. The policeman responding to the scene wrote "I noted that the rear guard rail of the crib, which is supposed to be fixed in place, was broken or had been taken apart. The upper right and rear corner of the crib side and the guardrail were not connected. The lower portion of this corner was still affixed. I observed that the crib bumper pad was hanging down in the middle and the ties had been broken away from the bumper itself."
Contact without Entrapment/Wedging (4)									
<i>Record # 35</i>	x			If the developmentally delayed baby (8 week preemie) placed in prone position to co-sleep with her twin, somehow become trapped in the crib corner, with her face against the bumper, a mesh bumper would likely have prevented a suffocation.	x			If the developmentally delayed baby (8 week preemie) placed in prone position to co-sleep with her twin, somehow become trapped in the crib corner, with her face against the bumper, a vertical bumper would likely have prevented a suffocation.	Limited information. The official document for this case appears to be a death certificate which is not fully legible (there is no indication of a related IDI assignment). Staff has to rely on the limited summary narrative found in the EPIR DTMS narrative which reports the death of a 2 month-old girl due to "Suffocation - accidental, in the corner of the crib against the bumper pad". Staff cannot determine whether any other relevant factors were involved in this case, but presumably the girl was lying prone. Based on the limited information staff believes the bumper likely played secondary role in this death but is unclear as to whether the crib bumper is relevant as the primary cause of death. Supplemental information included a very detailed child death review which notes multiple confounders involved in this case ruled suffocation, accidental. Staff cannot rule out bumper involvement but consider it is not likely the primary cause in this confounded case involving multiple confounders: CSS (vulnerable preemie (born 2m early) co-sleeping in same crib with twin, with much soft bedding present

	Mesh Bumper Addressable?			Explanation	Vertical/Mini Bumper Addressable?			Explanation	
	Likely	Unlikely	Unknown		Likely	Unlikely	Unknown		
<i>Cases Likely Addressable by Bumper Removal/Category</i>									<i>HS Case Summary</i>
<i>Record # 37</i>	X			If a child was found in the position depicted by a mannequin in the reenactment photos, a mesh bumper might likely have prevented a suffocation. However, staff emphasizes that the broken crib missing most of its hardware would still present a hazardous gap regardless of bumper presence.	X			If a child was found in the position depicted by a mannequin in the reenactment photos, a mesh bumper might likely have prevented a suffocation. However, staff emphasizes that the broken crib missing most of its hardware would still present a hazardous gap regardless of bumper presence.	The limited IPII-MECAP reports that a mother found her 2 month-old boy, who reportedly had a history of sleep apnea, unresponsive in his crib with his face against a bumper pad. It also notes that his second-hand wooden crib had been purchased at a garage sale and "had most of its hardware missing". No police investigation is noted on the MECAP report and there is no record of a follow-up CPSC IDI. The DCRT was received by CPSC a year later and notes the death was ruled as "positional asphyxia, accident, face obstructed by bumper pad". Although details are limited, in all probability, the second-hand crib missing most of its hardware lacked structural integrity. Staff considers that structural failure consequent to missing hardware likely explains why the death was ruled positional asphyxia, not just suffocation. Structurally unsafe cribs are recognized to present a risk of positional asphyxia (and mechanical asphyxia or hanging strangulation), regardless of the presence of a crib bumper. Staff notes supplemental version of MECAP report is the same as original IPII MECAP but without ME handwritten notes stating the broken secondhand crib was missing hardware. Although the ME's autopsy opinion appears to implicate suffocation in the crib bumper as the immediate cause of death, the recreation photos and photos of the incident crib clearly show crib structural failure with a hazardous gap in one corner where the doll's head is located (p12/12), which supports (possibly confirms?) HS staff's opinion of a primary crib structural integrity issue related to missing hardware.

	Mesh Bumper Addressable?			Explanation	Vertical/Mini Bumper Addressable?			Explanation	
	Likely	Unlikely	Unknown		Likely	Unlikely	Unknown		
<i>Cases Likely Addressable by Bumper Removal/Category</i>									<i>HS Case Summary</i>
<i>Record # 44</i>		X		Continuous mesh bumper presents same strangulation hazard as a continuous traditional bumper. Staff notes the victim in this case had multiple serious health issues (a preemie twin with cerebral palsy, meningitis at 2 months, hydrocephalus, seizures, and at 3.5 years weighed only 17 lb., equivalent to an average 7 month old baby). Furthermore, the ME regarded her death as suspicious and her caregivers were subsequently charged with criminal child endangerment.	X			vertical bumpers cannot present the same strangulation hazard as a continuous traditional bumper. Staff notes the victim in this case had multiple serious health issues (a preemie twin with cerebral palsy, meningitis at 2 months, hydrocephalus, seizures, and at 3.5 years weighed only 17 lb., equivalent to an average 7 month old baby). Furthermore, the ME regarded her death as suspicious and her caregivers were subsequently charged with criminal child endangerment.	This suspicious crib death of 3.5 year-old girl with serious preexisting medical issues (the emaciated girl [17lb] was a preemie twin with cerebral palsy, who had spinal meningitis at 2 months, hydrocephalus with brain shunts, and was on prescription barbiturates for seizure control). The mother and her boyfriend, both with a history of drug use, were charged 3 months after her death with criminal child endangerment /illegal drug use/manufacture/ distribution. The Sheriff's report says the mom reported putting the girl in a crib at ~9pm; she was not checked again until ~11am the next day (>14h later!). The boyfriend reported finding her lifeless, prone, "dark and cold" with the crib bumper wrapped around her neck (he said he had had to unwrap the bumper from her neck of a previous occasion). Police found a "good amount" of blood on the crib bumper near the contact position with her face and feet, and on the crib railing. The EPIR DTHS record, signed a day after death, noted the immediate cause of death as "Favor suffocation - crib bumper guard about decedent's head" with manner of death marked as pending. The ME reported the death as suspicious, and in the autopsy case discussion, noted the victim did "succumb secondary to changes consistent with suffocation" rather than strangulation, as reported by the boyfriend. The autopsy report also noted dried blood in the victim's mouth, multiple acute traumatic abrasions on her scalp, head face and on hand, but intact fingernails with no debris beneath them. Positive blood levels of prescribed barbiturates were in the therapeutic range for control of victim's seizures. Based on the extreme circumstances of this older child's suspicious death, and the subsequent criminal charges filed against the victim's mother and boyfriend, staff does not consider the death to be accidental and discounts the bumper as having any primary role.

	Mesh Bumper Addressable?			Explanation	Vertical/Mini Bumper Addressable?			Explanation	
	Likely	Unlikely	Unknown		Likely	Unlikely	Unknown		
<i>Cases Likely Addressable by Bumper Removal/Category</i>									<i>HS Case Summary</i>
<i>Record # 49</i>	X			If a child was found in the position depicted by a mannequin in the reenactment photos, a mesh bumper might likely have prevented suffocation.	X			If a child was found in the position depicted by a mannequin in the reenactment photos, a vertical bumper might likely have prevented suffocation.	A 5 month-old boy was found unresponsive in crib by his aunt ~2h after drinking 4oz formula. She said he was cold and blue, lying prone, with his face buried as if "snuggling" into the thick soft crib bumper padding in the corner of the crib. He was pronounced dead at the scene and a death scene investigation was conducted by the Sheriff and State Police. The baby was on a prescription Nystatin for treatment of oral thrush. The autopsy reported a red mark (superficial half inch diameter circular impression) on left side of his head, pulmonary congestion and edema, but no obvious signs of trauma. The ME ruled the death to be "Accidental: Positional asphyxia while laying face down in crib bumper". Reconstruction photos suggest the baby's chin face might have become caught in the improperly secured corner area of crib bumper. However, as shown in death scene photos, other thick bedding items were reported to be in the crib, including a comforter, heavy and light blankets, 2 plush toys (medium size), and a large stuffed toy keyboard that stretched nearly the width of the crib. They are not shown in the reconstruction photo and their potential role in any suffocation-type incident is not addressed by the coroner or police. Staff considers the death to be confounded by the baby's prone position, and presence of thick bedding and stuffed toys in the crib, plus an improperly tied crib bumper. Staff notes that while it is likely addressable, it is difficult to determine the exact role of the bumper in the death because of multiple confounding factors

TAB F

ESHF Staff Memorandum,

“Human Factors Assessment of Warning Requirements for and Safety Benefits of Crib
Bumpers”



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
ROCKVILLE, MD 20850

MEMORANDUM

DATE: May 6, 2016

TO: The File

THROUGH: Joel R. Recht, Associate Executive Director,
Directorate for Engineering Sciences

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

FROM: Timothy P. Smith, Senior Human Factors Engineer,
Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Human Factors Assessment of Warning Requirements for and Safety Benefits of
Crib Bumpers

BACKGROUND

On May 24, 2013, the Commission granted a petition by the Juvenile Products Manufacturers Association (JPMA or “the petitioner”) to initiate rulemaking to address the risk of injury associated with the use of crib bumpers. As part of this activity, the Commission directed staff to assess the effectiveness of any related voluntary consumer product standard safety standard and to assess whether a more stringent standard would further reduce the risk of injury associated with crib bumpers.¹

The ASTM International (ASTM) voluntary standard ASTM F1917, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*, contains requirements for crib bumpers and other infant bedding and related accessories in the United States. The current version of the voluntary standard was published in 2012 (ASTM F1917 – 12). Section 8 of ASTM F1917 – 12 specifies product and packaging marking requirements, which include requirements for warning labels that must appear on certain infant bedding and accessories covered under the standard. Section 8.2.1 identifies warning label content that is specific to crib bumpers. This memorandum, prepared by staff of CPSC’s Directorate for Engineering Sciences, Division of Human Factors (ESHF), discusses possible revisions or additions to the current warning requirements that may reduce the risk of death associated with crib bumpers, and discusses issues related to the safety benefits of crib bumpers and their alternatives.

¹ See the complete Record of Commission Action at <http://www.cpsc.gov/en/Newsroom/FOIA/Records-of-Commission-Action-and-Commission-Meeting-Minutes/2013/2015-DOCs/RCACrib-Bumpers-Petition-Request/>.

DISCUSSION

CRIB BUMPERS AND THEIR ALTERNATIVES

Crib bumpers, also referred to as “bumper pads,” “bumper guards,” or just “bumpers,” are infant bedding accessories that traditionally consist of one or more padded fabric panels that attach to the interior perimeter of a crib and function as barriers between the infant and the sides of the crib. These products are marketed as preventing injury to infants from impacts against the sides of a crib and preventing limb entrapments between crib slats. Bumpers also are used to decorate the infant’s sleep environment and are commonly promoted as making a crib more “cozy” or comfortable. Some bumpers have little padding, while others have several inches of padding and can even take on the appearance of pillows. Bumpers commonly attach to a crib with ties that are secured to the corner posts or crib slats, although other fastening methods exist. The warnings on these products recommend that bumpers be removed when a child can sit up unassisted or can pull to a standing position; an infant generally would reach one of these milestones at about 6 months old.

The market also includes so-called “vertical” bumpers, which essentially are a series of small bumpers that individually enshroud each crib slat, and similar alternatives that cover two slats at a time, sometimes referred to as “mini” bumpers. These products generally claim to offer benefits that are comparable to traditional bumpers while allowing airflow through the sides of a crib. Other bumper variants exist that look similar to traditional bumpers but claim to be breathable. Mesh crib liners are another alternative to traditional crib bumpers that claim to be breathable, but tend to be thinner than traditional bumpers because they lack padding; thus, liners do not offer as much protection from impacts against the side of the crib.

ESHF STAFF REVIEW OF FATAL INCIDENTS INVOLVING CRIB BUMPERS

As staff of CPSC’s Directorate for Epidemiology, Division of Hazard Analysis (EPHA), discusses in Tab C, staff has identified 107 fatal incidents that were reported to CPSC over the 26-year period from January 1, 1990, to March 31, 2016, and for which staff could confirm that a crib bumper was present in the sleep environment. Tables of these incidents, organized by hazard pattern as classified by the multidisciplinary Crib Bumpers project team, appear in Tab D. All of the bumpers involved in these incidents appear to be traditional crib bumpers.

CPSC staff classified more than one-quarter of these fatal incidents (29 percent, 31 fatalities) as “Incidental” because there was no evidence of bumper contact or involvement in the fatality. An additional five incidents involved contact with a crib bumper outside an infant crib.² In the original petition briefing package, staff considered such incidents to be out of scope (see Tabs E and F of Midgett, 2013).

² These incidents took place in a toddler bed, bassinet, or small daybed, which actually might have been a toddler bed as well. Three incidents classified as “Incidental” also involved a bumper that was outside of an infant crib; specifically, on a mattress located on the floor, in a bassinet, and in a play yard. Thus, a total of eight incidents involved crib bumpers outside an infant crib.

Staff classified the remaining 71 fatal incidents, all of which involved contact with a crib bumper, into the following hazard patterns and scenarios:

- Entrapment/Wedging
 - Against Object in Crib (23 fatalities)
 - In Perimeter of Crib (12 fatalities)
 - Other (6 fatalities)
- Contact without Entrapment/Wedging (23 fatalities)
- Contact with Possible Entrapment/Wedging (7 fatalities)

As indicated above, more than half of the 71 fatal incidents involve cases in which the child was entrapped or wedged against the bumper (41 fatalities), and more than half of those cases are ones in which the entrapment was between the bumper and another object in the crib (23 fatalities). Stated differently, about one-third (32 percent) of all fatal entrapments involving entrapment or wedging against the bumper involved entrapment against another object in the crib. In one case (incident 32), the “object” was a sibling; the objects involved in the remaining incidents were:

- a bed pillow (nine cases: incidents 10, 13, 27, 30, 55, 71, 72, 86, and 98);
- an infant recliner (five cases: 70, 75, 80, 84, and 99);
- a cushion (three cases: 6, 54, and 74), one (74) of which was used to prop up one end of an infant bounce seat;
- an infant nursing or positioning pillow (two cases: 47 and 76);
- an infant sleep positioner (two cases: 51 and 69); and
- a hand-held infant carrier, or car seat (one case: 107).

Many of these objects are similar in that they are intended for napping or sleeping, or it is likely that consumers will use the products to assist the infant in this activity. It is reasonably foreseeable that parents and other caregivers will use these products within infant cribs, because cribs are commonly designated sleeping environments and the sides of a crib provide a barrier from older siblings or pets, for example. Although incidents in this hazard pattern are unwitnessed, they appear to involve the infant turning, arching, or rolling over the side of the product and becoming wedged or entrapped between the side of the product and the bumper that is installed on the crib side. Entrapments of this kind would be expected to occur, regardless of the presence of a crib bumper, provided that the distance between the object and the side of the crib is close enough to permit entrapment.

Twelve fatalities were classified as entrapments “in the perimeter” of the crib, meaning that the child was found entrapped between the mattress and the side of the crib. Ten of the 12 cases involved the child’s torso slipping into a gap or space. This scenario was one of several identified by CPSC staff in the 1980s as part of the Structural Entrapment Project (Tyrrell, 1983), which led to the development of the wedge block that is used in the full-size crib standard³ to test for the potential for feet-first entrapment. Thus, this entrapment scenario is

³ See 16 C.F.R. part 1219, which incorporates by reference ASTM F1169 – 13, *Standard Consumer Safety Specification for Full-Size Baby Cribs*, with changes.

likely to occur only in old cribs that do not meet the mandatory full-size crib standard or are broken. Eight of the 10 cases that involved the child's torso slipping into a gap or space in the crib perimeter involved crib-integrity issues or failures, such as missing or detached crib slats (incidents 11, 22, and 28), and detached side rails (21, 33, 36, 45, and 106). One particularly illustrative example (21) involved a crib that was missing hardware and had been assembled from components of different crib manufacturers, with the side rail assembled upside down and mounted with corner braces, or "L" brackets. The other two cases that involved the child's torso slipping into a gap or space did not involve crib-integrity issues. In one case (26), the crib was reported to be an antique, and therefore, did not meet the current mandatory standard for cribs. The other case (59) involved a crib of unknown age, but a gap reportedly would form when the bumper was moved away from the side of the crib.⁴ The two perimeter-entrapment fatalities that did not involve the child's torso slipping into a gap or space (8 and 15) appear to have involved the child's head becoming entrapped in a space or gap between the mattress and the side of the crib.⁵ These cases lack details that might explain why the gap existed.

Six fatal incidents involved some other entrapment scenario not covered above. One of these cases (4) involved crib integrity issues; namely, a failure of the crib support, which caused the crib mattress to tilt down in one corner and the victim to become wedged in that corner. Twenty-three fatal incidents involved contact with the bumper but without entrapment or wedging. Two of the 23 non-entrapment cases (25 and 35) indicate that the bumper was "sagging."

Seven fatal incidents also involved contact with the crib bumper, but lacked sufficient details for staff to assess whether the child was entrapped or wedged against the bumper. These incidents are similar in that they typically described the child's face as being between the mattress and the bumper or side of the crib, and often used the phrase "wedged between" to describe the position. However, staff was unable to ascertain whether the child's face was truly entrapped in this space, or if the term "wedged" was being used merely to describe the orientation of the face relative to the two surfaces. One of these incident reports (63) included reenactment photos with a stuffed toy to illustrate the position of the victim, and the photos do not seem to support the idea that actual entrapment of the face or head took place. Thus, staff did not consider use of the term "wedging," alone, to be sufficient to conclude that the child was entrapped or wedged against the bumper. Another one of these fatalities (100) reportedly was caused by a medical condition that allegedly arose from a bumper-related incident a year earlier. As discussed in Tab E, staff of CPSC's Directorate for Health Sciences (HS) is unconvinced that the two are related.

ASTM WARNING REQUIREMENTS FOR CRIB BUMPERS

Section 8 of ASTM F1917 – 12 specifies product and packaging marking requirements for infant bedding and related accessories, and includes warning labels that must appear on certain products covered by the standard.

⁴ From p. 3 of the IDI: "[The victim's mother] told Detective A that their daughter likes to pull the bumper pad away from the inside perimeter of the baby crib. She suggested that her son's head could've gotten stuck in the gap created by the movement of the bumper pad. The father agreed with his wife's statement."

⁵ In one case (8), the victim was found with her head wedged between the side of the mattress and a bumper installed on the side of the crib. In the other (15), the victim was found face down and "entrapped" between the side of the crib and the edge of the mattress.

CONTENT

Section 8.2.1 specifies that each crib bumper or crib bumper panel, if the bumper consists of multiple panels that can be used separately, must include the following warning statements:⁶

▲ WARNING

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.

Because “vertical” and “mini” bumpers are identified and marketed as bumpers, the required warning statements for crib bumpers seemingly would apply to those products as well. Mesh liners are not specifically addressed in the standard, and therefore, they would not be required to include the warning statements above. However, the ASTM Infant Bedding Subcommittee Task Group has proposed that additional products, including crib liners, be added to the scope of ASTM F1917 to reflect what is currently on the market. Staff is unclear what warning-content requirements crib liners would be subject to if added to the standard.

FORMAT

ASTM F1917 – 12 includes two main design or form requirements for warning labels. First, section 8.2 states:

“The label(s) shall be in the ANSI format, which would include a delineated signal word panel containing the safety alert symbol before the signal word and a contrasting background.”

Section 2 of the standard, Referenced Documents, refers the reader to ANSI Z535.4, *American National Standard for Product Safety Signs and Labels*, which is the primary U.S. voluntary consensus standard for product safety signs and labels. The appendix to ASTM F1917 – 12 also references ANSI Z535.4 when discussing the rationale behind the section 8 requirements (see section X1.3). Thus, the clear intent of these requirements is for the warning labels covered by the voluntary standard to conform to ANSI Z535.4. No year of publication is specified for ANSI Z535.4, so warning labels apparently would have to conform to the version of that standard that is current at the time of product manufacture.

The second design or form requirement for warning labels is related to letter heights for warning text. Section 8.2 of ASTM F1917 – 12 specifies that the required signal word, “WARNING,”

⁶ 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.

must be in letters at least 0.2 inches (5 mm) high. The remaining warning text must be in letters whose uppercase is at least 0.1 inches (2.5 mm) high.

OTHER REQUIREMENTS

Section 8 of the ASTM voluntary standard also states that the warning labels must be “permanent” and “conspicuous.” However, the standard neither defines, nor specifies performance requirements for assessing conformance to these two requirements. The standard does not specify any requirements for instructional literature that would accompany crib bumpers or any other infant bedding or accessories covered by the standard.

INDUSTRY CONFORMANCE TO ASTM WARNING REQUIREMENTS

CPSC staff purchased samples of 19 different products for examination and testing: 16 different crib bumpers, including 3 “vertical” or “mini” bumpers (referred to here as “vertical/mini” bumpers), and 3 mesh liners. ESHF staff examined these samples to assess the extent to which they conform to the warning requirements of ASTM F1917 – 12. Table 1 summarizes staff’s findings.

Seven of the 16 bumpers, including all three of the vertical/mini bumper samples, lacked the ASTM warning label for crib bumpers. Thus, overall conformance of crib bumpers to the warning requirements of ASTM F1917 – 12 is not very high.⁷ All three mesh liner samples included a warning label similar to that required for crib bumpers, even though the standard does not require these products to include such a warning.

Among the 12 samples that include a warning label—9 crib bumpers and 3 mesh crib liners—all provide the label in the form of a sewn tag. The remaining discussion regarding conformance to the warning content, format, and other requirements focuses on these 12 samples.

Content

Eight of the nine crib bumper samples conform to the warning content requirements of F1917 – 12. The sole crib bumper sample that failed these requirements used the warning language from the earlier, 2008 version of the standard, which is missing the statements about reducing the risk of suffocation by keeping the top of bumper up and in position, not allowing the bumper to sag down or in toward the sleeping surface, and not using the bumper if sagging cannot be corrected. One bumper sample that met the warning content requirements included the following additional warning statement: “Only use this crib bumper in a full-size crib.” This statement is similar to one that ESHF staff had considered as an additional warning requirement for crib bumpers, an issue that is discussed in detail later in this memorandum.

⁷ Even if one ignores the vertical/mini bumpers, nearly one-third of the remaining bumper samples (4 of 13) did not include the warning label.

Product Type	Sample No.	Content	Text Size	ANSI Z535.4	Notes
Bumper	-0152	PASS	FAIL	FAIL	<ul style="list-style-type: none"> • Message text 0.085" • White-on-black signal word panel. • Safety alert symbol (SAS) not vertically aligned with signal word.
	-0153	PASS	FAIL	FAIL	<ul style="list-style-type: none"> • Message text 0.085" • White-on-black signal word panel. • SAS not vertically aligned with signal word.
	-0154	FAIL	FAIL	FAIL	NO WARNING PRESENT
	-0155	PASS	PASS	FAIL	<ul style="list-style-type: none"> • Black-on-white signal word panel. • SAS smaller than signal word.
	-0156	PASS	PASS	FAIL	<ul style="list-style-type: none"> • Red-on-white signal word panel. • SAS smaller than signal word. • Message text all-uppercase, centered, & condensed .
	-0159	FAIL	FAIL	FAIL	NO WARNING PRESENT
	-0160	PASS	FAIL	FAIL	<ul style="list-style-type: none"> • Signal word 0.145" & message text 0.085" • Black-on-white signal word panel. • SAS above signal word. • Message text fully justified.
	-0161	PASS	FAIL	FAIL	<ul style="list-style-type: none"> • Signal word 0.15" • Black-on-white signal word panel.
	-2640	FAIL	FAIL	FAIL	NO WARNING PRESENT
	-2641	PASS	PASS	FAIL	<ul style="list-style-type: none"> • Black-on-white signal word panel. • Message text all-uppercase & centered.
	-2654	PASS	PASS	FAIL	<ul style="list-style-type: none"> • Includes: "Only use this crib bumper in a full-size crib." • White-on-gold signal word panel.
	-2658	FAIL	PASS	FAIL	<ul style="list-style-type: none"> • Content based on F1917 – 08. • Black-on-white signal word panel. • Message text all-uppercase & centered .
	-2659	FAIL	FAIL	FAIL	NO WARNING PRESENT
	Vertical/Mini	-0157	FAIL	FAIL	FAIL
-0158		FAIL	FAIL	FAIL	NO WARNING PRESENT
-2653		FAIL	FAIL	FAIL	NO WARNING PRESENT
Mesh Liner*	-2655	PASS?	FAIL	FAIL	<ul style="list-style-type: none"> • Content refers to "liner." • Message text 0.095" & all-uppercase. • Black-on-white signal word panel.
	-2656	PASS?	PASS	FAIL	<ul style="list-style-type: none"> • Content refers to "liner." • Red-on-white signal word panel . • SAS smaller than signal word. • Message text all-uppercase, centered, & condensed.
	-2657	PASS?	PASS	FAIL	<ul style="list-style-type: none"> • Content refers to "liner." • Black-on-white signal word panel . • Message text all-uppercase & condensed.

TABLE I. ESHF staff assessment of sample conformance to warning requirements of ASTM F1917 - 12.

*Note: Crib liners technically are not required to meet crib bumper warning requirements.

Even though the ASTM standard does not require mesh liners to include the warning language for bumpers, all three mesh liner samples included these warnings, except for minor revisions to the language to reflect that they were "liners," rather than "bumpers." Thus, these samples seem to conform to the warning content requirements, at least in principle.

Format

All nine crib bumper samples fail the warning format requirements of F1917 – 12. Four of the nine samples fail to meet the letter height requirements for warning text, and none of the nine bumper samples fully conform to ANSI Z535.4.

For two samples, the signal word “WARNING” measures approximately 0.15 inches tall, which is smaller than the minimum 0.2-inch height requirement. Three samples, one of which also failed the signal word height requirement, failed the minimum 0.1-inch height requirement for the remaining warning text. In all three cases, the text measures about 0.085 inches.

ANSI Z535.4 – 2011 requires hazard labels that rely on the signal word “WARNING” to have a signal word panel consisting of safety black text on a safety orange background (section 7.2.2), except when special circumstances preclude the use of safety colors (section 7.6.3). Staff is unaware of any special circumstances associated with crib bumpers that would preclude the use of safety colors; yet none of the warning labels include an orange signal word panel. Rather, the signal word panels on these products consisted of

- black text on a white background (4 samples),
- white text on a black background (2 samples),
- red text on a white background (1 sample), and
- white text on a gold background (1 sample).

Five of the nine samples also failed the safety alert symbol size or alignment requirements specified in ANSI Z535.4. Specifically, ANSI Z535.4 – 2011 requires the safety alert symbol to precede the signal word, with the bases of both vertically aligned, and to be at least as tall as the signal word lettering (section 6.3). In three cases, the bases of the safety alert symbol and signal word did not align vertically;⁸ in the other two cases, the labels used a safety alert symbol that was smaller than the signal word text.

All three mesh liner samples also fail the F1917 – 12 requirements related to warning format. One of the samples technically fails the minimum 0.1-inch height requirement for message panel warning text, but the text measures about 0.095 inches, and therefore, nearly passes. None of the three mesh liner samples conform to ANSI Z535.4. For example, none of the warning labels include an orange signal word panel; two samples use black text on a white background, and one sample uses red text on a white background. One of the three samples also failed the safety alert symbol size requirements, because the safety alert symbol was smaller than the signal word text.

⁸ In one case, the safety alert symbol was positioned above the signal word.

Although technically not failures of the voluntary standard, ESHF staff also noted other warning format problems, such as the use of all-upercase text and centered or fully justified text in the message panel, and the use narrow or condensed typefaces.⁹ The warning tag shown in Figure 1 is particularly illustrative because it demonstrates all of these problems.

Other Requirements

As staff noted earlier, ASTM F1917 – 12 requires the warning labels on crib bumpers and other infant bedding to be “permanent” and “conspicuous,” but does not define or provide objective measures for these terms. Thus, ESHF staff cannot assess the extent to which the sample products meet these two requirements.



FIGURE 1. Warning on sample -2656.

Ten of the 12 samples containing a warning tag—8 bumpers and 2 mesh liners—had the warning tag at or near one end of the product. In three of these cases, all crib bumpers, the warning tag was positioned below other tags sewn into the same location, which means they would not be fully visible unless one or more tags were moved aside. An example of this appears in Figure 2, which includes an arrow to identify the location of the warning tag, under several other tags. In another case involving a crib liner, the tag was tucked into part of the liner and the printed side was not visible without the consumer actively pulling out the tag. An image of this appears in Figure 3. Two samples had the warning tag in a location other than the end of the bumper or liner: in one case the tag was positioned roughly halfway along the length of the crib bumper, and in the other case, the tag was positioned on the bottom edge of a liner.

Although ASTM F1917 – 12 does not include any requirements for instructional literature to accompany crib bumpers, ESHF staff took notice during its examination of the samples whether the products included such materials. None of the samples that were missing warning tags included instructional literature either, and only five of the nine bumper samples that had a warning tag included instructional literature. In terms of content, all five samples included installation instructions, and four of the five included at least some of the product warnings.¹⁰ Two of the three crib liner samples also included instructional literature.

⁹ Section 8.1.2 of ANSI Z535.4 – 11 states that message panel text “should” be a combination of upper- and lowercase letters (*i.e.*, sentence capitalization), with an allowance to use uppercase-only lettering for short messages or to emphasize individual words. Annex B of ANSI Z535.4 includes a similar recommendation (section B3.3.7), and recommends that text generally be left aligned, ragged right, rather than centered or fully justified (B3.3.6). “Condensed,” “compressed,” or “narrow” typefaces have letters with widths that are proportionally narrow relative to their heights, and commonly include such terms in its name (*e.g.*, *Arial Narrow*, *Gill Sans Condensed*). Wogalter and Vigilante (2006) have stated that dense “compressed” text may dissuade reading because such text requires too much effort to read and might suggest to the reader that the message is not important.

¹⁰ Three samples included all product warnings; one included the strangulation warning statements only.

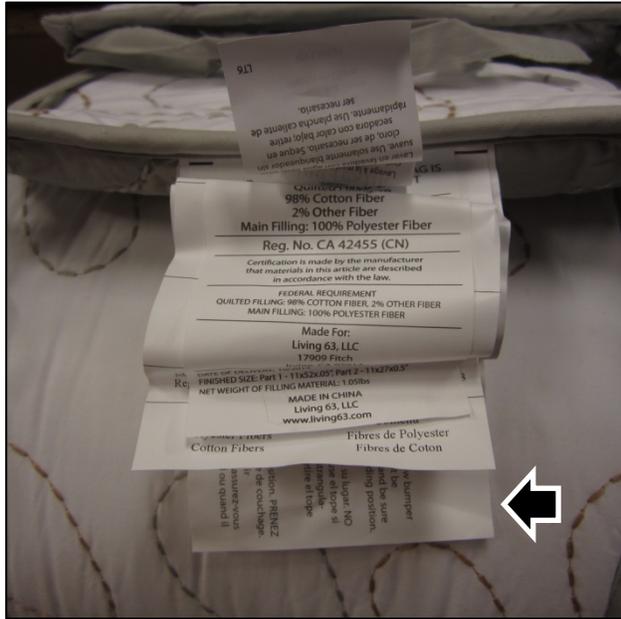


FIGURE 2. Multiple tags on product.

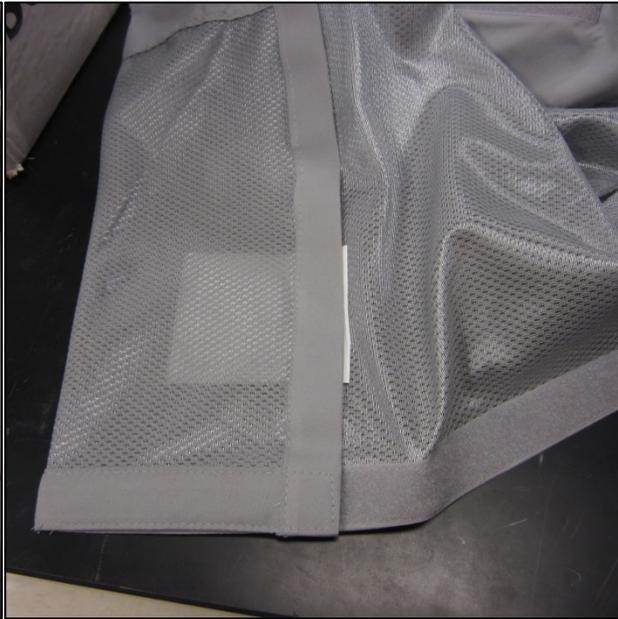


FIGURE 3. Warning tag tucked into liner.

POSSIBLE REVISIONS TO WARNING REQUIREMENTS

Safety and warnings literature consistently identify a classic hierarchy of approaches that one should follow to control hazards, primarily based on the effectiveness of each approach in eliminating or reducing exposure to the hazard. The use of warnings is viewed universally as less effective than either designing the hazard out of a product or guarding the consumer from the hazard, and, therefore, is lower in the hazard-control hierarchy than these other two approaches (Vredenburg & Zackowitz, 2005; Wogalter, 2006; Wogalter & Laughery, 2005). Warnings are less effective because they do not prevent consumer exposure to the hazard. Rather, warnings rely on persuading consumers to alter their behavior in some way to avoid the hazard. Thus, one should view warnings as “last resort” measures that supplement, rather than replace, redesign or guarding, unless these higher level hazard-control efforts are not feasible. Based on its review of fatal incidents and sample products, ESHF staff has considered several revisions and additions to current warning requirements that might reduce the risk of death associated with crib bumpers.

Revise Existing Warning Language

ANSI Z535.4, *American National Standard for Product Safety Signs and Labels*, and other literature and guidelines on warnings (e.g., Robinson, 2009; Wogalter, 2006; Wogalter, Laughery, & Mayhorn, 2012) consistently recommend that on-product warnings include:

- a description of the hazard,
- information about the consequences of exposure to the hazard, and
- instructions regarding appropriate hazard-avoidance behaviors.

The two hazards identified in the ASTM F1917 – 12 crib bumper warning label are: (1) suffocation, and (2) entanglement or strangulation in bumper ties. None of the 107 fatal incidents during the 26-year period examined by staff involved strangulation. The required warning

statement that instructs consumers to position ties securely to the outside of the crib might have played a role in addressing the strangulation hazard; however, the voluntary standard also includes a maximum tie-length requirement of 9 inches, and has included this requirement since at least the year 2000.¹¹ Although CPSC staff has found that some crib bumpers on the market include tie lengths that exceed the 9-inch requirement (see LSM staff’s memorandum in Tab G), this requirement is the most likely reason for the lack of recent strangulation fatalities. Either way, the available data do not support revisions to the strangulation-related language.

The suffocation hazard is the primary hazard associated with crib bumpers, and the current warnings instruct consumers to avoid this hazard by: (1) keeping the top of the bumper up and in position so it does not sag into the crib, and (2) not using the bumper if sagging cannot be corrected. Much of the emphasis, therefore, is on properly installing the bumper and making sure the bumper remains properly installed. Staff’s review of the fatal incidents only identified two cases (incidents 25 and 35) that specifically indicate that the bumper was “sagging.” Both of these cases involved bumper contact without entrapment or wedging. Another entrapment-related fatality (incident 107) also appeared to involve a sagging bumper. One of the challenges for consumers, in the context of trying to comply with the warning, is identifying when a bumper is sagging to a sufficient degree that it poses the suffocation hazard and must be corrected. Although the current warning language states that the top of the bumper must be “up and in position,” a more explicit instruction about how the bumper should look when it has been properly installed (*e.g.*, “keep bumper tight against side of crib”) may be useful and reduce the likelihood of loose or sagging bumpers. However, the available data suggest that few incidents involve loose or sagging bumpers, so such an addition is unlikely to prevent many fatalities, even if the warnings were effective at getting consumers to comply.

The current warnings also tell consumers to remove the bumper when the child can sit up unaided or can pull themselves to a standing position. However, it is unclear whether this directive pertains to the suffocation hazard, strangulation hazard, both, or some other undisclosed hazard. During discussions with the project manager on the original petition briefing package, ESHF staff learned that this language was based on earlier incidents in which it appeared that children used bumpers to climb out of the crib.¹² Additional information such as this, which describes why these developmental milestones are important to removing the bumper, would likely be helpful to improve compliance. However, ESHF staff notes that none of the 107 fatal incidents examined by staff clearly involved a child using a bumper to climb out of a crib.¹³ Thus, the available fatality data do not support revisions to add such explanatory material.

Add Warning Language Regarding Entrapment by Other Products in Crib

In 23 of the fatal incidents examined by staff, the victim was found wedged or entrapped between the side of the crib, which was covered by a bumper, and another object, such as a pillow, infant recliner, sleep positioner, or even another child. The entrapment almost certainly

¹¹ ASTM F1917 – 00, the earliest version of the standard examined by staff, includes such a requirement.

¹² Personal communication with Jonathan Midgett, Chairman Special Assistant, on March 30, 2016.

¹³ In two “Incidental” cases (incidents 16 and 105), the investigator speculated that the child who was involved might have stood on the bumper to climb over the side of the crib. However, there is no evidence that the child used the bumper in this way.

was the cause of death in these cases, and the fatality is unlikely to have occurred without entrapment. Thus, one might conclude that additional warning language on crib bumpers that warns against placing pillows or other products in the crib because of the risk of suffocation from entrapment has the potential to reduce this risk.

Although the potential benefits of labeling crib bumpers about this hazard seem obvious, several issues are likely to limit the effectiveness of such an approach:

- Nine incidents involved entrapment against a bed pillow, one of which was covered in a blanket. The mandatory standard for full-size cribs, 16 C.F.R. part 1219, already requires a warning about the suffocation hazard associated with soft bedding and instructs consumers not to place pillows, comforters, or extra padding in the crib. This standard incorporates by reference ASTM F1169 – 13, *Standard Consumer Safety Specification for Full-Size Baby Cribs*, with changes, and a warning to this effect has been in place since the 2007 version of the voluntary standard.¹⁴ This means that many cribs less than a decade old already warn against putting pillows in cribs due to the potential for suffocation. Thus, the potential benefit of adding such warning language to crib bumper labels is likely to be limited to those cases in which consumers purchase new bumpers for use in a crib that is about 10 years old or older, and this benefit is likely to decrease as consumers replace older cribs with newer models.
- Five incidents involved entrapment against an infant recliner produced by a particular manufacturer. These infant recliners were recalled, and CPSC has urged consumers to immediately stop using and immediately dispose of the products.¹⁵ In addition, it now is illegal for any person to sell, offer for sale, manufacture, distribute in commerce, or import into the United States any model of these recalled products. These actions, therefore, have already addressed these particular infant recliner-related entrapments.¹⁶ Other infant incline sleep products exist on the market, but they have not been involved in incidents with bumpers. In addition, ASTM recently published a voluntary standard for these products, F3118 – 15, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, which already requires warnings against using these products in cribs or other contained areas, or next to vertical surfaces.

¹⁴ Similarly, since at least 2002, the ASTM voluntary standard for non-full-size cribs and play yards has included a warning against placing pillows, an extra mattress, or soft bedding in the product. ASTM F406 – 02 is the oldest version of the standard that staff could examine, and that version included such a requirement.

¹⁵ See <http://www.cpsc.gov/en/Newsroom/News-Releases/2013/Nap-Nanny-and-Chill-Infant-Recliners-Recalled-by-Baby-Matters-LLC-After-Five-Infant-Deaths-CPSC-Firm-Settle-Administrative-Litigation-/>.

¹⁶ In addition, the administrative complaint filed by the Commission against the manufacturer states that even with “enhanced” warnings, it is foreseeable that caregivers will continue to use the products in a crib (item 117), and that warnings and instructions cannot adequately mitigate the risk of injury or death associated with the use of these products (item 127).



FIGURE 4. Reenactments of entrapments with nursing/positioning pillow, from incidents 47 and 76.

- Two incidents involved entrapment against an infant nursing/positioning pillow. Since at least 2008, the product in question has had a warning against using the product in a crib, cradle, bassinet, playpen, or bed, and against using it for sleep, including a large graphic of the word “SLEEP” covered by a red prohibition symbol.¹⁷ Thus, both incidents involved products that already warned against such use. In addition, in both cases the infant’s face was known to be straight down toward the mattress or into the positioning pillow itself, rather than into the bumper. Reenactment photos for the two incidents appear in Figure 4. Given the face orientation and body position of the infants when found, it seems unlikely that the bumper played a role in these incidents and that death likely would have occurred even if the bumper were not present.
- Two incidents involved entrapment against an infant sleep positioner. The infant positioner involved in one incident (incident 69) is known to have been discontinued by the manufacturer, who has discontinued the distribution of all sleep positioners.¹⁸ The positioner in the other incident (51) is unknown, but shortly before the fatality, when the bumper was removed, the child banged his face against the crib rails and sustained dental trauma. Thus, the consumer would have been highly motivated to install the bumper or alternative padding over the side of the crib, regardless of the presence of a warning. Furthermore, CPSC has explicitly warned consumers to stop using sleep positioners, regardless of the presence of a bumper,¹⁹ so a warning on a *crib bumper* that tells consumers not to use a sleep positioner could send a potentially confusing and contradictory message to consumers that using such products might be acceptable if a bumper is not present.
- One incident (74) involved entrapment against a cushion that was used to prop up one end of an infant bouncer that had been placed in the crib. The ASTM infant bouncer standard, ASTM F2167, *Standard Consumer Safety Specification for Infant Bouncer*

¹⁷ Staff was able to identify the label on the product involved in the 2008 incident, which is the earlier of the two incidents.

¹⁸ See <http://www.sassybaby.com/sleep-positioners-update>.

¹⁹ See <http://www.cpsc.gov/en/Newsroom/News-Releases/2010/Deaths-prompt-CPSC-FDA-warning-on-infant-sleep-positioners/>.

Seats, has included a warning against the use of bouncers on soft surfaces, such as beds or cushions, since 2005 (ASTM F2167 – 05a), and the Commission intends to consider a staff recommendation for a mandatory rule for infant bouncer seats this year 2016 that will mandate warning language related to this hazard. Thus, existing warnings already address this incident. In addition, the incident occurred in 2010, so it seems likely that the bouncer involved in this incident had such a warning statement. If true, the consumer's use of the bouncer in the manner described in the incident²⁰ would suggest that the consumer might not have heeded a bumper warning regarding the presence of other objects in the crib.

- Two additional incidents involved entrapment against a cushion: in one case (6), a thick homemade cushion, and in the other case (54), a sofa cushion or pillow. These incidents occurred in 1992 and 2008, respectively, so it is possible that the crib involved in the latter incident included a warning about pillows and other soft bedding. To some extent, these two incidents are addressed by the warnings specified in the mandatory crib standard, discussed earlier. However, because neither of these cushions would be considered “bedding,” it is possible that even if the consumers in these incidents had seen and read a warning about pillows and other soft bedding in a crib, they would not have believed that the cushions were the same type identified in the warning. That said, the sofa cushion or pillow in the 2008 incident does not look especially firm, so consumers who understand the suffocation hazard should recognize that the hazard applies to those products as well. Nevertheless, it is conceivable that a warning specific to entrapment between crib bumpers and other objects might have had some impact.
- One incident (107) involved entrapment in and against a handheld infant carrier. The child had been sleeping in the carrier, unrestrained, when the carrier was placed into the crib. The carrier then tipped over, resulting in the child's face and neck becoming entrapped between the top of the seat back and the carrier canopy. Portions of reenactment photographs for this incident appear in Figure 5. The images show an installed bumper and the top of the child's face and head in contact with the bumper; however, the incident report never mentions a bumper or its relevance to this incident. Thus, it is possible that the reenactment photo is inaccurate and the child was not in contact with the bumper at the time of the incident. Regardless, the child's face reportedly was entrapped against the carrier, which suggests that the bumper's presence was irrelevant to the fatality. Furthermore, even if the bumper had played a role in the fatality, the mandatory standard for handheld infant carriers, 16 C.F.R. part 1225, already requires warnings about (1) never placing the carrier on beds or other soft surfaces because of the potential for the carrier to roll over and result in suffocation, and (2) fully restraining the child, even when the carrier is used outside a vehicle. The standard incorporates by reference ASTM F2050 – 13a, *Standard Consumer Safety Specification for Full-Size Baby Cribs*, with changes, and product warnings related to these issues have been in place since the 2000 version of the voluntary standard. Thus, existing warnings

²⁰ As well as the presence of a pillow and other soft bedding in the crib, which, as described earlier, is already warned against on cribs.



FIGURE 5. Reenactment of entrapment with handheld infant carrier, from incident 107.

already address this incident. The carrier involved in this incident was manufactured at the end of 2012, and warnings pertaining to these issues are visible on the product.

- The last incident involved entrapment against a sibling who was sharing the crib with the victim. This scenario is not specifically addressed in the warnings, so relevant warning language on bumpers might have addressed this admittedly rare incident scenario.

For the reasons described above, ESHF staff concludes that additional warning language on crib bumpers about the potential for entrapment and suffocation when other objects are placed in a crib along with the bumper is unlikely to have a substantial impact on the risk of death. Staff acknowledges that such language would reinforce the suffocation warnings already required on infant cribs, is potentially useful in cases where a consumer installs a new crib bumper in an old crib that lacks warnings about pillows and other soft bedding, and might alert consumers to the potential for entrapment that otherwise is not addressed explicitly in those warnings. Yet, the potential benefits seem small, and additional language would increase the overall warning length, which could dissuade consumers from reading all or any of the warning statements. Therefore, ESHF staff is unconvinced that adding such warning language would reduce fatalities.

Add Warning Language Regarding Bumper Installation or Use in a Broken Crib

Twelve fatal incidents involved entrapment along the perimeter of the crib; that is, between the mattress and the side of the crib. Ten of these cases involved the child's torso slipping into a gap or space. Eight of these ten cases involved crib integrity issues or failures, such as missing or detached crib slats, detached side rails, and missing hardware, and are cases in which the bumper was used even after the crib was broken. Staff also is aware of one other incident (incident 37) where a bumper was installed in an already-broken crib, even though this incident did not result in entrapment in the crib's perimeter. Thus, staff is aware of nine fatal incidents associated with crib bumpers where the bumper was installed or used in an obviously broken crib, and the

integrity of the crib was the direct cause of the fatality or the precipitating event that likely led to the fatality.²¹

Although ESHF staff believes that the prime cause of incidents involving a broken crib is the crib itself, there may be some benefit to including a warning against using the bumper in a broken crib, particularly if the consumer believes that the bumper will serve to block an infant's access to missing slats or a detached side, and believes that the bumper will keep the child from being exposed to the resulting gap.²² A warning that states that the bumper is not designed to hold the child in the crib, for example, may communicate to consumers that the bumper should not be relied upon to prevent access to a hazardous gap in the crib. However, one of the supposed functions of a bumper is to help prevent limb entrapments in crib slats. Thus, consumers may find a warning that states that the bumper will not prevent access to the crib side disingenuous, and thus, may choose to ignore it. The effectiveness of such a warning on fatalities also depends on the extent to which consumers would respond by repairing the crib, rather than simply discontinuing the use of the bumper.²³ If consumers respond by removing the bumper, or by not installing the bumper in the first place, then access to the hazardous gap remains, and such incidents are still likely to result in death. Overall, ESHF staff believes that a warning about bumper use in a broken crib has some potential benefit, but its effectiveness at addressing fatalities is unlikely to be high.

Add Warning Language Regarding Bumper Use Outside a Crib

Staff identified eight fatal incidents (incidents 17, 19, 24, 29, 48, 60, 66, and 102) in which the crib bumper was used in a toddler bed, bassinet, or otherwise, outside an infant crib. Thus, ESHF staff considered the possibility of additional warning language on crib bumpers that warns against using bumpers in products other than a full-size crib. As ESHF staff noted earlier in this memorandum, when discussing sample conformance to ASTM F1917 – 12, one of the samples examined by staff included the additional warning statement: “Only use this crib bumper in a full-size crib.” Thus, the industry might be receptive to requiring such a warning statement.

Three of the eight relevant incidents (24, 60, and 66) are incidents that staff classified as “Incidental” because there was no evidence that the bumper was in contact with the child or was otherwise involved. Thus, even if a warning effectively persuaded consumers not to use the bumper in these cases, there is no reason to believe that the fatalities would have been prevented.

Of the remaining five incidents:

- One case (29) involved an 11-month-old who reportedly was “very active,” and was capable of climbing out of a crib, climbing on sofas and chairs, and running. As staff

²¹ One additional incident (incident 40) involved the use of makeshift mattress supports that likely led to the fatality; however, the consumer might have considered the installation of these makeshift supports as a repair that meant the crib was no longer broken. In such a case, a warning about bumper use in a broken crib would likely have been deemed irrelevant and ignored.

²² Staff also notes that in one incident that involved a crib bumper outside a crib (incident 29), the consumer reportedly installed the bumper in the small day bed (most likely a toddler bed) “to keep the victim from sliding off the day bed mattress.”

²³ And on the effectiveness of the repair. See footnote 21.

noted earlier, warnings that conform to ASTM F1917 – 12 must state: “Remove bumper when child can sit up unaided or can pull to a standing position.” Thus, the current warning requirements most likely would have addressed this incident. Nevertheless, the consumer reportedly installed the bumper “to keep the victim from sliding off the day bed mattress.” This lends some credence to the idea of including warning language that tells consumers that the bumper is not designed to keep the child in the crib, as staff discussed in the prior section.

- Two cases (17 and 48) involve a toddler bed and also should be addressed by the current warning language about removing the bumper when the child can sit up unaided or pull to a standing position, because children generally transition from a crib to a toddler bed after they have exceeded this developmental milestone, and, for example, can climb out of a crib.²⁴ One (48) of these two incidents involved a 21-month-old and is known to have involved a bumper that included this warning language. The consumer’s decision not to heed that warning suggests that additional warning language about not using the bumper outside a crib is also unlikely to be heeded. The other incident (17) involved a developmentally delayed 5-year-old, but use of a toddler bed, rather than a crib, suggests that the child might have met the milestones identified in the current warning requirements for crib bumpers.
- The final two cases (19 and 102) involved installation of a bumper in a bassinet. It is possible that the warning language considered in this section could have addressed these incidents.

Overall, staff’s review of the incidents suggests that a warning statement about bumper use in products other than a full-size crib is unlikely to substantially reduce the risk of death. ESHF staff believes that such warning language might have addressed two incidents in which the bumper was used in a bassinet, and might have had some effect on three incidents involving a toddler bed. However, the toddler bed-related incidents already seem to be addressed by current warnings about when bumpers should be removed.

Revise Warning Format Requirements

As staff mentioned earlier, ASTM F1917 – 12 requires the warning labels specified in the standard to conform to ANSI Z535.4. However, none of the new crib bumper samples purchased and examined by CPSC staff fully conforms to the ANSI standard, even in those cases in which the warning language meets the content requirements of ASTM F1917 – 12. This might be a consequence of manufacturers not being especially diligent about meeting the warning format requirements in general. For example, four of the eight crib bumper samples whose warning content matched that specified in the ASTM standard failed to conform to ANSI Z535.4 and also failed the letter height requirements for the warning text.

Staff also believes that the current wording of ASTM F1917 – 12 could be partially to blame. As a reminder, section 8.2 of the voluntary standard states, in part:

²⁴ In addition, toddler beds include mandatory warnings against use with children younger than 15 months.

“The label(s) shall be in the ANSI format, which would include a delineated signal word panel containing the safety alert symbol before the signal word and a contrasting background.”

It is possible that manufacturers are misinterpreting this requirement to mean that the warning labels are required *only* to include a delineated signal word panel containing the safety alert symbol before the signal word and a contrasting background, rather than those requirements being only part of what is included in, and required by, ANSI Z535.4. Thus, ESHF staff believes that non-conformance to Z535.4 might be addressed partially by revising this requirement to state, for example: “The label(s) shall conform to the warning format requirements of ANSI Z535.4.” ESHF staff has raised this issue with the ASTM Infant Bedding Subcommittee Task Group, and the Task Group is considering such a revision.

Alternatively, ESHF staff believes that there may be value in adding more stringent warning format requirements that are consistent with format requirements recently recommended for other juvenile products standards. These requirements specify conformance to certain sections of ANSI Z535.4, but with amendments that convert some advisory (*i.e.*, “should”) statements in the ANSI standard into mandatory (*i.e.*, “shall”) statements. Such requirements would address at least some of the other problems staff noted when examining the sample products, including the use of all-uppercase text, and centered or fully-justified text in the message panel of the warning.

Add a “Conspicuous” Definition or Separate Warning-Placement Requirements

ASTM F1917 – 12 currently requires warning labels for infant bedding and related accessories to be “conspicuous,” but fails to define this term within the standard. Numerous ASTM juvenile products standards include a requirement for warnings to be “conspicuous,” and define this term in a way that enables one to assess conformance. Typically, the term is defined in terms of when the label must be visible; for example: “a label that is visible when the [product] is in a manufacturer’s use position to a person standing near the [product] at any one position but not necessarily visible from all positions.”²⁵

Staff believes that a similar definition, or a separate warning label placement requirement that is specific to crib bumpers,²⁶ is needed to clarify when the label on crib bumpers must be visible to the consumer. Such clarity is required because conformance to ASTM F1917 – 12 cannot be assessed adequately without it, and also because staff’s examination of new crib bumper samples identified cases where the warning tag was positioned in such a way that consumers are unlikely to notice it, unless they are actively seeking warning or other information on the tags (see Figure 2, previously, for an example). ESHF staff has raised this issue with the ASTM Infant Bedding Subcommittee Task Group, and the Task Group is considering such an addition.

In terms of the specific requirement, ANSI Z535.4 states that warnings must be placed so they are “readily visible to the intended viewer” and will “alert the viewer to the hazard in time to

²⁵ Adapted from ASTM F1235 – 15, *Standard Consumer Safety Specification for Portable Hook-On Chairs*.

²⁶ Because the “conspicuous” requirement applies to all infant bedding and related accessories, selecting a definition that works equally as well among the various products may be challenging. Thus, a separate placement requirement for crib bumpers, in particular, might be a better approach.

take appropriate action” (Section 9.1).²⁷ The warnings required by ASTM F1917 – 12 instruct consumers to:

- keep the top of the bumper up and in position,
- not allow the bumper to sag down or in toward the sleeping surface,
- securely position the bumper ties to the outside of the crib, and
- remove the bumper when the child can sit up unaided or pull to a standing position.

The first three items are associated with the initial installation of the bumper, so they must be visible to consumers during installation. However, the last item involves the consumer having to assess when the bumper should be removed from the crib. Children generally can sit alone steadily at about 5 to 9 months of age and can pull to a standing position at about 5 to 12 months of age (Bayley, 1969). Thus, consumers who install crib bumpers when the child is a newborn would not have to comply with the portion of the warning related to removal for possibly 5 months after installation, or longer. One cannot depend on the consumer to remember what is stated in a warning for that length of time. Therefore, this statement should be visible to consumers after the bumper has been installed to enable consumers to read and comply. This suggests that the warning, as a whole, should be visible after the bumper is installed, or that the warning statement about when to remove the bumper should be separate from the other warning statements and made visible under these circumstances.

Add a Definition or Performance Requirement Related to Warning Permanence

As staff mentioned earlier, ASTM F1917 – 12 requires warning labels for infant bedding and related accessories to be “permanent.” However, the standard fails to define “permanent” or specify performance requirements that would allow one to assess conformance. This issue has been raised with the ASTM Infant Bedding Subcommittee Task Group, and the Task Group is considering such an addition.

Add Requirements for Instructional Literature

Currently, ASTM F1917 – 12 includes no requirements for instructional literature to accompany crib bumpers. ESHF staff’s examination of the samples revealed that few crib bumpers include instructional literature. As staff discussed earlier, the existing ASTM warning requirements for crib bumpers emphasize proper installation by instructing consumers to keep the top of the bumper up and in position so it does not sag into the crib. Given that caregiver compliance with the warnings on crib bumpers demands that consumers properly install the products, instructional literature regarding installation is essential.

Numerous ASTM juvenile products standards include an “Instructional Literature” section that requires instructions to be provided with the product. The requirements generally specify that these instructions shall

- be easy to read and understand;

²⁷ However, they must not be presented so far in advance of a hazard that the consumer might forget the warning when presented with the hazard.

- include information regarding specific tasks associated with the product such as assembly, installation, adjustment, maintenance, cleaning, and use; and
- address the warning and safety-related statements specified in the labeling portion of the ASTM standard, often formatted in a similar manner but without the need for safety colors.

ESHF staff believes that similar instructional-literature requirements would be appropriate for crib bumpers. Some ASTM juvenile products standards also specify that the instructions must address additional warnings that are not required to appear on the product itself. Such an approach may be an opportunity to include warning statements about some of the issues considered by ESHF staff, but for which there may be insufficient support for labeling on the product itself (*e.g.*, use in a broken crib, use in a product other than a full-size crib).

SAFETY BENEFITS OF CRIB BUMPERS AND THEIR ALTERNATIVES

Crib bumpers generally are touted as preventing injuries from impacts with the sides of the crib and limb entrapments between crib slats. On December 28, 2010, the Commission published its Final Rule for full-size and non-full-size baby cribs (75 Federal Register 81766). In the Rule, CPSC staff pointed out that infants getting their limbs caught between crib slats accounted for about 12 percent of the 3,520 incidents involving full-size cribs and cribs of an undetermined size. Staff further noted that some injuries requiring hospitalization involved limb entrapments or impacts with the crib structure after falling within the crib. Thus, crib bumpers provide a safety benefit if they effectively limit such injuries. EPHA staff found that slat entrapments of the arm or leg is the most common hazard scenarios among the nonfatal incidents associated with bumpers, accounting for 57 of the nonfatal incidents (see Tab B). Accordingly, staff acknowledges that crib bumpers do not completely prevent access to the side of a crib.²⁸ However, ESHF staff has found that a bumper was not present at the time of the incident in about one-third (18) of these 57 cases, and the incident was identified as bumper-related because the consumer merely mentioned a bumper as a possible solution, stated that he or she did not want to use a bumper, or was advised to use a bumper to prevent future incidents. Furthermore, because a bumper functions as a barrier between the child and the side of a crib, bumpers likely prevent some incidents and injuries involving limb entrapment or crib-structure impact that otherwise would have occurred. Given that more than half of the estimated 9.2 million cribs in use are equipped with crib bumpers,²⁹ it seems reasonable to conclude that the number of incidents and injuries cited above would increase if crib bumpers did not exist or were removed from the market.

The city of Chicago, IL, and the state of Maryland have banned the sale of crib bumpers, and one option available to the Commission would be a mandatory rule that bans some or all crib bumper designs. One claim advanced by the original petitioner JPMA that staff must consider seriously is that the elimination or ban of crib bumpers may encourage caregivers to use other soft bedding or makeshift materials as an alternative protective barrier against the crib structure. Staff is not

²⁸ In addition, in one fatal incident (incident 81), the victim was found with his legs passing beneath the bumper and through the crib slats.

²⁹ See Tab B. According to staff of CPSC's Directorate for Economic Analysis (EC), about 5.3 million of the estimated 9.2 million cribs in use are equipped with crib bumpers.

aware of any data on these types of consumer behaviors in the locales that have enacted a ban on crib bumpers, and cannot say with certainty whether consumers are likely to engage in these behaviors. However, soft bedding is a known suffocation hazard, and many consumers continue to put soft bedding in cribs, despite warnings against such practices.³⁰ Furthermore, some of the incidents examined by staff included cases of consumers using cushions as makeshift crib sides, or using the bumper to restrict access to openings or gaps. Staff also is aware of other crib-related incidents in which soft bedding was used to fill in gaps.

Concerns about the potential for suffocation with traditional crib bumpers have given rise to other varieties of bumpers and alternative products that often claim to provide increased airflow to infants within the crib, or describe themselves being “breathable.” These products include the previously mentioned vertical/mini bumpers, mesh crib liners, and other bumper variants that look similar to traditional bumpers but claim to be breathable. HS staff has addressed issues pertaining to suffocation and “rebreathing” in its memorandum in Tab E.

As staff discussed earlier, vertical/mini bumpers are designed to enshroud one or two slats at a time. Apparently, these products are intended to provide some protection against impacts with the crib side, while permitting increased airflow through the crib. These products also claim to keep infants’ limbs inside the crib, by narrowing the spaces between the slats; however, reduced open spaces remain to provide the advertised increase in airflow. In the staff briefing package containing the notice of proposed rulemaking (NPR) for full-size and non-full-size baby cribs, staff of CPSC’s Office of Hazard Identification and Reduction (EXHR) specifically considered the possibility of altering spacing requirements for crib slats to address limb entrapments. EXHR staff noted that although limb entrapments occur with high frequency, and that some associated fractures have been reported, narrowing the spaces between slats still would allow for the entrapment of limbs of smaller infants or the entrapment of smaller body parts of larger infants (Midgett, 2010). For this reason, staff did not recommend altering spacing requirements for crib slats. Although vertical bumpers could be designed to eliminate the spacing between slats, one of the marketed advantages of these products—increasing airflow through the crib—would largely disappear, and the result would be a continuous padded crib side like that offered by traditional crib bumpers. Vertical/mini bumpers might offer an advantage over traditional bumpers because they may be less prone to sag, but this likely depends on the specific bumper design and accompanying installation instructions.

CONCLUSIONS

Based on its examination of new crib bumper and related samples, ESHF staff concludes that overall conformance of bumpers to the warning requirements of ASTM F1917 – 12 is not very high. Although most products that include warnings conform to the warning content

³⁰ For example, the Commission’s Final Rule for full-size and non-full-size baby cribs noted that extra bedding in cribs accounted for the majority of infant deaths in cribs or other sleeping products (75 Federal Register 81766). The Final Rule references CPSC staff’s briefing package, which states: “The number one hazard shown in the fatality data is associated with caregivers adding extra bedding, such as pillows or comforters, to the cribs,” and, “Both ASTM F 1169-10 and F 406-10 [the then-current ASTM voluntary standards for full-size and non-full-size cribs] already contain labeling requirements that point out the deadly nature of this hazard” (Howell & Edwards, 2010, p. 12).

requirements, none of these products fully conform to the format requirements, which include minimum letter heights for warning text and conformance to ANSI Z535.4. Staff also notes that the ASTM standard requires the warning labels on crib bumpers and other infant bedding to be “permanent” and “conspicuous,” but neither defines nor provides objective measures for these terms. The standard includes no requirements for instructional literature, and few of the new samples examined by staff include installation instructions.

ESHF staff has considered several revisions and additions to current ASTM warning requirements that might reduce the risk of death associated with crib bumpers, such as:

- revising the current language to provide a more explicit description of how the bumper should look when it has been installed properly;
- providing additional warning statements about bumper use in a broken crib or in products other than full-size cribs;
- revising the format requirements to clarify that the warnings must conform to all warning format requirements of ANSI Z535.4, or adding more stringent format requirements;
- adding specific placement and permanence requirements for the required warnings; and
- adding requirements for instructional literature that must accompany the products.

The ASTM Infant Bedding Subcommittee Task Group is already considering some of these revisions and additions. Although staff believes that these changes would be helpful and generally improve the safety of crib bumpers, the overall impact on the risk of death associated with these products may not be very large.

In terms of safety benefits, crib bumpers are intended to prevent injuries from impacts with the sides of the crib and limb entrapments between crib slats. During rulemaking activities for full-size and non-full-size cribs, CPSC staff noted that limb entrapments were common and that limb entrapments and impacts with the crib structure sometimes result in injuries requiring hospitalization. Although bumpers do not prevent all access to a crib side, bumpers likely prevent some incidents and injuries involving limb entrapment or crib-structure impact that otherwise would have occurred. Furthermore, the majority of cribs in use are equipped with crib bumpers. Thus, the number of incidents and injuries would likely increase if crib bumpers did not exist or were removed from the market. The elimination or ban of crib bumpers also might encourage caregivers to use other soft bedding or makeshift materials as an alternative protective barrier against the crib structure, and this most likely would increase the incidence of fatal suffocations in cribs.

Vertical/mini bumpers are one alternative to traditional, continuous crib bumpers. Because these products enshroud one or more crib slats at a time, open spaces remain between slats to provide increased airflow. CPSC staff previously considered and rejected the possibility of altering spacing requirements for crib slats to address limb entrapments because narrowing the spaces between slats still would allow for the entrapment of limbs of smaller infants or the entrapment of smaller body parts of larger infants. Thus, vertical/mini bumpers may offer less protection from limb entrapment than traditional bumpers unless they were designed to eliminate the spacing between slats. Yet, this would eliminate the increased airflow that these products currently advertise, and the result would be a continuous padded crib side like that offered by traditional crib bumpers.

REFERENCES

- American National Standards Institute. (2011). *ANSI Z535.4. American national standard: Product safety signs and labels*. Rosslyn, VA: National Electrical Manufacturers Association.
- American National Standards Institute. (2011). *ANSI Z535.6. American national standard: Product safety information in product manuals, instructions, and other collateral materials*. Rosslyn, VA: National Electrical Manufacturers Association.
- Bayley, N. (1969). *Manual for the Bayley Scales of Infant Development*. New York: The Psychological Corporation.
- Deppa, S. W. (1989). *Procedures to Evaluate Openings in Children's Products for Head Entrapment Hazards*. CPSC Staff Report, U.S. Consumer Product Safety Commission, Washington, DC.
- Howell, R. J., & Edwards, P. L. (2010). *Staff's Draft Proposed Rules for Cribs – Full-Size and Non-Full-Size*. CPSC Memorandum to the Commission, Bethesda, MD. Available: <http://www.cpsc.gov/library/foia/foia10/brief/104cribs.pdf>.
- Midgett, J. (2010). *Human Factors Analysis of Children Climbing Out of Cribs and Getting Limbs Caught Between Slats*. CPSC Memorandum to P. L. Edwards, Project Manager, Cribs, U.S. Consumer Product Safety Commission, Bethesda, MD.
- Robinson, P. A. (2009). *Writing and Designing Manuals and Warnings* (4th ed.). Boca Raton, FL: CRC.
- Tyrrell, E. (1983). *Structural Entrapment Hazards to Infants and Children*. CPSC Memorandum to S. E. Dunn, Office of the Secretary, U.S. Consumer Product Safety Commission, Bethesda, MD.
- Vredenburg, A. G., & Zackowitz, I. B. (2005). Human Factors Issues to be Considered by Product Liability Experts. In Y. I. Noy & W. Karwowski (Eds.), *Handbook of Human Factors in Litigation* (Chapter 26). Boca Raton, FL: CRC Press.
- Wogalter, M. S. (2006). Purposes and Scope of Warnings. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 3–9). Mahwah, NJ: Lawrence Erlbaum Associates.
- Wogalter, M. S., & Laughery, K. R. (2005). Effectiveness of Consumer Product Warnings: Design and Forensic Considerations. In Y. I. Noy & W. Karwowski (Eds.), *Handbook of Human Factors in Litigation* (Chapter 31). Boca Raton, FL: CRC Press.
- Wogalter, M. S., Laughery, Sr., K. R., & Mayhorn, C. B. (2012). Warnings and Hazard Communications. In G. Salvendy (Ed.), *Handbook of Human Factors and Ergonomics* (4th ed.; pp. 868–894). Hoboken, NJ: Wiley.

Wogalter, M. S., & Vigilante, Jr., W. J. (2006). Attention Switch and Maintenance. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 245–265). Mahwah, NJ: Lawrence Erlbaum Associates.

TAB G

LSM Staff Memorandum,

“Existing Voluntary Standards and Testing Methods Associated with Crib Bumpers”



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
ROCKVILLE, MD 20850

MEMORANDUM

Date: June 20, 2016

TO: Tim Smith, Human Factors Engineer, Crib Bumpers Project Manager
Division of Human Factors, Directorate for Engineering Sciences

THROUGH: Andrew Stadnik, P.E., Associate Executive Director,
Directorate for Laboratory Sciences

FROM: John Massale, P.E., Mechanical Engineer
Division of Mechanical Engineering, Directorate for Laboratory Sciences

SUBJECT: Existing Voluntary Standards and Testing Methods Associated with Crib
Bumpers

This memorandum will review different performance requirements and metrics associated with the perceived hazards related to crib bumpers. It also includes a summary of testing using some of those metrics on a survey of commercially available crib bumpers. The implications of the testing, as they relate to the hazard pattern, are outlined in the conclusion.

I. Review of Existing Voluntary Standards

Firmness

There are two voluntary standards and one academic study that contain performance tests for firmness that can be applied to crib bumpers. The first standard is ASTM F1917-12 *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories* (ASTM F1917-12). The second standard is the Australian/New Zealand standard, AS/NZS 8811.1 *Methods of testing infant products Method 1: sleep surfaces-test for firmness* (AS/NZS 8811.1). The third document is an academic study, *The German case-control scene investigation study on SIDS: epidemiological approach and main results* ("Schlaud Study").

The only section of ASTM F1917-12 relevant to firmness is section 6.2 *Maximum Bumper Thickness*. The bumpers must compress to 2 inches of thickness, or less, when drawn through an aluminum gauge block (Figure 1) with up to 5 pounds of force. Two inches was chosen as the maximum thickness because a similar limit "already exists for other padded items infants interact

with such as play yard pads.”¹ The author’s rationale continues: “[the 2 inch limit] also allows for excessive fabric, fabric seams, and bumper ties. The 5-lb weight was selected as it was thought that this was a very small force that when applied would allow for bumpers to slide through the gauge during testing and compensate for any excessive fabric, fabric seams, and bumper ties.”

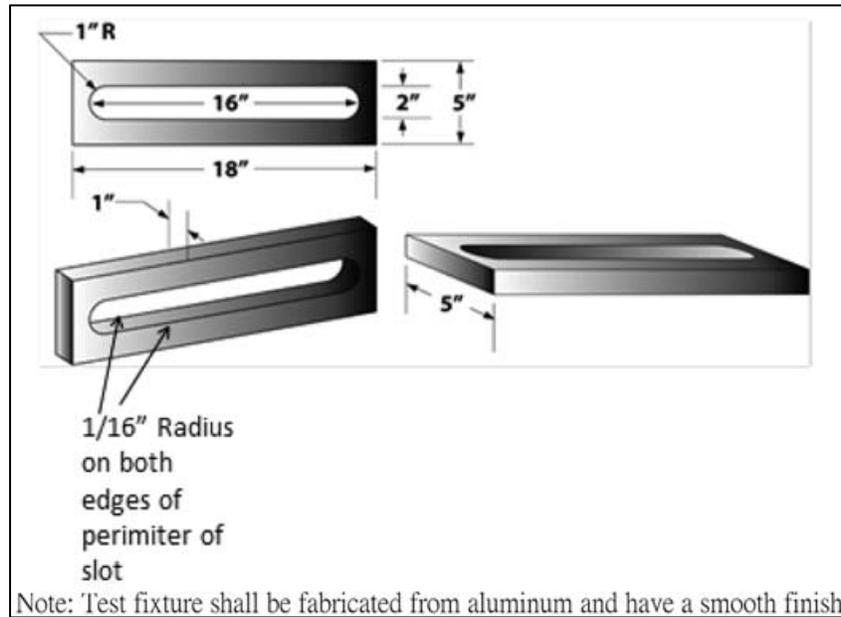


Figure 1. Maximum bumper thickness test gauge block.²

The Australian/New Zealand standard, AS/NZS 8811.1, is primarily intended to test the softness of horizontal sleep surfaces, not bumpers specifically. According to the scope:

“[This method] sets out the method for assessing whether a horizontal or nearly horizontal infant sleep surface exhibits excessive compression when subjected to a constant force applied through a standard load pad.”³ The test apparatus “consists of a circular bottom disk of [203 mm ±1 mm] diameter and [15 ±0.2 mm] thickness, ...a feeler arm clamped tight to the center of the upper disk face and extending over the edge of the disk by [40 ±2 mm]...The total mass of the apparatus shall be 5200 ±20 g. The radius of the lower edge of the disk shall not be larger than 1 mm. The feeler arm shall be a lightweight, flexible, flat bar 12 ±0.2 mm wide with square-cut ends.”⁴

The disk is placed on the sleep surface to begin the test. If the sample material compresses under the weight of the apparatus to the point where the feeler arm also touches the sample, the sample fails the test. See Figure 2 below for a diagram of the apparatus.

¹ ASTM F1917-12, rationale section X1.1, page 3.

² ASTM F1917-12, page 2.

³ AS/NZS 8811.1, page 1

⁴ AS/NZS 8811.1, page 2

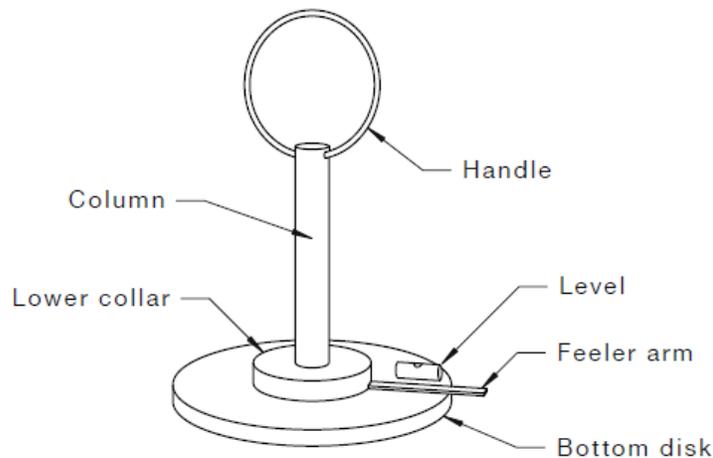


Figure 2. Softness testing apparatus

The third document, the Schlaud Study, was found in the footnote of an early draft of AS/NZS 8811.1. The draft referenced a “purpose-built instrument to assess surface firmness”⁵ that informed the design of their own test apparatus. CPSC staff also recreated a device similar to the one in the Schlaud Study. The square has a thickness of approximately 1.17 cm with the center hole slightly larger than the cylinder. The cylinder has a weight of 2 kg and a diameter of 6 cm.

To use the device, the sample is placed horizontally on a rigid flat surface. The square part of the device is laid upon the sample and then the cylinder is inserted into the hole in the square. If the cylinder plunges through the hole past the leading face of the square by 1.5 cm, the sample is considered a failure.

Attachment Means

ASTM’s infant bedding and accessory standard, ASTM F1917-12, is the only document to directly address the performance of attachment means for crib bumpers. Section 5 states that the crib bumper attachment means (*e.g.*, cords or straps) shall be no longer than 9 inches overall. The endpoints and midpoints of the bumper must also be capable of being secured at or near all corners and at the midpoints of the long sides of the crib. Section 6.3 states that bumper pad ties must not detach from the body of the bumper when subjected to a 20 lb pull force. Two ties that share a common attachment point to the body of the bumper shall be tested together. This addresses bumper pad ties becoming dislodged or loose in the sleep environment and creating a choking hazard.

⁵ AS/NZS 8811.1, page 1.

Airflow and Rebreathing

There are four standards and two studies that address airflow and rebreathing: (1) ASTM F1917-12, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*; (2) ASTM F963-11, *Standard Consumer Safety Specification for Toy Safety*; (3) ISO 11540:2014, *Writing and marking instruments - Specification for caps to reduce the risk of asphyxiation*; and (4) ASTM D737-04(2012), *Standard Test Method for Air Permeability of Textile Fabrics*. These standards contain performance metrics related to airflow through and around objects lodged or obstructing the mouth. Two studies, *Mechanical model testing of rebreathing potential in infant bedding materials* (“CDP study”) and *Forensic Engineering Evaluation of CO₂ Re-Breathing in Infant Bedding Materials* (“Leshner study”), attempted to assess potential carbon dioxide (CO₂) re-breathing using a mechanical model that simulated an infant breathing facedown and to the side on six different surfaces.

ASTM’s infant bedding and accessory standard, ASTM F1917-12, addresses potential suffocation from a materials perspective. Section 6.1 requires that unsupported vinyl be thicker than 0.012 inches to avoid a suffocation hazard. However, if it is inaccessible to the child, the unsupported vinyl is exempt from this requirement. For example, an unsupported vinyl exemption occurs when a liquid-proof mattress cover is used underneath a fitted sheet. Section 7.2 instructs the use of a paper micrometer to verify the thickness. There is no metric related to airflow through or around the material, only a prohibition.

ASTM’s toy safety standard, ASTM F963-11, has various requirements to address suffocation hazards when the airway is externally obstructed. It requires toy tea cups or toy bowls to have holes at least 0.66 inches in minor dimension. There is also a requirement, section 4.12, where any packaging film less than 0.00150 inches in thickness “shall be perforated with defined holes so that a minimum of 1 % of the area has been removed over any area of 1.18 inches by 1.18 inches.” The only numeric value assigned to airflow is found in section 8.13 *Test for Mouth-Actuated Toys*. It is a use-and-abuse test designed to dislodge any pieces of a toy that could be aspirated. Ten 3-second cycles of 18 in³ are applied to the toy without exceeding 2 psig. A release valve is incorporated into the system to ensure the maximum pressure is not exceeded.

The ISO specification for writing and marking instruments, ISO 11540:2014, requires the perforation of a cap pen with an opening that permits an airflow of 8 liters (488 in³) per minute when a source of 25 liters (1525 in³) per minute is applied to the apparatus. The specification reduces the likelihood of inhalation and delays asphyxiation to allow time for surgical extraction. This specification is approximately 1.3 times the volumetric flow rate of ASTM F963.

ASTM's standard test method for air permeability, ASTM D737-04, can ascribe a value of permeability of a thin fabric. Section 4.1 *Summary of Test Method* reads:

“The rate of air flow passing perpendicularly through a known area of fabric is adjusted to obtain a prescribed air pressure differential between the two fabric surfaces. From this rate of air flow, the air permeability of the fabric is determined.”⁶

This test method is limited to thin fabrics that can be clamped in a test head “without distortion and minimal edge leakage underneath the test specimen.” It would be difficult to apply this method to traditional crib bumpers, which are inherently thick, and garner repeatable results. Any plush center would allow both distortion of the external fabric and leakage around the edge of the test specimen.

The CDP study, published in *The Archive of Disease in Childhood* by former CPSC staff in 1998, attempted to develop a mechanical model for rebreathing of CO₂ in an infant when in contact with different bedding items and materials. This study was duplicated by the Leshner study. The mechanical model used in Leshner's study was a replica of the CDP methodology and is shown below as Figure 3.

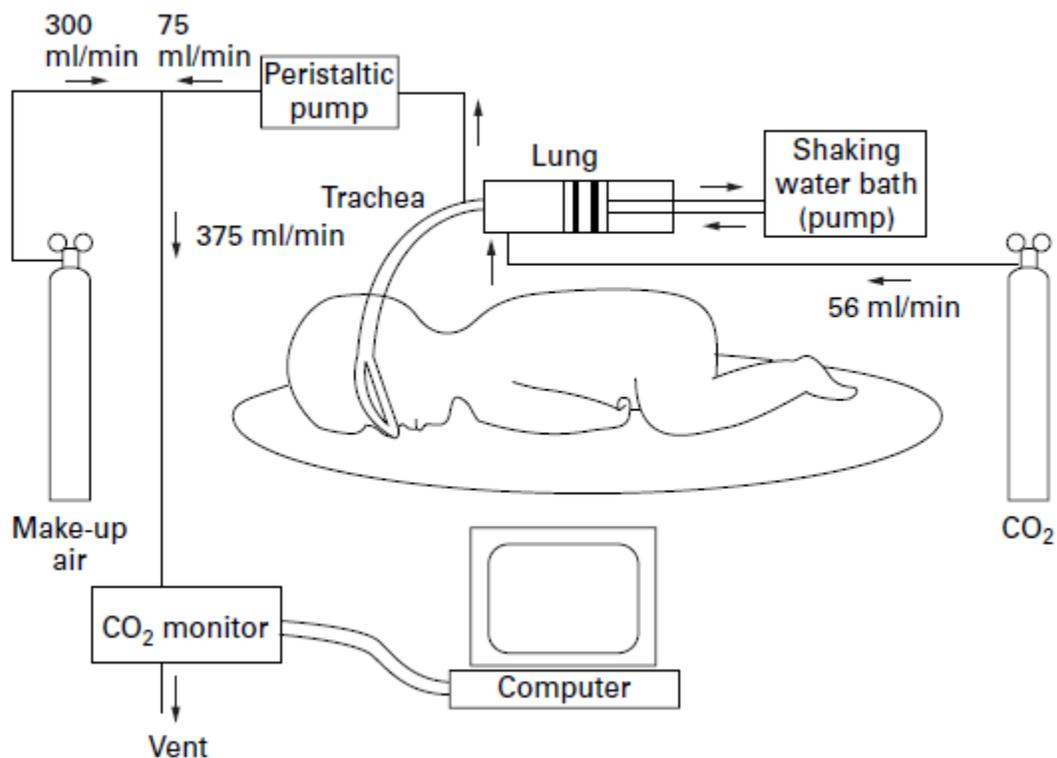


Figure 3. Diagram of model used. This image was reproduced directly from the CDP study.

⁶ ASTM D737-04, page 1

This model is an attempt to approximate infant breathing, which, to staff’s knowledge, has not been validated. The authors note that the levels of CO₂ are “probably exaggerated in the mechanical model compared with an infant, due to the model’s fixed breathing rate and volume”⁷ Therefore, the study can only provide relative assessments of the bedding items and materials tested and do not necessarily represent the values that might be present in a real-life scenario.

II. Sample Examinations

CPSC staff was not able to obtain any incident samples or exemplars of incident samples. Testing, instead, was performed on 26 samples selected as a convenience survey of the United States market. Nineteen samples were collected in 2016, their sample numbers begin with “16”; and seven were collected between 2010 and 2011, and their sample numbers begin with “10” or “11.” The three tests for firmness and the one test for attachment means described in the previous section of this memorandum were applied to the entire sample lot. A summary of testing is shown in Table 1, below.

Table 1. Raw testing data collected from samples. (P = Pass, F = Fail)

SAMPLE	ATTACHMENT			
	LENGTH (in.)	ASTM 1917-12	AS/NZS 8811.1	SCHLAUD
10-840-8682	7.5	P	P	P
11-302-2536	8.9	P	P	P
11-302-2541	7.75	P	P	P
11-302-2542	n/a	P	P	P
11-302-2543	12	P	P	P
11-810-5258	8	P	P	P
11-810-5261	13	P	P/F	F
16-800-0152	7	P	P	P
16-800-0153	8.5	P	P	P
16-800-0154	12	P	P	P
16-800-0155	8.5	P	P	P
16-800-0156	8	P	P	P
16-800-0157	0	P	P	P
16-800-0158	8.9	P	P	P
16-800-0159	8.5	F	F	F
16-800-0160	8	P	P	P
16-800-0161	13	P	P/F	P/F
16-800-2640	12.5	P	P	P

⁷ Carleton, J., Donoghue, A., Porter, W., Abstract, page 323.

16-800-2641	7	P	P	P
16-800-2653	0	P	P	P
16-800-2654	8.5	P	P	P
16-800-2655	7	P	P	P
16-800-2656	8.1	P	P	P
16-800-2657	0	P	P	P
16-800-2658	8	P	P	P
16-800-2659	14	P	P/F	P/F

The 2-inch gauge block from ASTM’s infant bedding and accessory standard, ASTM 1917-12, was the least restrictive test. Twenty-five out of 26 samples passed the test. The only sample to fail that test was 16-800-0159, which was part of the group collected in 2016.

Results were consistent between the tests described in the Schlaud study and the Australian/New Zealand standard, AS/NZS 8811.1. Six out of seven samples from the 2011 sample lot passed both tests. Sixteen of the 19 samples collected in 2016 passed both tests. Notably, only sample 16-800-0159 completely failed the two tests. The other pseudo-failures occurred when the locus of application was varied. For example, when the devices were centered on a continuous part of the bumper, the sample passed. But if it was centered on a crease in the bumper, both devices indicated a failure.

Six out of seven samples from 2011 had a means of attachment, two of the six had cords longer than 9 inches, which would be a failure. The attachment length for one sample was marked as “n/a” because it did not have any attachment means and was only meant to be placed in the crib. All 19 samples collected in 2016 had attachment means, and four out of the 19 had cords longer than 9 inches. Samples listed with a “0” in the column indicate either Velcro or zipper sewn directly into the bumper as an attachment means. None of the cords were liberated from the bumpers when subjected to the pull test.

The mechanical tests for firmness and attachment means were chosen because the current industry standard for the U.S. market is ASTM’s infant bedding and accessory standard, ASTM F1917-12. An airflow or rebreathing study was not conducted on the sample group. Staff cannot conclusively state that rebreathing played a role in any incidents. This assessment is discussed further by staff of CPSC’s Directorate for Health Sciences in Tab E. Therefore, the creation or adoption of a test for rebreathing would not address the cause of incidents. Staff can only establish a relative permeability of materials. However, similar to the missing link between rebreathing and incidents, the link between permeability and incidents cannot be accurately quantified. Therefore, available information is not sufficient to establish a “safe” threshold for material permeability.

III. Conclusion

The testing methodologies currently available to staff permitted a comparative study of commercially available crib bumpers. Importantly, none of the testing performed by staff or outside groups can be linked directly to fatality incidents. Therefore, some of the tools examined in this memorandum may be applicable as preliminary screening devices and methods, but these tools would not give a complete performance picture.

References

- AS/NZS 8811.1 Australian/New Zealand Standard *Methods of testing infant products Method 1: sleep surfaces-test for firmness*. 2013.
- ASTM D737-04(2012) *Standard Test Method for Air Permeability of Textile Fabrics*. Copyright © ASTM International Barr Harbor Dr., P.O. Box C-700 West Conshohocken, PA 19428, USA Published 2012.
- ASTM F1917-12 Standard for Consumer Safety *Performance Specification for Infant Bedding and Related Accessories*. Copyright © ASTM International Barr Harbor Dr., P.O. Box C-700 West Conshohocken, PA 19428, USA Published 2012.
- ASTM F963-11. Standard Consumer Safety Specification *Toy Safety*. Copyright © ASTM International Barr Harbor Dr., P.O. Box C-700 West Conshohocken, PA 19428, USA Published 2011.
- Carleton, J., Donoghue, A., Porter, W. *Mechanical model testing of rebreathing potential in infant bedding materials*. *Archive of Disease in Childhood*. 1998; 78: 323–328.
- ISO 11540:2014 *Writing and marking instruments - Specification for caps to reduce the risk of asphyxiation*. ISO/TC10. 2014.
- Leshner, Michael, P.E. *Forensic Engineering Evaluation of CO2 Re-Breathing in Infant Bedding Materials*. *The Journal of the National Academy of Forensic Engineers*. Vol XXIX No. 2 December 2012
- Schlaud, et al. *The German case-control scene investigation study on SIDS: epidemiological approach and main results*. *International Journal of Legal Medicine*. Springer International, Heidelberg. 2010 January 124: 19-26.