Staff Briefing Package

Crib Bumpers Petition
May 15, 2013

Table of Contents

Briefing Memo

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

Memorandum

Date: May 15, 2013

TO**:** The Commission
Todd A. Stevenson, Secretary

THROUGH**:** Stephanie Tsacoumis, General Counsel
Kenneth R. Hinson, Executive Director

FROM**:** DeWane Ray, Assistant Executive Director
Office of Hazard Identification and Reduction

Jonathan Midgett, PhD, Children's Hazards Team Leader
Office of Hazard Identification and Reduction

SUBJECT: Petition Requesting Commission Action Regarding Crib Bumpers

I. Introduction

In a letter dated May 9, 2012, the Juvenile Products Manufacturers Association (JPMA), requested that the U.S. Consumer Product Safety Commission (CPSC) initiate rulemaking to distinguish and regulate "hazardous pillow-like" crib bumpers from "non-hazardous traditional" crib bumpers under sections 7 and 9 of the Consumer Product Safety Act (CPSA). In support of their request, JPMA asserted the following:

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

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

Nine comments were received. Commenters included: JPMA; Safe Kids; Go Mama Go Designs; Bebe Chic; Hogan Lovells US LLP, for BreathableBaby, LLC; Kids in Danger; Consumer Federation of America (CFA) and Consumers Union (one comment); Patient, Consumer, and Public Health Coalition; and two individuals. The full comments can be found on the website: www.regulations.gov.

The petitioner asks the Commission to initiate rulemaking regarding crib bumpers under section 7 and 9 of the CPSA. For the Commission to issue such a consumer product safety standard, the Commission would need to determine in the final rule that the requirements of the standard are "reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product." 15 U.S.C. § 2056(a).

This memorandum provides background information and addresses the comments received. Based on the staff's review of available information and comments, the staff recommends that the Commission grant the petition and direct staff to initiate rulemaking in the Fiscal Year 2014 operating plan.

II. Discussion

Product Description

Crib bumpers are typically, although not universally, padded fabric panels with ties intended for lining the sides of an infant's crib. Bumpers are generally intended to prevent infants from getting limbs caught between crib slats; to pad crib sides against falls inside the crib; and to provide decoration. They are intended for use until a child begins to pull to a stand (typically around six to nine months of age).

Many different types of bumpers are available. Some are a single unit, intended to be wrapped around the inside of a crib. Some have separate long and short panels. Others have many parts that individually cover crib slats. Some are not padded very much, while others appear to be like pillows. Bumpers thicknesses range from a single layer of fabric to several inches of padding. Attachments vary from ties and ribbons to straps with mechanical fasteners. Various combinations of fabric or vinyl stuffed with fiberfill or foam have been used. Less frequently, rigid plastic mesh or firm foam has been used to make a bumper.

Market Information

The Directorate for Economic Analysis provided information on the market for crib bumpers (Tab C). At least 37 firms produce or distribute crib bumpers to the U.S. market. Thirty-four are domestic firms, including 26 domestic manufacturers, three domestic importers, and five domestic distributors. Three are foreign firms: two are foreign manufacturers, and the supply source of the third firm is unknown. Publicly available information is insufficient to identify the size and dollar sales of most firms. Retail prices for crib bumpers sold separately range from $14.99 to $250, depending on the brand. Bumpers may be sold individually or as one component of a set of infant bedding articles. Prices for crib bumpers sold with bedding collections range from $99.95 to $1,200, depending on the number of items in the set and the brand.

Past Agency Actions

Prior to the crib regulations in the early 1970s that decreased the width of spaces between crib slats, the Commission recommended that consumers use crib bumpers to prevent entrapments between the crib slats that occurred in older cribs. Staff later provided technical support to the ASTM subcommittee addressing strangulations associated with long ties, which resulted in a restriction on the length of ties used to attach bumper pads to cribs.

The agency's public education materials and statements have repeatedly warned consumers against the use of soft bedding in an infant sleep setting. The most common cause of soft bedding-related fatalities seemed to be pillows used beneath or adjacent to a sleeping infant. In addition to warning caregivers about the dangers of the prone sleep position, the agency's public health statements advocate a simple, but comprehensive message to "avoid soft bedding" in infant sleep environments. This advice was consistent with other organizations until recently (see Tab G). Recent safety messaging from the Chairman has promoted a "Bare Is Best" approach for parents and caregivers.

Compliance Actions

Since 1970, CPSC's actions related to crib bumpers have focused on product defects. There have been two recalls of crib bumpers since 1990. One recall, in 1990, involved reports of ties separating from bumper pads that presented a choking hazard. Another recall, in 2007, involved threads on bumper pads that presented an entanglement hazard (Tab D).

Voluntary Standard

The voluntary standard referenced by the petitioners, ASTM F 1917-12, *Infant Bedding and Related Accessories*, includes crib bumpers. In the most recent version, published in 2012, the standard included new requirements for the strength of ties used to install the bumpers inside cribs; warnings; and restrictions on the thickness of bumpers. The voluntary standard includes: (1) tests to ensure that the attachment means of the bumper guards cannot exceed 9 inches; (2) requirements for securing bumper guards to the crib; (3) requirements for maximum bumper thickness; (4) requirements for marking and labeling; (5) requirement for unsupported vinyl used in bedding; and (6) instructions for product labeling and warning labels. Information is unavailable regarding the number of firms that comply with the voluntary standard.

The standard states that bumpers must be capable of compressing down to 2 inches of thickness or less, when drawn through an aluminum gauge block with up to 5 pounds of force. Bumpers must meet this criterion before and after three wash cycles performed according to the manufacturer's recommended washing instructions. According to the rationale ASTM states for this provision, ASTM chose two inches as the maximum thickness because this is the thickness for other padded items that infants interact with, such as play yard pads and because this is a thickness "that has not been known to present a hazard." However, the rationale does not reference data to support the claim of 2 inches as an acceptable limit. Staff from the Directorate for Laboratory Sciences provides a brief review of the standard (see Tab B). Of particular note, staff's review found that more research was needed on the rationale for the parameters used for the requirements associated with the thickness of bumpers.

State and Municipal Standards

Staff is unaware of any international standards that cover crib bumpers. The city of Chicago banned the sale of crib bumpers in 2012, using the following definition:

> "Crib bumper pad" means 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. (Municipal Code of Chicago, Title 7, Ch. 7-36, section 7-36-112.

The state of Maryland convened a panel of experts to examine the potential risks and potential benefits associated with the use of crib bumpers. The panel determined that a small risk exists and that the purported benefits crib bumpers were unsubstantiated. Maryland's Department of Health and Mental Hygiene (DHMH) has published final regulations to ban the sale of crib bumpers, effective June 21, 2013, using the following definition:

> "Baby bumper pads" means a pad or pads of non-mesh material resting directly above the mattress in a crib, running the circumference of the crib or along the length of any of the interior sides of the crib, and intended to be used until the age that an infant pulls to stand. (Code of Maryland, Title 10-11-07)

Maryland's ban does not apply to bumpers that wrap around individual crib slats, sometimes called "vertical bumpers"; nor does it apply to mesh barriers intended to prevent limb entrapments between crib slats.

Epidemiology Evaluation

The Directorate for Epidemiology characterized the number of reports and the types of hazard patterns related to reports mentioning bumper pads from January 1990 to October 2012 (see Tab A). There were 71 fatal incidents. Of all the reported fatalities, 90 percent (64 out of 71) were infants 12 months old and younger; and 65 percent (46 out of 71) of the reported fatalities were infants 4 months old and younger. About half of the reported incidents have occurred since 2005. This was true for both fatal and nonfatal incidents. Staff found 212 nonfatal incidents. Of these, about 60 percent (128 out of 212) were coded as having no injury. Information in the reports was not sufficient to determine the thickness of bumpers that were present in the incidents. Epidemiology staff states that almost all of the fatal incidents were due to suffocation or sudden infant death syndrome (SIDS), and a few incidents were strangulations. Note that this analysis did not categorize the deaths as bumper related or identify whether the bumper was incidental to the death. Rather, the analysis included all incidents where the presence of a bumper was reported.

The CPSC's National Electronic Injury Surveillance System (NEISS) contains 24 cases that mentioned a crib bumper; however, a NEISS estimate of emergency department-treated injuries to children is not available. There are not enough cases to compute a national estimate.

Epidemiology staff identified five hazard pattern categories present in the non-fatal incidents and reports in which a bumper pad was present. The hazard patterns identified include suffocation, head entrapments, wedge entrapments, slat entrapments, strangulation or entanglements, choking

or ingestion of small parts, and climb outs. The memorandum notes that crib bumpers are associated with the reported injuries and fatalities, but the memorandum also states that crib bumpers may not necessarily have caused the injuries or fatalities in every case.

Health Sciences Evaluation

Staff in the Directorate for Health Sciences (HS) examined all of the available information for each case (*e.g.*, first responders' reports, medical examiner and/or coroner investigations, scene reenactments, autopsies, and CPSC investigational findings, including patient medical histories). Staff used this information to assess whether it was possible to determine an actual or probable cause of death, as well as to identify confounding factors related to the sleep environment or to the infant that might have contributed to the deaths (Tab E).

HS staff identified the following confounding risk factors that can compromise infant safety by creating entrapment and/or suffocation hazards: (1) crib integrity issues involving the crib frame and/or mattress fit, such that hazardous gaps are created in the crib. Such gaps have been known to result in fatal infant entrapments leading to suffocation, positional asphyxia, and hanging strangulation with or without the presence of bumpers; (2) the presence of multiple occupants in the crib; (3) the presence of specialized infant products, such as sleep-positioning devices or infant carriers, and nursing pillows in the crib (these products are now known to pose risks when placed in an infant sleep setting[1]); (4) the presence of adult pillows, additional bedding, thick comforters or quilts, or a combination of multiple kinds of bedding placed on the mattress surface under or around the infant; and (5) the improper installation of the upright bumper pads, which allows the bumper pads to sag and assume a horizontal position.

HS staff also identified confounding risk factors related to the infant. These include: (1) infants found in a prone sleeping position, which is a known high-risk factor for SIDS and suffocation in susceptible young infants between birth and 6 months; (2) the position of the infant's body, especially the infant's head and face, regarding whether the infant's airway openings were blocked (*i.e.*, occlusion of the mouth and nose), and if so, by what specific item(s); and (3) premature infants and/or infants with preexisting medical conditions, particularly those with respiratory issues at the time of death. Infants who are premature, or who have certain birth defects, are at higher risk of suffocation because of developmental delays and compromised respiratory systems.

HS staff concluded that the presence in the sleep environment of risk factors identified in the incident reports pose greater concerns than properly installed crib bumpers. Of highest concern to HS staff are prone sleep positioning; pillows; crib integrity issues; and the presence of other objects in the sleep setting, such as large items that restrict an infant's space, and thick, compressible bedding beneath the baby's face and head. HS staff concluded that the risks associated with crib bumpers, in the absence of these other risk factors, are unsubstantiated. HS staff believes that in several cases bumpers were involved in deaths as secondary entrapment/suffocation surfaces but that the primary cause of death was due to a crib integrity

[1] Centers for Disease Control and Prevention, Suffocation deaths associated with use of infant sleep positioners – United States, 1997-2011. MMWR Morb Mortal Wkly Rep. November 23, 2012; 61(46):933-937.

issue, objects other than bumpers added to the crib interior that caused the infant to get trapped in these positions, or the infant's underlying medical issues. HS staff believes many of these deaths could have occurred whether the bumper was present in the crib or not, reasoning that the side wall crib frame always provides a secondary entrapment surface.

Project Manager, Infant Suffocation Project (1992-1995) Analysis

Additionally, NJ Scheers, project manager of the Infant Suffocation Project (1992-1995) with expertise in infant suffocation hazards, also reviewed the 71 deaths in which a crib bumper was mentioned, as well as five crib bumper deaths from the 1980s, for a total of 76 deaths. This review provided an analysis that relied primarily on medical examiners' findings (Tab F) and identified 48 of the 76 deaths as either causally related to, or associated with, crib bumpers. NJ Scheers identified three primary hazard patterns for infants who died with crib bumpers: (1) wedging between a crib bumper and another object; (2) no wedging reported, but the infant's face against the bumper; and (3) strangulations.

NJ Scheers classifies 33 infant deaths as wedgings, based on the narratives in the autopsy findings, death certificates, and investigations. In these incidents, infants were found wedged between a crib bumper and: (1) a mattress in 13 cases; (2) a pillow or cushion in 9 cases; (3) with recliners in 5 cases; or (4) other objects and outside the crib in 6 cases. NJ Scheers identified 12 bumper-related deaths, where the primary description of the deaths from the ME/pathologist or investigation was that the infant suffocated with his/her face against a crib bumper pad. NJ Scheers classifies three deaths (all from the 1980s) as strangulations in which the bumper ties became wrapped around an infant's neck.

In contrast to the HS analysis, NJ Scheers believes that the presence of other risk factors, such as clutter inside the crib that was not in physical contact with the infant's face, should not be considered contributory in any way. She also notes that risk factors associated with suffocation deaths in a population are not necessarily the cause of death in a specific case and concludes that crib bumper deaths are likely an addressable hazard that the Commission could direct staff to study and consider a range of regulatory options, including performance requirements for bumpers; a ban of "non-mesh-sided" bumpers; and continued public education.

III. Public Comments

Recommendations to Ban

Some commenters believe that the petitioners make a false distinction between "hazardous" and "non-hazardous" crib bumpers. They note that neither the petition, nor any other research, supports the petitioner's claim that only pillow-like bumpers have been identified as hazardous. Their contention is that many thicknesses of bumpers have been involved in incidents. They contend that there is no evidence that one type of bumper is any less dangerous than any other type. In their opinion, no crib bumper is safe, and they urge that the product category is not a good candidate for a mandatory rule other than a ban.

Response: Few incident reports contain enough information to ascertain the thickness or softness of the bumper involved. Incident samples are difficult to obtain. Consequently, the term "pillow-

like" has never been defined with a measurable parameter. As such, it remains vague and subjective, potentially causing confusion among consumers.

Staff believes that a definition of the term "pillow-like" may be addressed with objective performance criteria, such as a probe or a compression test. The performance criteria could be developed from known physiological parameters. Airflow into and around an infant's face could be modeled and measured. Minimum thresholds for airflow could be selected to ensure a factor of safety. Defining "pillow-like" with a performance test would enhance consumer safety by eliminating the subjective judgments of "softness." The development of a better understanding of the characteristics that make bumpers hazardous, and the subsequent creation of industry guidance from that knowledge, would benefit the entire juvenile product industry, not just the bedding industry.

Additionally, several commenters have provided examples of alternative designs for lining a crib that they claim are safer than traditional bumper designs. In staff's opinion, these claims deserve examination and could potentially provide a solution that is superior to the status quo.

Limb Entrapment

Some commenters state that the putative benefit of bumpers, *i.e*., preventing children from getting arms and legs stuck in crib slats, is not based in research. Contrary to this assumption, they cite research showing that more than 80 percent of the children involved in slat entrapment were older than the bedding industry's recommended age to stop using bumpers, commonly between 5−8 months old at the age when a child starts to pull to a stand.

Response: Reports of limb entrapment with bumpers present are evident in the data. Staff is not aware of any peer-reviewed studies that confirm bumpers prevent limb entrapment, but it seems unlikely that barriers placed between slats would not have some effect on limb entrapment. That older children who experience limb entrapments are more frequently represented in national injury databases than younger children does not necessarily mean that younger, smaller children are not getting entrapped. It could also be that younger, smaller children are freed more easily without a reportable injury. Unreported incidents could still disturb caregivers enough that they may want and value bumpers in their child's crib.

Unintended Consequences of a Ban

Some commenters challenge the petitioner's claim that consumers will turn to unsafe materials to pad crib rails, claiming instead that ongoing education by pediatricians, nurses, and consumer advocacy nonprofit organizations will be sufficient to prevent this from occurring.

Response: Additional study would be required to ascertain the unintended consequences of any regulatory action regarding bumpers. If the Commission grants or defers the petition, staff could evaluate the unintended consequences of the various options open to the Commission and generate better information to make public health advice as effective as possible.

Costs and Benefits

Some commenters conclude that the risks crib bumper pads pose far outweigh the benefits and therefore maintain that crib bumper pads should never be used. Even the commenters who agree that some injuries may result from limbs being caught in slats argue that these minor injuries are

preferable to suffocation and falls from climbing out of a crib by using a bumper as a foothold. Several commenters pointed out that the American Academy of Pediatrics, Health Canada, the city of Chicago, SIDS of Illinois, and the state of Maryland have warned against or prohibited the use of bumpers.

Response: Staff has not evaluated the costs or benefits of any of the regulatory alternatives. Such an analysis would be conducted during a regulatory proceeding.

Installation Problems

Some commenters argue that the current voluntary standard does not address the risk of suffocation except for a warning about preventing bumpers from sagging into the sleeping surface. They claim that no evidence has been presented indicating that sagging bumpers create a scenario that leads to suffocation and that most incidents involve a properly installed bumper.

Response: Staff believes that some installation problems can be identified in the case reports on record. Additional study would be required to ascertain the appropriate performance criteria for evaluating bumper installations. If the Commission grants or defers the petition, staff could evaluate all of the known hazard scenarios and consider the parameters of proper bumper installation and instructions.

Vertical Bumpers

Another commenter suggested that the petitioners should not make a distinction between hazardous pillow-like bumpers and "non-hazardous traditional" bumpers because no horizontal bumper is safe. In their view, only vertical bumpers without ties can constitute a safe bumper design, such as those that the city of Chicago and the state of Maryland will allow in their respective bans. The commenter describes multiple benefits of vertical bumpers, including increased airflow, expanded use range, protection from falls in the crib, no risk of airway occlusion, no risk of wedging beneath the bumper, no risk of strangulation on a tie, and no risk of using the bumper as a foothold to climb out of the crib. The commenter further notes that caregivers of special needs populations want bumpers. The commenter also submitted a third party evaluation of the carbon dioxide dispersal rates in a crib with various bumper types along with comments from prominent pediatricians with expertise in newborn respiration.

Response: Staff has not yet evaluated the possible distinctions that might be made among different types of bumpers. Such an evaluation would be conducted during a regulatory proceeding.

Mesh Crib Liners

Another manufacturer submitted comments about the advantages of mesh crib liners as alternatives to traditional, "non-mesh" bumpers. This commenter notes that the state of Maryland's ban on crib bumpers exempts bumpers constructed of mesh materials. The commenter claims that it is virtually impossible to suffocate on a mesh fabric crib liner, unlike traditional quilted fabric bumpers. The commenter cites statistics supporting the significance of limb entrapments in the slats of cribs. Between 1980 and April 2012, they identified more than 1,400 incidents of arm or leg entrapment; more than 200 cases with difficulties freeing the victim; and 23 cases that required emergency responders to free the victim. The commenter notes

that 107 incidents involved children up to 6 months of age. The commenter's conclusion was that traditional crib bumpers are those made of non-mesh materials and that bumpers are only valuable to the extent that the bumper does not present a risk of injury.

Response: Staff cannot confirm at this time that mesh bumpers are a safe alternative. Additional study would be required to ascertain the appropriate performance criteria for evaluating bumper hazardousness. If the Commission grants or defers the petition, staff could evaluate mesh products.

Public Education

One manufacturer states that bumpers serve a necessary purpose to protect infants from entrapment in crib slats. The manufacturer believes that public education is the best action for the CPSC, not banning bumpers.

Response: Additional study would be required to identify the characteristics of effective public health advice involving safe sleep settings. If the Commission grants or defers the petition, staff could consider the alternatives available for preventing or mitigating limb entrapment in crib slats. Better information would also help to inform public health education strategies.

IV. Options Available to the Commission

A. Grant the petition.

If the Commission determines that bumpers may be associated with an unreasonable risk of injury and that a mandatory standard may be necessary to address this risk, the Commission could grant the petition and consider a wide range of possible regulatory actions. If the Commission pursues a rulemaking, staff will need to determine the amount of work necessary to create performance tests designed to differentiate, if possible, between safe bumpers and those that are associated with an unreasonable risk of injury. Staff could modify the fiscal year 2014 operating plan to begin the work necessary in that fiscal year.

B. Deny the petition.

If the Commission determines that the information presented by the petitioner and staff does not support initiating a rulemaking to address an unreasonable risk of injury associated with some or all bumpers, then the Commission could deny the petition.

C. Defer decision on the petition.

If the Commission determines that additional information is necessary to decide whether to grant or deny the petition, the Commission may defer action on the petition and direct staff to obtain additional information.

Conclusions and Staff Recommendation

Some evidence suggests that crib bumpers may increase the risks present in unsafe sleep settings. Study of the performance characteristics of potentially hazardous crib bumper designs could increase the level of safety in juvenile products. Staff recommends that the Commission grant the petition and direct staff to initiate rulemaking in the Fiscal Year 2014 operating plan.

TAB A: Epidemiology Memorandum

TAB A

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

Memorandum

Date: May 15, 2013

To: Jonathan Midgett, Ph.D., Children's Hazards Team Coordinator,
Office of Hazard Identification and Reduction

Through: Kathleen Stralka, Associate Executive Director,
Directorate for Epidemiology
Stephen Hanway, Division Director
Division of Hazard Analysis

From: Adam Suchy, M.S., Mathematical Statistician,
Division of Hazard Analysis

Subject: Overview of Crib Bumper Incident Reports Since 1990

I. Introduction

In May 2012, the JPMA petitioned the Consumer Product Safety Commission (CPSC) to adopt a rule 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 not to exceed two inches. This memorandum characterizes the number of incidents or concerns and the types of hazard patterns related to reported bumper pad incidents from January 1990 to October 2012. It is intended to provide a brief preliminary overview of the general hazard patterns for reported incidents. The incidents are based on all reports received by CPSC staff that included mention of a bumper pad in the infant's sleeping environment.

II. Incident Data

The DTHS, INDP, IPII, and NEISS databases were searched for incidents or reported concerns involving bumper pads over the time period of January 1990 to October 2012. Any incident reported to CPSC after October 2012 is not included. Because there is no product code strictly for bumper pads, multiple searches consisting of a combination of product codes and narrative word searches were performed to find all of the bumper pad incidents. The search criteria used to compile the data consists of two separate sets of specifications. The first data search includes the product codes for portable cribs (1529), baby mattresses or pads (1542), cribs (excluding portable cribs) (1543), and cribs (not specified) (1545) that have either "bump" or "pad" (or both) in the narrative field. The second data search criteria includes any incident that includes both "bumper" and "pad" in the narrative field, with no restriction on the product code. The incidents were characterized as fatal and nonfatal. Sufficient detail was not available to determine, as requested by the petitioner, the thickness of the bumpers involved in the incidents.

There were 71 fatal and 212 nonfatal incidents found that included the hazard patterns below. Of the 71 fatal incidents, all but eight occurred inside a crib. Of the eight fatal incidents outside a crib that mentioned crib bumpers in the sleeping environment, two occurred in a toddler bed, two in a mesh sided crib, one in a play pen, one in a day bed, one in an adult bed, and one in a bassinet. There was a single letter the CPSC received that simply stated the awareness of four fatalities "within the last year" associated with "unsafe crib bedding," which generally includes bumper pads. There is no further information about these four fatalities, so they are not included among the fatalities in the tables below. The four incidents with unknown injury status in Tables 1 through 4 are separate and distinct from the fatalities described in the letter. All tables in this section include all NEISS cases.

In Table 1, of the nonfatal incidents, about 60 percent (128 out of 212) were coded as having no injury. Incidents in which no injury was coded range in severity from a concern about a bumper pad not fitting properly, to a near death incident that without intervention by a caregiver would have resulted in a fatality.

Table 1: Reported Incidents Citing Bumper Pads and Injury Status January 1990−October 2012

Fatalities	Injury	No Injury	Unknown	Total
71	80	128	4	283

Source: DTHS, INDP, IPII, and NEISS databases, *November 2012*
Reporting continues for these databases and reported number of incidents may change in the future.

In Table 2, of all the reported fatalities, 90 percent (64 out of 71) were infants 12 months old and younger, and 65 percent (46 out of 71) of fatalities were infants 4 months old and younger. There were only three fatalities involving children older than the age of 23 months; ages 2, 3, and 5 years of age. One child had health issues, and one was developmentally delayed. Of known-age children, the majority of the nonfatal incidents were infants 12 months old and younger.

Table 2: Reported Incidents Citing Bumper Pads and Injury Status January 1990−October 2012 by Age

Age	Fatalities	Injuries	No Injury	Unknown
1 to 4 months	46	21	22	1
5 to 8 months	12	24	40	1
9 to 12 months	6	20	15	1
13 to 23 months	4	7	5	0
2 years and older	3	1	2	1
Unknown Age	0	7	44	0
Total	71	80	128	4

Source: DTHS, INDP, IPII, and NEISS databases, *November 2012*
Reporting continues for these databases and reported number of incidents may change in the future.

In Table 3, incident and fatality statistics are categorized for each 5-year period since 1990. About half of the reported incidents have occurred since 2005. This was true for both fatal and nonfatal incidents. Reports involving nonfatal incidents have increased since 2000.

Table 3: Reported Incidents Citing Bumper Pads and Injury Status January 1990−October 2012 by Year

Year	Fatalities	Injuries	No Injury	Unknown
1990 to 1994	12	8	10	1
1995 to 1999	8	10	8	0
2000 to 2004	15	18	49	0
2005 to 2009	22	23	41	1
2010 to October 2012	14	21	20	2
Total	71	80	128	4

Source: DTHS, INDP, IPII, and NEISS databases, *November 2012*
Reporting continues for these databases and reported number of incidents may change in the future.

In Table 4, there is no apparent difference in the overall counts of reported fatalities and injuries among males and females. Comparing sex among each age group in the fatality counts, there do not appear to be any meaningful differences. There were more male injuries in the 1- to 6-month age group and more female injuries in the 7- to 12-month age group. However, these differences do not necessarily imply a trend.

Table 4: Reported Incidents Citing Bumper Pads and Injury Status January 1990−October 2012 by Age and Gender

Age	Fatalities Male	Fatalities Female	Injuries Male	Injuries Female	Injuries Unknown
1 to 6 months	27	24	20	14	0
7 to 12 months	6	7	12	18	1
Older than 12 months	4	3	3	5	0
Unknown	0	0	1	2	4
Total	37	34	36	39	5

Source: DTHS, INDP, IPII, and NEISS databases, *November 2012*
Reporting continues for these databases and reported number of incidents may change in the future.

III. NEISS Data

The Directorate for Epidemiology staff was unable to provide a NEISS estimate of emergency department-treated injuries to children interacting with bumper pads between January 1990 and October 2012. There were 24 NEISS incidents found involving a bumper pad during this time frame. The data did not meet the minimum criteria for computing an estimate. A minimum NEISS estimate of 1,200 is required and was not met.

IV. Hazard Patterns

Almost all of the fatal incidents were due to suffocation or sudden infant death syndrome (SIDS), and a few incidents were strangulations. Note that this analysis of fatalities did not categorize the deaths as bumper related or identify whether the bumper was incidental to the death. Fatal incidents tended to lack an eye witness to the fatality, and the child was found in a prone position with evidence of suffocation or choking in a crib, sometimes containing multiple additional items in addition to a crib bumper, such as pillows, blankets, stuffed dolls, or other items. In these incidents, it may be unclear what role, if any, the crib bumper played in the death of the child; therefore, the cause of death becomes more speculative than conclusive. In other cases, the child was found with the head or face in or beneath the bumper pad, or was found between the bumper pad and other items, such as the crib mattress or blankets.

Table 5 summarizes the nonfatal incidents and reports in which a bumper pad was present. Where multiple hazards were mentioned, the more primary hazard was used. Nonfatal incidents below range in severity, from a simple concern about a bumper pad not fitting properly, to a near-death incident that, without intervention by a caregiver, would have resulted in a fatality. There are more than 20 nonfatal incidents and complaints in each of five different hazard pattern categories, disregarding the "Other" and "Concerns" categories. The "Other" and "Concerns" categories account for 28 percent (61 out of 212) of all nonfatal incidents and complaints. There are no injuries in the "Concerns" category, and the "Other" category includes incidents or complaints that do not fit into the other categories.

Table 5: Reported Nonfatal Incidents of Complaints Citing Bumper Pads January 1990−October 2012 by Hazard Pattern

Hazard	Incidents/Complaints
Suffocation hazard	22
Head entrapments	26
Wedge entrapments	9
Slat entrapments	29
Strangulation hazard or Entanglements	24
Choking or Ingestion of small parts	32
Climb outs	9
Concerns	30
Other	31
Total	212

Source: DTHS, INDP, IPII, and NEISS databases, *November 2012*
Reporting continues for these databases and reported number of incidents may change in the future.

Suffocation hazard: These incidents involve the face of the child being found pressed against the crib bumper pad. Potential suffocation incidents may be a result of the child becoming wedged between two items in some way; one of the two items in wedging incidents is often a crib bumper. Potential suffocations with only the face pressed into 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.

Head entrapments: The incidents in this category state that the head of the baby was found under or between the bumper pad and other objects, such as the crib rail or the mattress; but do not include further information about the primary injury mechanism. When the head of the baby was found under the bumper, either the face was obstructed, causing a potential suffocation hazard; or the neck or other body part lay over the bumper pad tie, causing a potential strangulation or entanglement hazard; or the tie may have been found in the mouth of the baby, causing a potential choking hazard.

Wedge entrapments: These incidents mention that the "baby" or "child" was found wedged, caught under, or trapped under the bumper pad, without any mention of the head or face.

Slat entrapments: These incidents include only arm or leg entrapments between the slats of the crib with a bumper present.

Strangulation hazard or Entanglements: These incidents were usually a result of a bumper pad tie becoming loose or untied and then wrapped around the neck or limb/digit of the child. Other potential strangulation or entanglement incidents occurred when thread or characters sewn into the pad become unsewn or unravel from the bumper pad. About half of the potential strangulation or entanglement incidents specifically mention the head, mouth, or neck being wrapped up by a piece of a bumper pad.

Choking or Ingestion of small parts: These incidents were most common when either a decorative piece of fabric was pulled off the bumper pad, or when thread became unsewn, leaving the stuffing of the bumper pad accessible to the child to put into the child's mouth. Included in this category were incidents where a piece of fabric or stuffing detached and was found in the crib with a child. This did not include incidents in which a parent found a defect with the bumper pad and a child was not involved. Incidents or complaints with bumper pads in which no child was involved appear in the "Concern" category. Most of the "Choking or ingestion of small parts" category incidents involved a child putting a piece of the bumper pad into the child's mouth.

Climb outs: These incidents occurred when the bumper pad was being used in a crib at a time when the child was old enough to stand up and the child used the bumper pad as a step to climb over the edge of the crib and fall back into the crib or fall out of the crib. The youngest climb-out incidents involving children under 12 months old included one incident each involving a 7-, 9-, 10-, and 11-month-old child.

Concerns: These incidents did not indicate directly that a child was involved, but instead indicated that there were generally problems with the bumper pad perceived by the parent or complainant. Many incidents involved the inability to install the bumper pad properly or the bumper pad did not fit the crib properly. Common examples of concerns with bumper pads were: the bumper did not fit in a crib; the bumper was too thick; the bumper sagged; there was a gap between the bumper and the slats or the mattress; the ties were too long; the bottom ties were missing; there were not enough ties; or the ties were unable to be attached to the crib. Additional

concerns involved pieces coming apart in the process of washing the bumper pad. The concerns may indicate a hazard that could result in injury or death.

Other: There are other incidents involving bumper pads that are far less common than the above types of hazards. Some examples were: contusions and abrasions caused by contact with rough or prickly bumper pads; a non-breathable bumper pad; a bumper pad that is pulled off from the slats in one piece; three incidents of needles found in the pad (one infant scratched an eye; one adult pricked their thumb; and one needle was found in the bumper with no injury); crib rails or slats breaking and the bumper either hindering the child from further injury, or the bumper causing the child to become entrapped; paint coming off the bumper pad; and an incident in which a bed sheet was used in place of a bumper pad when a bumper was not available.

V. Limitations

Incidents presented in this memo should be considered a minimum number that have occurred. There may be additional incidents involving crib bumpers that were not reported to CPSC. Crib bumpers are associated with the reported injuries and fatalities but may not necessarily have caused the injuries or fatalities in every case. Other factors (*e.g.,* health condition of the child, other items or additional children in the crib, improper use of the bumpers) may play important roles in some cases.

TAB B: Engineering Memorandum

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

Memorandum

DATE: May 15, 2013

TO : Petition CP 12-2

THROUGH: Andrew Stadnik, PE, Associate Executive Director
Laboratory Sciences Directorate

James C. Hyatt, PE, Division Director
Laboratory Sciences Directorate, Mechanical Division

FROM : John Massale, Mechanical Engineer
Laboratory Sciences Directorate, Mechanical Division

SUBJECT : Explanation of Existing Voluntary Standards and Voluntary Standards Development Associated with Crib Bumpers – Petition CP 12-2

Review of Existing Voluntary Standards

The voluntary standard, ASTM F1917-12 *Standard for Consumer Safety Performance Specification for Infant Bedding and Related Accessories,* specifies designs and performance requirements for crib bumpers sold in the United States.[2] A crib bumper is defined by the standard as a long, narrow padding that attaches to the lower, interior sides of cribs. These products are intended to prevent entrapment hazards and reduce gaps between the mattress and crib rails. In addition to crib bumpers, the standard covers all infant bedding and accessories. Therefore, the standard is intended also to address hazards resulting from decorative ribbons, bumper guard ties, wall hangings, fitted sheets, and threads resulting from unraveled seams as a means of addressing potential causes of suffocation and/or strangulation in the sleep environment.

After the Scope, the remainder of the standard is comprised of three groups of sections. The first group consists of definitions, external reference documents, and other clarifiers that lay the foundation for the following sections. Next is the group with General Requirements, Performance Requirements, and their corresponding Test Procedures. The last group of sections specifies the warning labels required on the product and the warning and instructional language to be included in the instructional literature.

A list of formal definitions is contained in section 3, which includes terms from the Scope. For example, "infant bedding and related accessories" are defined as, "fitted sheets, blankets, dust ruffles, covers and drapes for canopies, pillows, mattress covers, diaper stackers, fabric wall

[2] Copyright © ASTM International Barr Harbor Dr., P.O. box C-700 West Conshohocken, PA 19428, USA Published 2012

hangings, bumper guards, headboard bumper guards and comforters." The terms "unsupported vinyl" and "supported vinyl" are differentiated; unsupported vinyl is a flat sheet material calendared from 100 percent vinyl plastic, while supported vinyl is often laminated or bonded to another material. These definitions become important in the performance requirements and test methodologies of sections 5, 6, and 7.

Section 4 outlines the proper testing procedures. Any of the tests can be performed on any sample in a batch, in any order, unless the sample becomes damaged. The damaged sample may not be subject to any further tests. This improves the repeatability of the testing, and therefore, the quality of the results.

The four general requirements are listed in section 5. First, the "crib bumper attachment means," *e.g.*, cords or straps shall be no longer than 9 inches overall. Second, decorative components shall not exceed 7 inches and, if any two components can tangle, they shall not exceed 14 total inches. The rationale[3] states that the neck circumference of a fifth percentile 0−3 month-old infant is 7.2 inches. Therefore, any attachment means or decorative object less than 7 inches could not strangle a child. Attachment means have a greater maximum length limit, 9 inches, because 7 inches may not be enough to secure them to the crib rails or headboard sufficiently.

The third general requirement of section 5 bans the use of monofilament thread. The last general requirement says the endpoints and midpoints of bumpers shall be secured to the crib. It also covers the special case of a circular crib, by requiring that bumpers designed for circular cribs are to be secured at intervals less than 26 inches. The test for bumper guard retention in both rectangular and circular cribs is a visual inspection involving a measuring tape.

There are three performance requirements in section 6. The first requirement mandates that unsupported vinyl be thicker than 0.012 inches to avoid a suffocation hazard. Supported vinyl is exempt from this requirement, and so is unsupported vinyl if it is inaccessible to the child. For example, an unsupported vinyl exemption occurs when a liquid-proof mattress cover is used underneath a fitted sheet.

The second performance requirement, found in section 6.2, Maximum Bumper Thickness, is the first time bumper pads are selectively addressed among all infant bedding materials. This performance requirement seeks to address only the suffocation hazard that arises when bumpers are too thick. The bumpers must be capable of compressing down to 2 inches of thickness or less, when drawn through an aluminum gauge block (fig. 1) with up to 5 pounds of force. The bumpers must meet this criterion before and after three wash cycles performed according to the manufacturer's recommended washing instructions. Two inches was chosen as the maximum thickness because, according to the rationale,[4] it "already exists for other padded items infants interact with such as play yard pads. The two inch opening of the test fixture limits the overall thickness of bumpers to a thickness that has not been known to present a hazard." However, data to support the claim of 2 inches as an acceptable limit is not referenced. The rationale[5]

[3] ASTM F1917-12, Rationale section X1.2, page 3.
[4] ASTM F1917-12, Rationale section X1.1, page 3.
[5] ASTM F1917-12, Rationale section X1.1, page 3.

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." This implies that the only goal of this test was to measure the thickness of the bumper body.

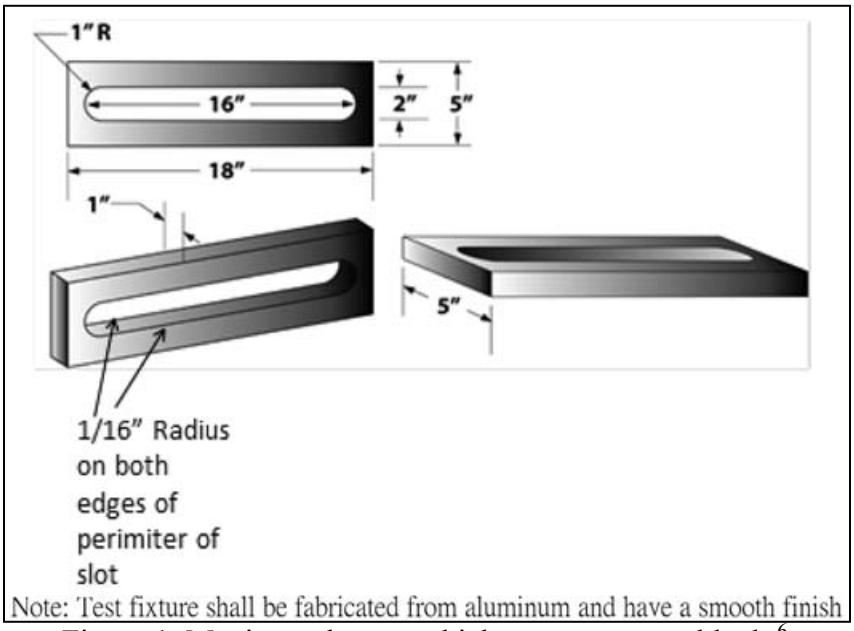


Figure 1. Maximum bumper thickness test gauge block.[6]

The final performance requirement, per section 6.3 and its test in section 7.4, is that bumper pad ties must not detach from the body of the bumper when subjected to a 20 pounds 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.

Section 8 lays out the warning label requirements. It covers fabric wall hangings, fitted mattress covers, flat mattress covers, pillows, diaper stackers, fitted sheets, and crib bumpers. If a crib bumper comes as a set, each piece of the set must have all warning labels. Specifically, it states that all items that fall under this standard must have a permanent and conspicuous label that identifies the name and address of the manufacturer, distributor, or seller of the product. This is in addition to the product-specific safety warning label that must also be present on the item and its packaging. The style, size, and font of all labels are prescribed by this section. These requirements are derived from *ANSI Z535.4 Product Safety Signs and Labels* and ensure that the labels are uniform, noticeable, permanent, and ultimately effective.

[6] Bumper Thickness Test Fixture, seen as Fig. 1 on page two of ASTM F1917-12. Copyright ©2012 ASTM International.

ASTM F1917-12 is the industry's voluntary benchmark for crib bumper product safety. In addition, it is the only voluntary standard known to staff that specifically addresses hazards associated with crib bumpers.

TAB C: Economics Memorandum

T
A
B

C

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

Memorandum

Date: December 18, 2012

TO : Jonathan Midgett, Project Manager
Crib Bumper Petition

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

Deborah V. Aiken, Ph.D., Senior Staff Coordinator
Directorate for Economic Analysis

FROM : Samantha Li, Economist
Directorate for Economic Analysis

SUBJECT : Petition on Crib Bumpers: Market Information and Economic Considerations

Background

The Commission received, and the Office of the General Counsel docketed, a petition (CP 12-2) requesting that the Commission initiate rulemaking for a mandatory standard for crib bumpers. The petitioner advocates a standard rather than banning traditional crib bumpers because banning crib bumpers could encourage the hazardous use of adult bedding, such as towels, adult blankets, or pillows, as a protective barrier in an infant sleeping environment. Although crib bumpers are already subject to a voluntary standard, the petitioner believes that a mandatory standard is necessary to distinguish hazardous (soft) pillow-like crib bumpers from nonhazardous (traditional) crib bumpers.

This memorandum provides information on the market for crib bumpers. The discussion is based on information that was readily available, including information provided by the petitioner and public comments.

The Product

A crib bumper, also referred to as a bumper guard, is designed to be used in full-size and non-full-size cribs. A crib bumper is placed inside the crib, where the mattress and crib bars meet. Ties secure the bumper guard to the crib. A crib bumper has a cotton or vinyl exterior and may have polyester or foam filling. Crib bumpers may be sold in conjunction with infant bedding sets.

Market for Crib Bumpers

At least 37 firms produce or distribute crib bumpers to the U.S. market. Thirty-four are domestic firms: 26 are domestic manufacturers, three are domestic importers, and five are domestic distributors. Three are foreign firms: two are foreign manufacturers and the supply source of the third firm is unknown.

Publicly available information is insufficient to identify the size and dollar sales of most firms. The North American Industry Classification System (NAICS) lists product codes for U.S. firms. Firms that supply crib bumpers may list their business under several possible NAICS product codes. The most common NAICS code is children's clothing store (*448130 Children's & Infants' Clothing Stores*). However, in addition to crib bumpers, this code encompasses infant and children apparel, including infant and toddler clothing, crib mattresses, and toddler bedding, which are beyond the scope of the petition. Additionally, some firms may list their businesses under categories other than children's clothing retailers and often under more than one product code. Domestic firms may list their businesses as a manufacturer or wholesaler of infant apparel (*315240 Women's Girls' & Infants' Cut & Sew Apparel Manufacturing* or *424330 Women's, Children's, and Infants' Clothing and Accessories Merchant Wholesalers*), textile manufacturer (*314999 All Other Miscellaneous Textile Product Mills*), or a product code unrelated to children's apparel (*442110 Furniture Stores* or *541613 Marketing Consulting Services*).

Retail prices for crib bumpers sold separately range from $14.99 to $250, depending on the brand. Prices for crib bumpers sold with bedding collections range from $99.95 to $1,200, for the entire set depending on the number of items in the set and the brand.

Two domestic firms manufacture products marketed as an alternative to a traditional crib bumper. The first firm manufactures a mesh crib bumper liner that adjusts to fit full-size cribs. A second firm manufactures a 24-inch-long polyester crib bumper that is placed vertically against an individual crib slat in a full-size crib, as well as a crib bumper that can be used in a non-full-size crib. One retail estimate for the mesh liner crib bumper is approximately $29.99. Prices for vertical crib bumpers used in full-size cribs sold separately range from $9.99 to $239.99, depending on the number of crib bumpers.

National estimates of crib bumper product-related injuries or the societal costs of these injuries are not currently available because the National Electronic Injury Surveillance System (NEISS) data does not allow for clear identification of crib bumpers.[7]

Crib Bumper Performance Standard

The petitioner advocates a mandatory crib bumper standard to promote the use of nonhazardous (traditional) crib bumpers. Crib bumpers are covered by ASTM F1912-12, *Standard Consumer Performance Specification for Infant Bedding and Related Accessories*, which applies to bedding

[7] Memorandum from Adam Suchy, Division of Hazard Analysis, dated January 30, 2013, Subject: Overview of Crib Bumper Incident Reports Since 1990.

items intended for use in a nursery. The voluntary standard includes: (1) tests to ensure that the attachment means of the bumper guards cannot exceed 9 inches; (2) requirements for securing bumper guards to the crib; (3) requirements for maximum bumper thickness; (4) requirements for marking and labeling; (5) requirement for unsupported vinyl used in bedding; and (6) instructions for product labeling and warning labels. Information is unavailable regarding the number of firms that comply with the voluntary standard. However, JPMA believes several manufacturers supply crib bumpers that meet the maximum thickness requirement.

References

ASTM F 406 — 11b Standard Specifications for Non-Full-Size Baby Cribs/Play Yards.

ASTM F 1169 — 10 Standard Specification for Full-Size Baby Cribs.

ASTM F 1917 — 12 Standard Specification for Infant Bedding and Related Accessories.

TAB D: Compliance Memorandum

T
A
B

D

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

Memorandum

Date: 2/20/2013

TO: Jonathan Midgett, Engineering Psychologist, EXHR

Through: Marc Schoem, Acting Director, Compliance & Field Operations, EXC

CC: Scott Simmons, Director Defects Investigations, CDI

FROM: Terri Nelson, Compliance Officer, Safe Sleep Team, CDI

SUBJECT: History of Compliance actions on Crib Bumper Pads

An historical search of bumper-pad related activities in the Office of Compliance indicates that ties or loose threads on the bumper pads have been the focus of previously opened cases from 1970 to the present.

Specifically, the following activities, to date, include:

1) Recalls─two recalls since 1990:
   - #90-122 - recall completed in 1990, involving 19 reports of ties separating from bumper pads presenting a choking hazard:
   - http://www.cpsc.gov/en/Recalls/1990/Giggle-See-Bumper-Pad-Recalled-Ties-Present-Choking-Hazard/
   - #07-252 – recall completed in 2007, involving two reports of threads on bumper pads presenting entanglement hazard: http://www.cpsc.gov/en/Recalls/2007/Pottery-Barn-Kids-Recalls-Crib-Bumpers-Due-to-Entanglement-Hazard/

2) Preliminary Determinations (PD) of hazards made:

   - Elastic tapes attached to bumper pads presenting choking hazard to infants.
   - Vinyl ties tear off bumper pads presenting choking hazard to infants.
   - Threads that come loose posing and entanglement hazard to infants.

3) PSA request related to bumper pads:

   - Request to search for all bumper pad related incidents from 1990 to May 2010.

TAB E: Health Sciences Memorandum

TAB E

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

Memorandum

Date: April 15, 2013

TO : Jonathan Midgett, Ph.D., Children's Hazards Team Coordinator,
Office of Hazard Identification and Reduction

THROUGH: Mary Ann Danello, Ph.D., Associate Executive Director
Directorate for Health Sciences

Jacque Ferrante, Ph.D. Division Director
Division of Pharmacology and Physiology Assessment

FROM : Suad Wanna-Nakamura, Ph.D. Physiologist
Division of Pharmacology and Physiology Assessment

SUBJECT : Analysis of Available Records for 71 Fatalities Occurring January 1990 through October 2012 Citing Crib Bumpers

Introduction:

In May 2012, the Consumer Product Safety Commission (CPSC) received a petition from the Juvenile Products Manufacturers Association (JPMA), 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 petition (CPSC–2012–0034) was docketed on June 6, 2012.

The petitioner advocates a standard rather than banning traditional crib bumpers because the petitioner is concerned "that the elimination of crib bumpers from the marketplace will lead to unintended consequences and may encourage parents to use towels, adult blankets, pillows or other makeshift structures or materials as a protective barrier from the tight dimensions and hard wooden surface of the crib slats". Although crib bumpers are already subject to a voluntary standard, the petitioner believes that a mandatory standard is necessary to distinguish hazardous (soft) pillow-like crib bumpers from nonhazardous (traditional) crib bumpers. Currently, the designs and performance of crib bumpers sold in the United States are specified by the voluntary

standard, ASTM F1917-12, *Standard for Consumer Safety Performance Specification for Infant Bedding and Related Accessories*.[8]

Background:

Crib bumper pads are cushioned linings intended for use around the inside perimeter of a baby's crib. They are intended 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. They are secured to the crib by ties located at regular intervals along the length of the bumper pad. This memorandum provides an in-depth review of 71 incidents reported to CPSC from January 1990 to October 2012, (Tab A, Suchy, 2013) and assesses the role of the crib bumpers, if any, in the fatalities.

In late 1973, CPSC developed and implemented mandatory crib standards (CPSC 16 C.F.R. §1508.4)[9] to address the large number of unintentional infant deaths that were occurring in cribs (an estimated 150–200/year, according to a 1973 CPSC alert). At that time, one of the common death scenarios involved a crib design that allowed an infant's body, but not head, to slip through the widely spaced slats, resulting in strangulation by hanging. To prevent this from happening, one of the performance requirements in the new federal safety standard mandated that the distance between crib slats could not exceed 6 cm (2 3/8 inches). In November 1973, CPSC issued a press release in advance of the effective date of the new crib standard, highlighting the new requirement on slat spacing, as well as other crib design requirements for crib and mattress sizing, side rail height, and crib hardware. The release recommended that families with older cribs take appropriate precautions, and specifically regarding older cribs with widely spaced slats, the release advised families to "use bumper pads at least four inches high all around the crib and secure them with at least six ties"[10] to reduce the likelihood of hanging strangulation deaths.

Since the early 1990s, there has been an increased public health focus on reducing the risks of infant crib deaths, particularly those associated with Sudden Infant Death Syndrome (SIDS) and infant suffocation, with an emphasis on the proper supine infant sleep position. The National Institutes of Health's (NIH) National Institute for Child Health and Human Development launched the "Back to Sleep" campaign in 1994, "to educate parents, caregivers, and health care providers about ways to reduce the risk of SIDS (See http://www.nichd.nih.gov/sids/). NIH partnered with the American Academy of Pediatrics (AAP), SIDS organizations, and other federal agencies, including the CPSC, to increase the visibility of this issue among consumers and medical professionals. In addition to supporting the campaign to put infants on their backs

[8] Copyright © ASTM International Barr Harbor Dr., P.O. box C-700 West Conshohocken, PA 19428, USA Published 2012.
[9] The standard went into effect on January 31, 1974.
[10] (Ref: *http://www.cpsc.gov/CPSCPUB/PREREL/prhtml73/73040.html and then click on "View Original Page First Match" to view the 11/26/1973 original document*.

to sleep, the CPSC looked at what constituted a safe sleep environment for infants. This review included an assessment of the sleep location (crib, cradle, bassinet, and others) and the items placed in the sleep location (*i.e.,* the sleep setting or environment) that might pose hazards. The CPSC staff developed a number of publications aimed at educating consumers about a safe sleep environment for infants.[11] At that time, the CPSC recommended that infants be placed to sleep on their backs, in a crib that meets federal and industry safety standards, with a firm, tight-fitting mattress, with no extra padding, pillows, or thick comforters under the baby.

In 2004, CPSC Health Sciences (HS) staff reviewed data collected by CPSC Epidemiology staff on infant deaths associated with soft bedding. While bumper pads were mentioned as being in the crib at the time of death, there was insufficient detail for HS staff to determine whether they caused or played a role in the infants' deaths. Therefore, HS staff believed that no reliable conclusion could be made. *(*Source: letter to Mr. Fredrick Locker, 2004, included in the petition.)*

In 2007, Thach, et. al., published a paper,[12] reporting "a number of fatal accidents directly attributable to crib bumper pads." The authors concluded that "bumpers should not be placed in cribs or bassinets." The authors stated that their paper was based on 27 deaths reported to CPSC databases and indicated that their analysis was based on the complete record available for these deaths. Shortly after publication of the Thach paper, the CPSC's Health Sciences (HS) staff reviewed the journal article and cases. Contrary to the conclusion of the Thach paper, HS staff found that there was no conclusive evidence implicating crib bumper pads as a primary cause of infant deaths when the bumpers were installed properly,[13] according to manufacturer's directions, and used in an appropriate infant sleep setting.[14]

In 2010, CPSC HS staff reviewed the reported incidents for all infant deaths in the sleep environment associated with the use of various infant products, including bumper pads (Wanna-Nakamura, 2010). With regard to bumper pads, staff reached the same conclusion as in their 2007 data review: *i.e.,* for most in-scope cases, it was not possible to determine with certainty what role crib bumper pads played, if any, in the infants' deaths). In some cases, bumpers could clearly be ruled out as being involved in the death. As in its previous 2007 informal review, staff identified confounding factors in the sleep setting/environment that they believed were more likely than bumpers to have caused or contributed to the deaths. Because this is the only published article on crib bumpers related incidents and it seemed to have played such an

---

[11] *http://www.cpsc.gov/nsn/safesleep.pdf ;and video http://www.cpsc.gov/Trans/SafeSleepPSA.html.*

[12] Thach T., Rutherford G., and Harris, K. Deaths and injuries attributed to infant crib bumper pads. The Journal of Pediatrics 2007;151:271-4.

[13] The exception to this is three cases identified in the Thatch paper that involved strangulation of the infant on bumper ties that were too long. This hazard was subsequently addressed by a voluntary standard. *Ref: ASTM International. ASTM F 1917 – 00 Standard Consumer Safety Performance Specification for Voluntary Safety Standards for Bumper pads and Related Accessories.*

[14] CPSC information advises that "bumpers pads be installed according to manufacturer instructions and properly secured to crib slats. *(Ref: ASTM International. ASTM F 1917 – 08 Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories.* Safe sleep setting means placing infant(s) to sleep on their backs in a crib that meets federal and industry safety standards with a firm, tight-fitting mattress with no extra padding, pillows or thick comforters under baby or in their sleep environment. http://www.cpsc.gov/nsn/safesleepbabiesai.pdf.

influential role in raising concerns about bumpers, staff has considered it to be imperative to provide a separate analysis of the 27 fatal cases in the Thach et al. article. (see Appendix A, Table A – Staff Review of Incidents Cited in Thach et al.).

Although HS staff cannot substantiate and does not believe the available records suggest that there is a risk of infant suffocation and/or entrapment death posed simply by the use of properly installed bumper pads in an appropriate safe sleep setting**,** public concerns about perceived risks of crib bumper pads persist, heightened by recent bans on crib bumpers implemented by the city of Chicago, and proposed by the state of Maryland. As detailed below, as part of activities related to the current JPMA Crib Bumper Petition, HS staff has undertaken a systematic review of the available information on 71 fatal cases identified by CPSC Epidemiology staff during a search of CPSC EPIR databases for cases mentioning bumper pads (Suchy, 2013) in an attempt to classify objectively, where possible, the primary factor that initiated/caused the child's death and identify any role played by a crib bumper.

Methods:

CPSC's Division of Hazard Analysis staff conducted searches of all available reports of incidents, injuries, and deaths mentioning crib bumper pads and reported to the CPSC. Together, these searches covered deaths that occurred from January 1990, and were reported to the CPSC as of October 31, 2012 (Suchy, 2013.) The search criteria used to compile the data consist of two separate sets of specifications. The search used CPSC product codes for infant sleep products with which bumper pads might be used: code 1542–"Baby mattresses or pads"; code 1543–"Cribs (excluding portable cribs)"; code 1545–"Cribs, not specified"; and code 1529–"Portable cribs." A second search was run using the keywords "bumper," and "pad" in the report narrative field, with no restriction on the product code. These data were divided into fatalities and nonfatalities. Four CPSC databases were searched: the Injury and Potential Injury Incident (IPII) files[15]; Death Certificates (DTHS)[16]; the National Electronic Injury Surveillance System (NEISS)[17]; and the In-Depth Investigation (INDP) files.[18] INDP case files (also known as IDIs) typically have more detailed incident information than the other Epidemiological Reporting (EPIR) records, and can include an autopsy report, a death scene investigation, police and first

[15] The IPII file contains data on consumer product-related incidents extracted from consumer complaints, as reported to the CPSC through letters and telephone calls. The IPII database also includes media articles, medical examiner reports, reports from fire and police departments nationwide, and referrals from other federal agencies.

[16] The DTHS file includes information from death certificates purchased by the CPSC from all 50 states and the District of Columbia. The EPIR summaries of the source death certificates include the immediate cause of death, the manner of death, some (but not necessarily all) of the contributing factors noted, and information on whether an autopsy was done.

[17] The NEISS database is a statistically based CPSC injury file that contains patient information collected from NEISS hospitals for every patient treated in the emergency department for an injury associated with a consumer product. The NEISS database file is a probability sample of hospitals in the United States and its territories that have at least six beds and an emergency department. National estimates are made of the total number of product-related injuries treated in U.S. hospital emergency departments based on the data collected from NEISS hospitals. The NEISS is a stratified sample based on emergency department size and geographic location. Information for NEISS cases is limited to a short case summary narrative.

[18] The INDP file contains data from follow-up investigations reported by CPSC staff. These investigations are done to gather detailed information on a death or injury associated with a particular consumer product.

responders' reports, and an interview with the victim's family. IDIs can range from a few pages to more than 100 pages; some voluminous IDIs might lack clear information on the specific cause of a death; whereas, brief IDIs of a few pages, may contain sufficient information to show clearly the primary probable cause of death. The DTHS, IPII, and NEISS database reports are much less detailed, and are generally limited to a short synopsis of the incident and anecdotal information; but at times, they do contain more detailed information, such as autopsy reports and full death investigation reports. A total of 71 infant deaths fitting the search criteria were retrieved.

HS staff physiologists reviewed the cases using the same type of systematic analysis routinely used to review incident data for any product category. For all cases, staff attempted to identify the actual or the primary probable cause(s) of death, taking into consideration information reported in all of the available case documents that could include death scene investigations, autopsies, caregiver reports, police reports, and death certificates. Staff first assessed whether the cases were considered in scope or out of scope. Cases were considered to be out of scope if the deaths occurred outside an infant crib, or where a crib bumper was used in a sleep setting for which it was not intended, such as in portable cribs/bassinets, toddler beds, or play pens. HS staff determined that nine of the 71 cases were out of scope. (see Results Section, # 4)

Staff then divided the in-scope cases into three categories: (1) cases in which staff considered the actual cause of the infant death could be determined (AC); (2) cases in which staff considered that it could identify a probable primary cause of death (PPC); and (3) cases where the existing case data was limited, unknown, inconsistent, ambiguous, or otherwise unclear, precluding staff's ability to make a reliable determination of the primary cause of death and the bumper's role (UNK). For each of the in-scope cases, staff also considered whether the bumper had any clear involvement in the death scenario. For example, in cases involving wedging of a baby between a pillow and a bumper-covered crib side/end, HS staff considers the pillow the primary (initiating) entrapment surface and the bumper-covered crib side/end the secondary entrapment surface (because even if the bumper is removed, the entrapment surface represented by the crib side/end is always present).

Confounding risk factors in the crib environment that are not part of the crib structure itself (crib frame plus mattress), but which can compromise infant safety by creating entrapment and/or suffocation hazards, include: (1) the presence of multiple occupants in the crib; (2) the presence of specialized infant products, such as sleep-positioning devices or infant carriers and nursing pillows in the crib (these products are now known to pose risks when placed in an infant sleep setting); (3) the presence of adult pillows, additional bedding, thick comforters or quilts, or a

combination of multiple kinds of bedding placed under or around the infant; and (4) the improper installation of the bumper pads, which allows them to sag and assume a horizontal position.[19]

While reviewing the cases, staff also identified any issues pertaining to the structural integrity of the crib or confounding factors related to the infant sleep environment or the health of the infant. HS staff took note of deaths that were likely to have occurred in cribs that were broken or appeared to have other structural integrity issues involving the crib frame and/or mattress fit. Large gaps between crib components or gaps caused by an ill-fitting mattress have been known to result in fatal entrapments, with or without the presence of a bumper pad. Cribs with such structural integrity issues are known to have caused deaths that result from a variety of causes, including suffocation, positional asphyxia, and hanging strangulation.

HS staff also identified confounding risk factors related to the infant. These included: (1) infants found in a prone sleeping position, which is a known high-risk factor for SIDS and suffocation in young infants between birth and 6 months; (2) the position of the infant's body, especially the infant's head and face, calling into question whether the infant's airway openings were blocked (*i.e.*, occlusion of the mouth and nose); and (3) premature infants and/or infants with preexisting medical conditions, particularly those with respiratory issues at the time of the death. Infants who are premature or who have certain birth defects are at higher risk of suffocation because of developmental delays and compromised respiratory systems.

HS staff ruled out crib bumpers as the primary cause of death in cases where the medical examiner's report clearly stated that it was not involved in the infant's death, and staff either had no other available information or found nothing contradictory in other official documents to question the medical examiner's findings. Staff notes that there is a recognized lack of consistency in the way asphyxia deaths are classified by individual medical examiners and coroners, which can make interpretation of their rulings uncertain, particularly when case details are limited. [20] Staff also notes that knowledge of SIDS risk factors has increased significantly over the past 25 years. Accordingly, with hindsight, some earlier SIDS rulings might be considered questionable when other known suffocation risk factors are clearly present. HS staff also ruled out bumper pads as the primary cause of death in cases where the reported information stated that the bumper pad was not physically touching the infant's face.

In a number of cases that HS staff examined, the available reports did not provide a level of detail that was sufficient to assess the likely cause of death or the role, if any, that might have been played by a bumper pad. However, for some of these cases that had limited information, words or statements, such as "wedged" or "entrapped between adult pillow and bumper," were

[19] CPSC information advises that "bumpers pads be installed according to manufacturer instructions and properly secured to crib slats. *(Ref: ASTM International. ASTM F 1917 – 08, Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories.*
.

[20] Sauvageau A. Boghossian E., Classification of Asphyxia: The Need for Standardization. J. Forensic Sci, (2010)55:1259-1267.

considered to be indicative of the probable primary risk factor involved in the death. For example, HS staff considered the presence of an object, such as a pillow, to be a likely primary hazard because staff believes such objects present a suffocation/entrapment hazard when used in the infant sleep setting (about 38 deaths/year, Wanna-Nakamura 2010). Finally, there were cases where there were conflicting accounts or facts (*e.g.*, in police reports, first responder reports, or parent/caregiver accounts of an incident, and medical examiners' reports), or inconsistencies in the case files. In such cases, HS staff could not determine reliably if a bumper pad played a significant role in the infant's death; and therefore, these cases were classified by HS staff as "unknown" or "unclear."

Results

Table 1 describes the 71 cases and provides a case overview and description of HS staff's assessment. The results of the HS staff data analysis groups the cases into those where staff felt the actual cause of death could be determined, those where probable primary cause of death could be determined, and those where the cause of death was unknown or unclear. The table also indicates for each case whether staff believed the crib bumper played a secondary role in the infant death.

1. Actual Cause of Death (n=32)

HS staff determined that in 32 in-scope cases, the actual cause of the infant death could be determined. The deaths were categorized based on what staff believed to be the primary risk factor contributing to the death. These are: (1) compromised sleep setting; (20 crib not set to lowest position; (3) crib and/or mattress integrity issues; and (4) presence of specialized infant product in crib. The table below summarizes how staff categorized the 32 cases.

● Compromised Sleep Setting (n =12) (Table 1: #s 6, 13, 22, 26, 28, 38, 46, 47, 53, 61, 62, 67)

Staff determined that in 12 cases where they believe the actual cause of death can be determined, the primary factor contributing to the deaths were known hazards present in the sleep setting. Ten of these cases involved the presence of a pillow.

As noted above, a pillow(s) in a crib can present a recognized suffocation hazard to a young baby, even without the involvement of any other factor, and this is especially true of situations involving developmentally immature babies, who are placed to sleep lying prone on a pillow, or who otherwise roll to a prone position on a pillow. Pillows also present entrapment/suffocation hazards by creating confined spaces between the pillow and the crib frame, which does not have to be covered by a crib bumper. Suffocation can subsequently occur if an infant becomes "trapped" or "wedged" in this space with their face pressed into the pillow, the underlying mattress/other soft bedding, or a bumper-covered crib side. Only two of these 12 cases did not mention the presence of a pillow in the crib. Case 28 notes that the 4-month-old boy was "face down in crib, pinned between bumper pad and sibling sister," who was his twin. For case 53,

regarding the death of a 7-month-old girl, found prone in her crib, the ME noted: *asphyxia, accidental, "wrapped in blankets that were reportedly somewhat constrictive about her neck"* and did not mention any crib bumper involvement. It appears to staff that this case is captured by the EPI search simply because a bumper is mentioned incidentally as part of the crib contents in the CPSC IDI summary narrative. For the 10 cases where a pillow was present, seven indicate the baby became entrapped or wedged between the bumper-covered crib side and the pillow. Five of these noted the baby was lying in a prone position and with the face oriented downward (#46, 61), or more specifically, pressed down into either the pillow (#47) or soft bedding/mattress (#6, 13). One case noted a prone infant was found with the infant's face turned to the right, as supported by facial lividity patterns, but the object in contact with the baby's mouth and nose was not specified (#26). The remaining case was reported as SIDS in a one page MECAP report, which simply said the victim's face was up against a crib bumper, but review of the more detailed police report informs that the baby had long-term congestion and was placed prone on a pillow, then found prone with the right **side** of his face against the bumper, suggesting to staff that his mouth and nose must have been facing down, into bedding/mattress/pillow (#38).

The remaining three cases involving pillows HS staff considers did not likely involve the bumper. In case #22, the initial limited NEISS report of bumper involvement in the death of a 3-month-old girl was eventually attributed to "being wedged between pillows in a crib with blanket in mouth" by the ME; staff notes that the father gave inconsistent reports about whether he found the baby wedged between the bumper or the pillows that were in the crib. Case #62, involved the suffocation death of a 3-month-old boy face down on a large pillow in a cluttered crib, and it is unclear if the side of the boy's head was ever wedged against the bumper or simply touching it. In case #67, the ME determined the death of a 2-month-old boy to be a natural death, due to lymphohistiocytic myocarditis; however, given the baby was placed on pillow in his crib and later found dead, face down on the pillow, HS staff considers a prone, pillow-related suffocation death to be a more plausible explanation, perhaps with some preexisting cardiac condition increasing susceptibility *(it is specifically noted for this case that the EPIR narrative for IPII X1160145A is erroneous in reporting the child was found lying supine).*

- **Mattress Not Set at Lowest Position for an Older Child (n = 1) (Table 1: #16):**

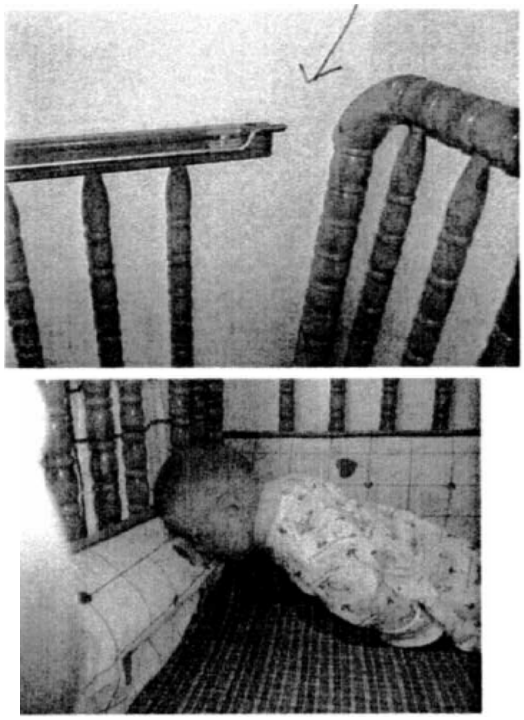
This case involves a 10-month-old boy reported to have been "larger-than-average" and a crib side rail, when raised, only 15 inches above the mattress surface. This death was judged by staff to have occurred because the mattress was set too high for the height of the 10-month-old boy, reported to be large for his age. Staff believes that the infant stepped out of the crib and dropped in a face-forward direction in the narrow space between the crib and the adjacent dresser. The infant was found with his chin resting on the dresser, compressing his neck. Staff believes it is unlikely that the infant used the bumper pad to climb out of the crib. According to the IDI, the mattress platform was set at a position that allowed for only a 15-inch difference between the mattress surface and the top of the crib side rail. The projected height of an above average, 10-month-old is about 30 inches; and therefore, a 15-inch clearance would allow a child to fall or

climb over the crib side rail, regardless of the presence of a crib bumper. The scene re-creation photograph shows the child was facing forward with his chin resting on the dresser; staff believes it is more likely that the child stepped out of the crib and fell in the space between the dresser and the crib.

- **Crib and Mattress Integrity Issues (n=7) (Table 1: #s 7, 11, 27, 31, 32, 35, 50):**

Seven of these incidents involved cribs that had some structural issue related to broken or missing pieces. One crib was missing hardware that resulted in separation of the crib side and crib end, creating a hazardous gap in the corner of the crib where the baby's head could be entrapped (as shown in ME's photos of the incident crib for case #32 shown below); another broken crib resulted in separation of the crib frame at the corner, and the baby fell through the gap and strangled on the bumper (#31); one crib was missing a mattress support, so the caregivers had fashioned an inadequate makeshift mattress support from wood struts (#35); one broken crib was missing both a headboard and mattress, so the parents used adult pillows and blankets in lieu of the missing crib components (#27), and two cribs had broken or missing slats, or slats that were too widely spaced (#7, #11). In the remaining case (#50), the 7.5-month-old boy's head was reportedly wedged between the mattress and the headboard with his nose pressed into the mattress, suggesting an excessive gap between the mattress and the frame.

Case #32 - MEs Photos Showing Separated Crib Frame with Hazardous Gap in One Corner and Reenactment Photo Showing Doll's Head on Bumper in Corner Where Gap Was Located.



- **Presence of Specialized Infant Products in Sleep Environment (n=8) (Table 1: #s 49, 59, 60, 64, 65, 66, 69, 70)**

Cases #s 60, 65, and 69 each involved a suffocation consequent to entrapment of an infant between an infant sleep seat and the bumper-covered crib side. The sleep seat was not supposed to be used in a crib. The infants were found with their heads hanging off the infant sleep seat and tilted backward with neck hyperextended beyond the edge of the infant seat in which they were either loosely strapped or unharnessed. Even though the babies' faces were reportedly against the bumpers, HS staff believes that sustained hyperextension of an infant's neck, with the unsupported head tilted backward and downward below the level of the heart, ultimately could have caused the deaths of a young infant in such a compromised position. HS staff considers misuse of the sleep seat in the crib resulting in entrapment of the baby's hyperextended head and neck, clearly the primary cause of these deaths. Another death involving misuse of an infant sleep seat in a crib resulted when an unharnessed infant rolled out of the seat and became entrapped face down between the seat and the bumper-covered crib side (#70).

Cases #s 49 and 66 involved a suffocation hazard due to each infant's entrapment between a large C-shaped nursing pillow and the crib side. In case #49, the father found the baby 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." Police photos show a very cluttered crib; in addition to the C-shaped pillow, there were quilts, blankets, toys, a bottle, a book, and a wall clock. The ME report/autopsy states: "*Probable asphyxia due to obstruction of the nose and mouth,"* and notes: *"found unresponsive lying with his face wedged against the bumper of his crib and the mattress,*" but the report does not mention the nursing pillow. However, the nursing pillow is mentioned specifically as a contributing factor in the death certificate. In case #66, the 4-month-old boy had been propped supine on a C-shaped nursing pillow, but he was discovered unresponsive in a prone position with his head and shoulders up over the pillow and tilted downward, his head trapped in the space between the pillow and bumper-covered crib side. Staff considers both babies' deaths were caused primarily by the misuse of the large, C-shaped nursing pillow in the crib.

Case #59 involves the overnight death of a 7-week-old boy who had a significant medical history of breathing issues (described by the parents as "infant asthma" and sleep apnea). About two weeks before his death, he had been hospitalized for two days for a viral illness. He died after being placed on his side in an inclined infant sleep positioning device, intended for use in a crib. He had rolled out of the positioner, which had been used while covered with a blanket; and he was found wedged face down between the bumper-covered crib sides and the outer raised edge of the positioner. The ME's autopsy report notes that his death was ruled an accident and reported as: "*Probably asphyxia, a) found prone with face wedged between bumper pad and*

mattress, b) use of sleep positioner." The father reported finding the boy *"face down in the corner of the crib"* with "*his nose between the bottom of the bumper pad and the mattress."* The reported case details are ambiguous about whether the baby's face was pressed against a comforter that was between him and the mattress or against the crib bumper, as reported by the ME. The baby's reported history of breathing issues, which influenced the parents to use the sleep positioner, are possibly related to the autopsy toxicity screen report findings of significantly elevated dysfunctional hemoglobin (Hb) species: COHb (5%), MetHb (10%), and Sulf Hb (12%), indicating reduced oxygen availability to tissues. Curiously, these Hb aberrations of an unclear basis, and any potential contributions to the baby's history of breathing issues, are not discussed by the ME in the autopsy report. HS staff considers the primary cause of this baby's death to be suffocation, consequent to entrapment by the sleep positioner. Use of infant sleep positioning devices in a crib is now recognized as presenting an entrapment hazard that can cause positional asphyxia/suffocation death, regardless of the presence of a bumper.

Case #64 involves the suffocation death of a 1-month-old girl under extremely unusual circumstances, described as an unsafe sleep setting by the ME. In an attempt to facilitate breastfeeding by keeping the baby next to their bed, the parents had devised a primary crib sleep setting with multiple hazards (a reclined bouncy seat covered with blankets used to position the unharnessed baby; the seat was placed on a pillow used as a seat propping device; the pillow was placed on a crib mattress raised to the height of the parent's mattress; the seat, pillow, and mattress were in a crib in which the side rail was removed). The baby fell out of the seat and was found dead in the crib, wedged between the bouncy seat, pillow, and bumper-covered crib frame. HS staff considers the bumper was the least of the multiple hazards contributing to death in this unsafe sleep setting, and staff considers the primary cause to be the initial use of the bouncy seat in the crib.

- **Infant's Health (Preexisting Medical Concern or Ongoing Illness) (n=4) (Table 1: #s 18, 34, 44, 45)**

There were four cases in which HS staff considered there was clear evidence of a primary medical concern that led to the older victim's death. Cases #34 and 44 involved deaths of 19- and 22-month-old children, respectively, who had severe neonatal brain injuries, and who were physically compromised. They each became entrapped in their cribs, one (#44) trapped by the foam positioner with his back to the bumper at one end of the crib and his face turned into the bumper on the side of the crib, and one (#34) in a facedown, prone position, having rolled for the first time. Case 18 was a natural death due to cardiac arrest consequent to chronic asthma in an 11-month-old boy; and case #45 was a natural death due to cardiopulmonary arrest consequent to a history of seizure activity in a 25-month-old girl.

2. Probable Primary Cause of Death (n = 16)

Although the actual cause of death was not clear in these 16 cases, HS staff believes that the presence of confounding factors (for example, the compromised sleep environment and the infant's medical status) were more likely to have been the cause of death, rather than the presence of the crib bumper. The cases fell into the following categories:

- **Adult Pillows, Cushions, and Other Multiple Confounders (n= 9) (Table 1: #s 4, 9, 10, 30, 33, 42,43, 48, and 71)**

Several of these fatalities lacked detailed reports. From the available information, staff considered four were caused, in all likelihood, by the presence of pillows in the cribs (#s 10, 33, 43, 71). There are three cases that HS staff considers likely involved compromised sleep settings that were not clearly pillow related. Each included the presence of thick bedding items (quilts, blankets, comforters) in the crib beneath the babies who were found prone, in a facedown position (#s 4, 9, 48). One of the remaining two cases involved a 2-month-old premature baby found in the corner of the crib; she was lying on top of a padded comforter and thick afghan blanket, and reportedly was co-sleeping with her twin, whose position was not specified (case #30). The last case HS staff considered to be a probable confounded sleep setting is case #42, where scene re-creation photos show a baby doll's chin resting on a bumper (unclear how nose and mouth would be occluded). HS staff notes that the police incident crib scene photos, showing a cluttered crib, including thick bedding and large stuffed toys, could offer a more plausible explanation of this fatality (case #42).

- **Confounders Related to the Infant's Age or Health (n = 6) (Table 1: #s 2, 5, 12, 14, 19, 29)**

Five of these six cases were ruled SIDS by the ME (#s 2, 5, 12, 19, 29), and HS staff notes that other findings at autopsy indicate other potential medical issues may have played a role (see Table 1, staff view of key details). The remaining case, #14, concerns a 14-month-old boy who had a recent history of extensive breathing treatment for a respiratory infection. The initial IPII summary stated that the 14-month-old boy had his face pressed firmly against the bumper pad. From a developmental perspective, staff believed that a healthy 14-month-old should be physically able to move his head if the airways became occluded, which suggested to staff that perhaps other confounders were involved. Recent supplemental information notes that the boy recently had been diagnosed with reactive airways, for which steroid treatment was recommended but rejected by his parents. He had been seen by his doctor for ongoing airway congestion just two days prior to his death, suggesting to HS staff that an acute asthma attack was likely involved in his death. Both parents clearly reported finding the boy lying prone, unresponsive, with his face down between the mattress pad and bumper pad, and no objects nearby. An indistinct photo appears to show the boy lying face down on the mattress, with the top of his head simply touching the crib bumper. Pressure marks on the baby's nose, noted in the

ME's autopsy, are consistent with the reported facedown position. The basis of the ME's opinion that the baby's death was due to positional asphyxia appears to be based on what HS staff believes to be the ME's erroneous understanding that the baby's face was pressed into the bumper pad, rather than the mattress.

- **Crib Structural Integrity Issues (n=1) (Table 1: #36)**

In case #36, the ME reported that the 4-month-old girl's arm was wedged between the crib and the mattress and that death resulted from "asphyxia due to compression of the head against crib bumper." Although the specific object contacting the baby's face is not specified (bumper implied?), and it is not clear why the baby could not turn her head if her head was facing into the bumper, staff considers that an excessive side gap crib issue is likely to be the primary cause of the child being stuck in this position. This is because the report of her arm being wedged between the crib and mattress suggests either an ill-fitting mattress or unstable/broken frame. 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. HS staff does not consider the crib bumper to be the primary cause of death.

3. Unknown/Unclear (n=14) (Table 1: #s 3, 8, 15, 20, 21, 37, 40, 52, 54, 55, 56, 58, 63, 68):

There were 14 cases with limited, ambiguous, or conflicting information that precluded HS staff from assessing the actual or probable cause of death.

In four of these cases, HS staff believes the available information was sufficient to rule out the bumper as playing a primary or secondary role in each baby's death (cases #s 3, 40, 54, 68)

One case (#63) appears to suggest a possible secondary role for the bumper as a wedging surface, and the case involves a baby initially reported to be found prone with her face against the bumper. However, HS staff notes that recently obtained information reported multiple confounders (*i.e.*, presence of her twin and a bath towel in the crib, plus conflicting officials' reports, where the coroner specifically advised the CPSC investigator that the baby's face was against the mattress not the bumper, as noted in written reports). As such, HS staff believes no reliable conclusions can be drawn concerning the bumper's role in this death.

The remaining nine cases (#s 8, 15, 20, 21, 37, 52, 55, 56, 58) have limited, ambiguous, or conflicting information, as summarized in Table 1, and the events leading to/circumstances of death are not clear; accordingly, from HS staff's perspective, these cannot be attributed to a bumper as the primary causative factor.

There were two cases (#s 8, 15) that HS staff considers most likely to involve an excessive side wall gap. These contained limited or ambiguous information as to whether the baby was: (1) somehow wedged between the *side* of the crib or mattress and a bumper, or (2) lying prone *on top* of the mattress surface with his/her face turned against the bumper. New information

received for one of these cases did not clarify the scenario sufficiently to negate any ambiguity. Staff recognizes that there are many documented cases of fatal wedge entrapment in excessive crib side gaps (broken cribs and cribs with missing hardware), but no clear cut cases of simple suffocation against a bumper have been documented.

In HS staff's opinion, in the majority of the cases, the initial available information reviewed by HS staff and the additional documentation recently obtained from medical examiners, provide clear or additional evidence of other primary causes that are known already to have caused multiple infant deaths in sleep settings (*e.g.*, crib structural defects, additional pillows, thick bedding, unhealthy baby, prone position).

4. Out of Scope

- **Ruled Out by CPSC Staff - (n = 9) (Table 1: #s 1, 17, 23, 24, 25, 39, 41, 51, 57)**

Nine cases were determined to be out of scope. Cases were considered to be out of scope if the deaths occurred outside an infant crib, and where a crib bumper was used in a sleep setting for which it was not intended, such as in portable cribs/bassinets (#s 1, 23, 51), toddler beds (#s 17, 25, 41), or in a play pen (#57). Another two cases were ruled out of scope for different reasons. In one case, the initial report of a supine child found unresponsive near a bumper was amended because supplemental information determined the death to be due to overlay while bed sharing in an adult bed (#24). This case is just one of several where HS staff's suspicions of the primary probable cause of death were substantiated by supplemental information. Staff notes that witness reports of the death scene, for many reasons, are not always reliable. In fact, they are sometimes deliberately misleading as in this case.

Another case involving the suspicious death of a 42-month-old child was considered out of scope because the caregivers were eventually charged with child abuse (#39).

Discussion and Conclusions:

The death of an infant is a tragic event, no matter what the cause. HS staff's analysis of 71 infant deaths (62 in-scope incidents retrieved with the current CPSC EPHA dataset) found no conclusive or persuasive evidence implicating crib bumper pads as the primary cause of death, when the bumpers were used properly in an appropriate infant sleep setting (*i.e.*, infant placed on its back in a crib meeting current voluntary standards and equipped with a firm, properly fitting mattress, with no additional pillows, comforters, positioning devices, or other occupants or bulky items placed inside the crib environment). By reviewing complete records available to CPSC staff, HS staff determined that many of the 62 in-scope incidents, where the actual cause of death was not clearly evident, had confounding factors that were considered to be the more likely primary cause(s) of death as opposed to the crib bumper. These included issues related to the sleep environment, crib and mattress integrity, and preexisting medical issues of the infant.

However, HS staff determined that in several cases, the presence of the crib bumper played a secondary role because some victims did ultimately suffocate when trapped between a bumper and another object, regardless of whether their face was pressed against a bumper, the mattress, or the other object. However, HS staff questions the interpretation of these deaths as being directly attributed to the bumper.

In differentiating between a primary and a secondary role for a crib bumper, HS staff approached each case from the perspective of trying to identify the precipitating factor that directly lead to the fatal scenario, in much the same way as an engineer approaches a root cause analysis for any failure event. From this perspective, in any crib death wedging/entrapment event, the two entrapment surfaces do not play equal roles. The crib side (whether covered by a bumper or not) is always present and cannot be removed; accordingly, the crib side is always considered the passive, secondary entrapment surface by HS staff. In contrast, a large object (pillow, twin, or specialized infant product) when placed in a crib, is a well-recognized sleep environment hazard, even when a bumper is not present. For that reason, HS staff considers any large object, introduced into a crib, to be the active, primary entrapment surface, and therefore, the primary cause of death in any wedge-entrapment fatality, regardless of whether the baby's face is ultimately pressed into the object, the mattress, or the crib bumper. In other words, HS staff considers that a baby is always wedged **against** the secondary surface (crib frame/bumper) by a primary hazard (pillow/twin/infant product), rather than simply being wedged **between** two "equal" surfaces. HS staff recognizes that MEs try to describe key details of the final death scenario that contribute to a death. In crib deaths, some MEs might specify both entrapment surfaces, while others might simply note "face pressed against the bumper." However, at least for the entrapment cases where MEs describe both surfaces involved, HS staff does not believe that MEs expect readers to conclude that each surface contributed equally to the death scenario; and HS staff considers it incorrect to take this approach.[21] HS staff draws attention to case #6 (Thach #20). On the death certificate, the ME recorded this death as *"face wedged in crib between pillow, mattress & bumper, asphyxia; external facial compression (suffocation)."* However, in the case file for this fatality, additional information clearly reports 2-month-old twins were placed in the same crib, each laying on top of a large semirigid foam cushion the size of an adult pillow. One twin died after she rolled off her cushion/pillow mattress and became wedged in the space between the cushion and the bumper-covered crib side. Most importantly, the final written entry on the ME's investigation report concerns a paramedic who responded to the death scene— the entry reads: *"Told Officer (who is also a state trooper and neighbor of mother) to advise her of the cause of death from autopsy, and to remove cushions from crib so that the same problem wouldn't occur with brother."* HS staff believes this clearly shows that, although all entrapment surfaces are identified by the ME on the death certificate, the ME

[21] *e.g.*, "trapped between a brick wall and a car" does not indicate that both surfaces contribute equally to the cause and circumstances of injuries or death.

obviously considered the cushion/pillow, not the crib bumper or mattress, to be the actual cause of death.

Although, HS staff does not believe that the simple presence of a crib bumper in a crib poses any risk of injury or death to a healthy child, in the absence of any other primary hazard, clearly, the presence of a crib bumper can add to the risk of fatal injury in wedge-entrapment scenarios where the baby's face is ultimately wedged into the bumper to occlude the nose and mouth.

Given the significant number of times a single infant is likely to be exposed to any putative hazard presented by a crib bumper, staff would expect to see at least a few clear-cut cases of bumper-related infant deaths, in the absence of other recognized infant sleep or health-related hazards, if such a risk existed. However, staff notes that it did not find one case where a correctly installed crib bumper clearly caused the death of a healthy infant, in the absence of other well-recognized risk factors. Based on the weight of evidence, staff does not find a correctly installed and properly secured (*i.e*., according to manufacturer's direction) crib bumper to present a primary risk of infant suffocation in a crib.

HS staff found no conclusive evidence implicating crib bumper pads as the probable primary cause of death, when the bumpers were properly used in an appropriate infant sleep setting (*i.e.,* infant placed on its back in a crib meeting current voluntary standards, and equipped with a firm, properly fitting mattress, with no additional pillows, comforters, positioning devices, or other occupants or bulky items placed inside the crib environment).

While the HS staff analysis was focused on the possible hazard posed by crib bumpers, it is clear from the case information evaluated by staff that other serious hazards in the infant sleep environment existed that are of significantly greater concern than crib bumpers. These very real hazards of great concern to staff are:

1. Prone Sleep Position—The prone sleep position is a known risk for SIDS, yet young, particularly vulnerable, infants are still placed in this position to sleep, as evidenced by the data staff reviewed.

2. Pillows—Pillows placed under or around an infant create hazardous suffocation and/or entrapment risks (about 38 deaths/year) (Wanna-Nakamura, 2010).

3. Crib Integrity Issues—Broken cribs, makeshift cribs, cribs missing hardware, improperly fitting mattresses, or makeshift mattresses, all can create gaps that can lead to entrapment and 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 twin, an older sibling, or an adult. The cases staff reviewed also showed many instances where the infant sleep environment was cluttered with folded quilts, comforters, infant

positioners, baby carriers, and other objects. These also create entrapment and/or suffocation hazards.

Although HS staff does not believe the reviewed incidents support a concern about hazards related to the correct use of crib bumpers in a safe sleep environment, they believe that there is an urgent and continuing need to educate parents and caregivers about known infant sleep hazards that can be prevented and about what constitutes a safe sleep environment for their infants.

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

Memorandum

Health Sciences Table 1

FA = face against; WB = wedged between; BTS = bumper tie strangulation)

AC (actual cause); PPC (probable primary cause); UNK (unknown); OOS (out of scope)

SIC (structural integrity of crib); CSS (confounded sleep setting); SIP (specialized infant product); MI (medical issue); LI (limited information)

Count	IDI/ Document	Date	Age/ Sex	The EPIR Case Narrative Provided by Epi Staff	HS assessment in Columns to the right	Staff Classification** AC, PPC, UNK, OOS	Staff's View of Actual or Most Probable Primary Cause(***	HS View of Key Summary Case Details (for additional detail, See link	Bumper Clearly the Primary Cause?	Any role for bumper? (2^0= secondary contribution)
1	Terminated IDI 910422HCC0206 9006023863	2/23/1990	11 MO M	An 11-month-old boy strangled in a cord formed by the broken side of a portable crib. The crib side was torn where the mesh side connects with a plastic bumper pad. A plastic cord was formed by the break. The victim fell out of the crib feet first. His feet were on the floor, but his head was trapped with the cord around his neck.		OOS	OOS	portable crib, strangulation death on a plastic cord in a broken portable crib	NA	N
2	Terminated IDI 900606HEP1201 900602715 X12C0891A	6/5/1990	2 MO M	A 2-month-old preemie presents with cardiac arrest; mom went in to check baby in crib; found him with face against plastic bumper.		PPC	MI	SIDS per ME -MI in-preemie with apnea, autopsy found GI hernia found and 20cc turbid peritoneal fluid	N	?

3	Terminated IDI 911010HCC2004 X91A0075A	1/10/1991	3 MO M	This investigation involved a 3-month-old male infant found dead by his father. 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.		UNK	MI	SIDS per ME, in prone baby - face was not touching the bumper as found by father	N	N
4	Terminated IDI 911023HCC0025 X91A0207A	9/26/1991	8 MO F	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.		PPC	CSS	SIDS per ME - CSS-older baby (8 month) prone on waterbed mattress, on multiple layers of thick bedding, with large stuffed toys in crib	N	N
5	920320HWE4006 F9234000A	3/20/1992	2 MO F	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.		PPC	MI	SIDS per ME, in prone preemie twin with history of dry cough - face not touching bumper as found	N	N
6	X9344404A X12C0720A 9254009025 920909HCC1843	6/3/1992	2 MO F	A 2-month-old female died sleeping on cushions (bumper pads & crib mattress) in her crib.		AC	CSS	CSS - entrapped face down into mattress between semi-rigid pillow-sized foam cushion and bumper covered crib side	N	Y-2[0]
7	9254008697 X12C0723A 920828HCC1830	6/6/1992	5 MO M	Child put head through slats in crib & died - asphyxia; hyperextension of neck associated with crib bumper resting on anterior neck - autopsy yes		AC	SIC	Broken crib with missing slats - death due to head and neck entrapment in hazardous gap between slats	N	N

8	920916HCC3257 9105015929	7/22/1992	7 MO F	A 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.		UNK	SIC?-LI	Limited information - head "wedged against side of mattress" suggests excessive mattress side gap but information is ambiguous and not clear cut	N	?
9	921116HWE4010 F92B4007A	11/10/1992	2 MO M	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.		PPC	CSS	SIDS per ME, baby found prone in CSS - face down into thick quilt, face not touching bumper, head partially covered by quilt edge	N	N
10	9318015061 X12C0724A	3/10/1993	1 MO M	Found unresponsive wedged between pillow and bumper pad. Positional asphyxia - autopsy yes		PPC	CSS	CSS -coroner's report says found prone, face down on blanket-covered pillow, facial marks matched blanket, but also reports head was wedged between the pillow and crib bumper (ambiguous); plus thick blanket used as mattress pad.	N	Y-2^{0}
11	940818HCC2202 X9474925A 9317613265	7/12/1993	9 MO F	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.		AC	SIC	Broken crib with missing slats - death due to hanging when body fell through hazardous gap between slats and neck got caught by bumper pad	N	Y-2^{0}

12	X94C0721A X12C0888A	8/10/1994	4 MO M	A 4-month-old male died of SIDS, sleeping with his face down between the mattress and bumped pad of his crib.		PPC	MI	SIDS per ME - MI- preemie with history of perinatal brain hemorrhage and significant brain pathology	N	N
13	9612104372 X12C0726A	9/3/1996	2 MO F	Baby's head went between pillow and padded crib wall, face down in soft bedding - asphyxia; suffocation-face down in soft bedding - autopsy yes		AC	CSS	CSS-pillow-related entrapment of prone baby's head against bumper covered crib side with face described as being down into soft bedding or mattress, but not into bumper. Other confounders congenital heart defect and chronic cough.	N	Y-2[0]
14	X9730790A X12C0730A	9/26/1996	14 MO M	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.		PPC	MI, MC	MI- history of serious breathing, reactive airways, ongoing illness issues, abnormal brain symmetry at autopsy. Note father specified no objects were close to his head when found which conflicts with ME's report	N	N

15	980224HCC2316 9713018731	4/21/1997	2 MO M	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.		UNK	SIC?-conflicting reports	Limited information: "entrapment between the crib side wall and the edge of the mattress" (ME) suggests excessive mattress side gap but verbal input collected 1 year later during IDI noted "head got caught between a baby blanket and the bumper pad" (sheriff's dept.). Ambiguous - not clear	N	?
16	970916CCC2413 9729018036 X12C0721A	5/21/1997	10 MO M	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.		AC	Mattress not set at lowest position	Asphyxia by compression of upper neck while wedged between furniture and crib per ME-consequence of falling/climbing over crib rail only 15 inches above the mattress, set at its uppermost position (too high for 10 month old boy)	N	N
17	X9853332A	6/12/1997	5 YR M	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.		OOS	OOS	death in a toddler bed, 5 year old	NA	NA

18	980107HCC3504 X9811449A	1/2/1998	11 MO M	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.		AC	MI	MI- natural death caused by cardiac arrest due to chronic asthma -per ME	N	N
19	H0030299A X12C0798A	2/24/1998	1 MO F	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.		PPC	MI	SIDS per ME in prone 6 week infant.- no discussion of adrenal hemorrhage found at autopsy or mention of bumper in ME or coroner's report	N	N
20	981118HCC2075 9829025725 X12C0729A	6/23/1998	7 MO M	A coroner determined a 7-month-male infant died in a crib due to positional asphyxiation - face in corner of crib against bumper pad.		UNK	MI	Unclear - ruled positional asphyxia by ME ambiguous information in autopsy re likely respiratory infections /MI and crease on forehead of supine child seems overlooked?-	N	?
21	001018HCC2040 X0073156A	2/14/2000	4 MO M	On February 14, 2000. A 4-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.		UNK	CSS- MC-LI	Multiple confounders and inconsistencies in death of prone child in CSS - thick blankets and sagging bumper	N	?

22	Terminated IDI 000725HEP9012 742339 X12C0727A	7/12/2000	3 MO F	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.		AC	CSS	Positional Asphyxia (wedging), baby found wedged between pillows in crib with blanket in mouth and could not be resuscitated" per ME. CSS-pillows (2) entrapment in thick bedding	N	N
23	'0019023709	11/3/2000	1 MO M	Baby boy face down on crib, a pad and side mesh obstruction of nose and mouth─obstruction of nose and mouth; lying face down on pad and side mesh of baby crib - autopsy yes		OOS	OOS	death in a portable crib	NA	NA
24	X0131265A	2/3/2001	3 MO M	A 3-month-old boy was found by his father unresponsive on his back in baby crib. There was a pillow, blankets, and side bumper around the inside of the crib. Cause of death: positional compressive asphyxia.		OOS	OSS	death in an adult bed. Note - this overlay death was originally reported as a death of a supine child in which a bumper was present	NA	NA
25	010417CNE6292 N0140174A 0112049868 X01B5336A N0160212A	4/11/2001	11 MO F	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 victim's neck and as she slid forward, was unable to breath and suffocated. The cause of death is mechanical asphyxia. The manner of death is considered accidental.	-	OOS	OSS	death in a toddler bed	NA	NA
26	X0252630A 0137042763 X1260527A	8/9/2001	3 MO F	A female infant, age 3 months, who was found wedged between adult pillows and crib bumper on an adult bed, died from asphyxia.		AC	CSS	CSS-pillow (adult pillow related - prone wedging)	N	Y-2^{0}

27	020912HCC2662 0226024886	4/21/2002	7 MO F	A 7-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 makeshift 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.		AC	SIC	SIC- broken crib missing mattress, headboard- makeshift pillows used as substitutes. Entrapment death due to neck hypertension, head inversion, face into pillow used as headboard	N	N
28	X0273240A 0255015455	4/22/2002	4 MO M	A male infant, age 4 months, 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.		AC	CSS	CSS- prone boy found wedged face down between bumper/crib side and twin	N	Y-2^{0}
29	X0394435A	4/5/2003	2 MO M	A male infant, age 10 weeks, was found deceased against the bumper pad in his crib with his face down in mattress.		PPC	MI	SIDS per ME in prone 10 week infant, face down on mattress against bumper-Limited information	N	?
30	0318019177 X12C0890A	6/15/2003	2 MO F	Baby suffocated at home in the corner of the crib against the crib bumper. Suffocation - accidental. Autopsy - yes.		PPC	CSS	Suffocation in corner of the crib against bumper pad per ME. Coroner's report noted - CSS-co-sleeping with twin - soft bedding under babies (blanket over mattress, afghan, padded comforter and bumper that sagged inwards in corner where baby was found)	N	Y-2^{0}

31	0331011150 X12C0732A	9/20/2003	12 MO F	Child found hanging by crib pad after falling out of crib - asphyxiation - autopsy no.		AC	SIC	SIC-broken crib. Atypical bumper strangulation death of an older 12m baby who fell through a gap where the crib side and guardrail were not connected.	N	Y-2[0]
32	X03B5090A 0326061992 X12C0722A	9/29/2003	2 MO M	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.		AC	SIC	SIC- entrapment death in a secondhand crib missing its hardware - this resulted in crib frame failure and creation of a hazardous gap.	N	Y-2[0]
33	0318045538 X12C0728A	11/19/2003	3 MO F	Decedent lying prone in a crib with a full-size pillow & bumper pads - positional asphyxia - autopsy yes.		PPC	CSS	CSS-pillow - Coroner notes scene had been totally altered, but ruled positional asphyxia, accidental. No clear cause evident to staff. Pillow appears the most likely cause of death	N	?
34	0444004043 X12C0770A	5/20/2004	19 MO F	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.		AC	MI	MI -severe brain damage from birth-physically compromised older (19m) child unable to roll to supine	N	Y-2[0]

35	040827CCN0935 G0480262A X0494794A 426061031	8/24/2004	4 MO F	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.		AC	SIC	SIC -thrift store crib missing original mattress support - makeshift repair using diagonally spaced wood pieces (2 x4s) left corner unsupported -allowed the mattress to tilt down in one corner, causing the prone baby's head to be entrapped and pressed face down on to a quilt.	N	Y-2^{0}?
36	070723CCC1639 0566054487	12/15/2005	4 MO F	A 4-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.		PPC	SIC	SIC -excessive mattress-frame gap trapped prone, face down, baby's arm with head reportedly compressed against bumper- object in contact with baby's face is not specified (mattress or bumper?)	N	Y-2^{0}
37	0626045306 X12C0889A	5/26/2006	5 MO F	Trapped face-down against padding in the corner of the crib - pending, position asphyxia - autopsy yes.		UNK	MI?	UNCLEAR ruled Positional asphyxia by ME but vomit in lungs documented in autopsy is not addressed. Note ambiguous conflicting information - re face down in padding per ME v face up against side rail bumper pad per Nanny	N	?

38	X0760223A	10/4/2006	4 MO M	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.		AC	CSS	SIDS per ME -CSS-pillow related entrapment of prone baby with right side of face up against crib pad. He had been put to sleep on adult pillow.	N	Y-2[0]
39	081006HCC2015 0728001038	1/6/2007	3 YR F	A 3-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.		OOS	OOS	A criminal child abuse case of a 42 month old. Mother and boyfriend were charged with her death	NA	NA
40	X07B0120A 0727018784	7/6/2007	4 MO F	A 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.		UNK	Unclear	Positional Asphyxia per ME -confounded by enactment photos with prone baby face down, next to crib side, not in corner, and no obvious "round mat." History of respiratory illness? Unclear cause	N	N
41	090713HCC3744 '0708020537	9/3/2007	21 MO M	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.		OOS	OOS	death in a toddler bed (21 month old)	NA	NA

42	091021HCC2091 0717054853	9/7/2007	5 MO M	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 facedown 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 lying face down in thick soft crib bumper pad bedding at the corner of the crib."		PPC	CSS	CSS -bumper role not clear, death scene recreation photos show infant in corner, chin resting on bumper, but unclear that mouth and nose are obstructed. Potential role of thick bedding and large stuffed toys in crib death scene photos is unknown.	N	Y-2^0?
43	080702HCC1698 X0860273A 0712125844	10/2/2007	2 MO F	A 2-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 herself up to breathe. There were several other items in the crib that may have contributed to the incident.		PPC	CSS	CSS -face against bumper not considered a suffocation hazard unless the infant is trapped between objects.- specific items of concern in the crib include an adult pillow, plus baby pillow, comforter, blanket and toys.	N	Y-2^0
44	0733008220 X12C0769A	10/24/2007	22 MO M	Face became pressed against crib bumper pad while sleeping - asphyxia; suffocation - - autopsy yes.		AC	MI	MI -severe brain damage from birth-physically compromised older child + CSS entrapped by foam sleep positioner with back towards bumper covered crib side.	N	Y-2^0

45	80401510 X1260268A	1/6/2008	2 YR F	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		AC	MI	MI- cardiopulmonary arrest due to seizure activity per MD autopsy in older child (2y) (several months of seizures) - CSS? pillow and bumper only mentioned in brief NEISS narrative	N	N
46	090901HCC1016 0812049146	3/27/2008	2 MO F	The 2-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.		AC	CSS	CSS - "partially wedged" "face-down" between a pillow and the bumper pad. Two adult pillows, a sofa cushion (square, throw type), toys, and other items in crib.	N	Y-2^{0}
47	0845026186 X12C0725A	8/17/2008	3 MO F	Wedged between bumper guard and pillow. Positional asphyxia. Autopsy-yes.		AC	CSS	CSS - wedged between a pillow and the bumper. MD's final pathological diagnosis specifies face, nose and mouth in mattress and pillow.	N	Y-2^{0}
48	090331HCC1560 X0920560A	8/31/2008	2 MO F	Within 6 hours of being fed and placed in her crib, a 2-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.		PPC	CSS/MI?	Acute cerebral anoxia, manner undetermined per coroner in prone baby on foam mattress covered by thick comforter. MI? congenital arterial defect identified at autopsy	N	N

49	090611HCC2690 0827026623	9/9/2008	2 MO M	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.		AC	SIP	CSS - entrapment between crib side and a specialized infant product (nursing pillow)	N	Y-2[0]
50	110105HCC3323 0949000490	1/12/2009	7 MO M	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.		AC	SIC	SIC accidental positional asphyxia - ME noted "head wedged between the mattress and the headboard of the crib" "nose was into the mattress". - indicates excessive mattress crib frame gap	N	N
51	101110HCC3164 0953003043	3/19/2009	2 MO F	A 2-month-old female was discovered dead in a bassinet. The infant was last seen alive 8 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.		OOS	OOS	in a bassinet	NA	NA
52	120302CCC2408 0913023166	5/6/2009	2 MO F	A 2-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.		UNK	Unclear-LI	UNCLEAR-Limited information on cardiorespiratory failure due to severe brain injury-asphyxiation (delayed death after 16 days)	N	?

53	091204HCC2201 X09A0396A	7/16/2009	7 MO F	A father placed his 7-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.		AC	CSS	CSS - Asphyxia-sleeping prone in crib with multiple blankets per ME investigator - no mention of a bumper involvement.	N	N
54	110914CCC2938 0926041921	7/25/2009	2 MO F	A 3-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.		UNK	Unclear	Unclear-CSS? Prone baby in cluttered crib Inconsistent reports (especially medical experts). Position of baby's face relative to bumper unclear.	N	N
55	090904CNE0001 I0981399A	8/20/2009	4 MO F	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.		UNK	MI?	SIDS per ME -- after a 10 month investigation. (ambiguous and inconsistent witness information)	N	?
56	110412HCC3610 0948106858 X11B0029A	9/2/2009	2 MO M	A 2-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.		UNK	Unclear	Suffocation death of prone baby in crib with head near/against bumper per ME - unclear whether nose and mouth were obstructed by mattress (which had large wet stain with small red area) or bumper.	N	N

57	X1080578A X1030216A	11/20/2009	2 MO M	A 2-month, 11-day-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 three standard sized blankets folded.		OOS	OOS	death in a playpen	NA	NA
58	100420CWE2055 H1040227A 1048022029 Y1054522A	2/27/2010	6 MO M	A 6-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, lying on his back for a nap. When she returned 2 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.		UNK	Unclear	Unclear-Inconsistent ambiguous report (by caregivers, police and medical staff) note: CSS? crib was very cluttered (pillows, fleece blanket, 2 beach towels, ~8 soft toys) per police report photos	N	?
59	100810HWE2299 1002001720 N1080137A Y1164502A Y1164511A	4/8/2010	1 MO M	A 7-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.		AC	SIP	Specialized infant product (crib sleep positioner) entrapped baby against crib side	N	Y-2^{0}
60	110328HCC2400 1001014759	4/17/2010	6 MO F	A 6-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.		AC	SIP	Specialized infant product (infant sleep seat) entrapped unharnessed baby against crib side with neck hyperextended and head inverted below shoulders	N	Y-2^{0}

61	X10A0077A	4/17/2010	1 MO M	A 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.		AC	CSS	Positional asphyxia ME- CSS- adult pillow related entrapment of prone baby against crib side, other another wedge device in crib.	N	Y-2^0
62	101007HCC1021 X1090392A	5/10/2010	3 MO M	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.		AC	CSS	CSS-pillow suffocation. Positional asphyxia crib death with bedding, a pillow and bumper pad" per ME. Father reported face down in a pillow, with his head described as being "against" and "next to" the crib bumper.	N	N
63	110915CCC2952 1018021460	5/28/2010	2 MO F	A 2-month-old female infant decedent in prone position with face against crib bumper at home. Positional asphyxia. Autopsy- yes.		UNK	CSS	NOTE: Coroner corrected coroner and sheriff's documents stating the victim's face was against the bumper; he clarified positional asphyxia resulted from the baby's face being against the crib mattress, not the bumper. CSS twin and bath towel in crib	N	Y-2^0?

64	120217HCC3389 1048069877	6/3/2010	1 MO F	A 5-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.		AC	SIP-CSS	Suffocation in unsafe sleep environment: SIP-CSS-MC (misuse of bouncy seat, pillow used as propping device, crib used with side rail removed and mattresses raised too high)	N	Y-2^{0}
65	100802HNE0563 1026045811 N1080026A	7/9/2010	4 MO F	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.		AC	SIP	Specialized infant product (infant sleep seat) entrapped loosely harnessed baby against crib side with neck hyperextended and head inverted below shoulders and face into bumper	N	Y-2^{0}
66	110308CCC2350 H1130043A	8/20/2010	4 MO M	A 4-month-old male died from positional asphyxia when he was found face down wedged between a nursing/feeding pillow and the crib bumper pad.		AC	SIP	SIP - entrapment between crib side and a specialized infant product (nursing pillow)	N	Y-2^{0}

67	110617HCC3847 X1160145A	3/8/2011	2 MO M	A 2-month-old male died after he was put in the crib against the bumper pad on the pillow. He was found unresponsive, lying supine in the crib.		AC	CSS	Lymphohistiocytic myocarditis, natural death, per ME. CSS: Fixed lividity on right torso and face appears more consistent with suffocation of child who routinely slept prone on an adult pillow with face turned to right. NOTE IPII narrative that victim was found supine is a coder error.	N	N
68	110912CCC3141 X1190012A	5/22/2011	3 MO M	A 3-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 3 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.		UNK	Unclear	The autopsy concluded the boy died as a result of "undetermined causes" -the child was found prone in a confounded sleep setting containing a pillow, blankets, bumper, and stuffed toy,	N	N

69	120109CAA1337I11C0712A	11/21/2011	4 MO M	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.		AC	SIP	SIDS per ME. Specialized infant product (infant sleep seat) entrapped unharnessed baby against crib side with neck hyperextended and head inverted below shoulders, face into bumper	N	Y-2[o]
70	120710CWE2037I1270178A	4/23/2012	7 MO M	A 7-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.		AC	SIP	SUID per ME. Specialized infant product (infant sleep seat) unharnessed baby entrapped face down between seat and crib side	N	Y-2[o]
71	X1280799A	6/14/2012	1 MO M	A 1-month-old male 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		PPC	CSS	limited information suffocation in prone position wedged between adult pillow and crib padding	N	Y-2[o]

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

Memorandum

Appendix A to HS Memo
Staff Review and Analysis of the 27 Cases Reported in Thach et al., 2007 "Deaths and Injuries Attributed to Infant Crib Bumper Pads" [22]

Subject: Continuing public concern that crib bumpers present a potentially fatal hazard has led to the banning of bumper pads in certain jurisdictions and has prompted media, medical, government, and consumer groups to release statements urging that bumpers not be used in the infant sleep environment.[23] Health Sciences (HS) staff believes the basis of this concern stems primarily from the conclusions in a paper published by Thach et al., in 2007.[1] To respond to concerns that such products present an unreasonable risk of suffocation to infants, HS staff provides a case-by-case analysis of all available documents and records associated with the 27 deaths reported in Thach et.al.[1] and examines the potential hazards associated with the use of bumper pads in infant cribs. The likely match of case summaries is catalogued in Table A, which also provides an overview of all available case details highlighting key facts and causes, as well as HS staff's opinion of whether the bumper played a primary role in the death.

Background: In 2007, Thach et al., or "Thach" published a paper reporting "a number of fatal accidents directly attributable to crib bumper pads" and concluded that "bumpers should not be placed in cribs or bassinets." The paper described 27 incidents of infant death involving bumper pads in cribs and other infant products. Six of the 27 deaths occurred outside an infant crib in a sleep setting for which a crib bumper was not intended (*i.e.,* a non-crib sleep setting, such as cradles, bassinets, wicker baskets, and toddler beds). The authors concluded that "bumpers should not be placed in cribs or bassinets." Moreover, the authors stated that their paper was based on 27 deaths reported to CPSC databases, and they indicated that their analysis was based on the complete U.S. Consumer Product Safety Commission (CPSC) record available for these deaths. Shortly after publication of the Thach paper, HS staff reviewed the cases in the journal article, and contrary to the conclusion reached by the authors, found (with the exception of three strangulation incidents) that there was no conclusive evidence implicating crib bumper pads as a primary cause of infant deaths when the bumpers were installed properly, according to manufacturer's directions, and used in an appropriate infant sleep setting.

Staff not only reviewed and carefully scrutinized the information on fatalities included in the publication, but it also attempted to match the information to cases in the CPSC databases (Table A). Although Thatch et al. concluded that bumper pads were a primary cause of death, based on available information, HS staff respectfully cannot concur with their interpretations and

[22] Thach T., Rutherford G., and Harris, K. *Deaths and Injuries Attributed to Infant Crib Bumper Pads*. The Journal of Pediatrics 2007;151:271-4.
[23] The city of Chicago banned the sale of bumper pads on September 8, 2011. The state of Maryland also issued regulations banning the sale of crib bumper pads that will take effect June 21, 2013.

conclusions. HS staff notes that Thatch et. al.'s bumper pad report included cases where it is not clear that conventional crib bumper pads were involved (*e.g.*, three cases described as some type of padding in an infant basket) and one case in which a crib bumper pad was inappropriately used in a non-crib settings (*e.g.*, on a toddler bed reported as daybed). Two other cases involved older children (>12 months) who, based on typical developmental capabilities, are not considered at high risk of suffocation in such settings. HS staff considers that most of the other cases included did not provide reliable, clear-cut evidence of a *primary* role of bumper pads. Furthermore, HS staff concluded that other items present in the crib were more likely to have been the primary contributor to the death (*e.g.*, pillows and or soft bedding placed on top of the sleep surface or the presence of a sibling). In these cases, staff interprets the role of the bumper pads as being incidental or having a secondary role. Staff notes that based on data patterns, even if a bumper pad is not present, the presence of pillows and soft bedding in an infant's sleep environment present a high risk for suffocation. According to CPSC data, about 38 deaths a year are attributed to pillows in the sleep environment (Wanna-Nakamura, 2010), whereas the reported bumper pad death total is 27 over a 20-year period.

Methods: The authors reported that the 27 deaths were identified through a search of four CPSC databases: the Injury and Potential Injury Incident files (IPII),[24] Death Certificates (DTHS),[25] and the In Depth Investigation files (INDP)[26] (also known as IDIs), and the National Electronic Injury Surveillance System (NEISS). The DTHS, IPII, and INDP databases were searched from January 1, 1985 through December 31, 2005; whereas the NEISS[27] files were searched from January 1, 2000 through December 31, 2004. According to the paper, the databases were searched using product codes for cribs, portable cribs, crib extender rails or youth bed rails, and cribs, as well as keywords "bumper," "pad," and "padding" for deaths involving infants between the ages of 1 month through 2 years. The authors also reported that their search was "not restricted in sleeping location, external cause of death code, or other identifier"; and "The files on these deaths and injuries were obtained and reviewed and cases with evidence of nontraditional use of bumper pads were excluded." The authors grouped the 27 deaths into three categories: (1) face against bumper (FAB) (11 deaths), (2) infants wedged between bumper (WEB) and other object (13 deaths), and (3) strangulation deaths (STR) bumper tie around infant's neck (3 deaths).

Because the Thach paper did not include CPSC case numbers, incident dates, or record identifiers, and because the raw data were not available from the authors when requested,[28] it

[24] The IPII file contains data on consumer product-related incidents extracted from consumer complaints, as reported to the CPSC through letters and telephone calls. The IPII database also includes media articles, medical examiner reports, reports from fire and police departments *nationwide, and referrals from other federal agencies.

[25] The DTHS file includes information from death certificates purchased by the CPSC from all 50 states and the District of Columbia. The EPIR summaries of the source death certificates include the immediate cause of death, the manner of death, some (but not necessarily all) of the contributing factors noted, and information on whether an autopsy was done.

[26] The INDP file contains data from follow-up investigations reported by CPSC staff. These investigations are done in an effort to gather detailed information on a death or injury associated with a particular consumer product.

[27] The NEISS database is a statistically based CPSC injury file that contains patient information collected from NEISS hospitals for every patient treated in the emergency department for an injury associated with a consumer product. The NEISS database file is a probability sample of hospitals in the United States and its territories that have at least six beds and an emergency department. National estimates are made of the total number of product-related injuries treated in U.S. hospital emergency departments based on the data collected from NEISS hospitals. The NEISS is a stratified sample based on emergency department size and geographic location. Information for NEISS cases is limited to a short case summary narrative.

[28] Personal communication with Dr. Thach and co-author George Rutherford.

was necessary for CPSC staff to match the cases with incidents found in the CPSC databases. HS staff used Thach's search criteria, in addition to an extensive word search of the CPSC databases, using many of the keywords, found in the excerpts in (Table 1 of Thach et. al., 2007) such as "pad," "bumper," "crawl," and "facial compression." While the information provided by the authors was limited to the narrative summaries, which in most cases were based on verbatim or near-verbatim text extracts from one or more relevant CPSC Epidemiological EPIR database case summaries, HS staff is confident that they have identified and matched all of Thach's 27 cases. Table A shows a comparison of Thach case narratives with the EPIR summaries retrieved by HS staff. This "Thach-Match" table also includes: (1) a staff summary of the sleep settings, event descriptions, conditions; (2) confounding factors that may have contributed to the death of the infant; (3) HS staff analysis and interpretation of the records; and (4) a classification of the cause or contributor to the infant's death.

Staff reviewed all available reports on the 27 cases and attempted to identify the actual or the primary probable cause(s) of death, taking into consideration information reported in the available case documents from death scene investigations, autopsies, caregivers, police reports, and death certificates. Staff also noted any major inconsistencies among the available records.

Staff divided the cases within their own groups into three, in-scope categories: (1) cases in which staff considered the actual cause (AC) of the infant death could be determined; (2) cases in which staff considered it could identify a probable primary cause (PPC) of death; and (3) cases where the existing case data were limited, unknown, inconsistent, ambiguous, or otherwise unclear, precluding staff from making a reliable determination of the primary cause of death and the bumper's role (UNK). While reviewing the cases, staff identified any issues pertaining to the structural integrity of the crib or confounding factors related to the infant sleep environment or the health of the infant.

Confounding risk factors that relate to the crib environment and risk factors related to the infant were also identified and taken into consideration. These include: (1) the presence of adult pillows; (2) prone sleeping, which is a known high-risk factor for SIDS and suffocation in young infants between birth and 4 months; (3) multiple occupants in the crib; (4) the presence of specialized infant products, such as sleep-positioning devices or other infant products in the crib, which are known to pose risks when placed in an infant sleep setting; (5) additional bedding, thick comforters or quilts, or a combination of multiple kinds of bedding placed under or around the infant; and (6) the improper installation or use of the bumper pads outside the crib.[29]

Results:

Out-of-Scope Cases

Staff reviewed the 27 cases and determined that six of the 27 were out-of-scope because the deaths occurred outside an infant crib in a non-crib sleep setting and/or did not involve a

[29] CPSC information advises that "bumpers pads be installed according to manufacturer instructions and properly secured to crib slats. *(Ref: ASTM International. ASTM F 1917 – 08, Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories.*

traditional crib bumper pad. In three of these six cases, the product involved was not actually a crib bumper pad, but rather, the inner lining of a cradle/bassinet product (#10) or a padding in a wicker basket (#s 9, and 22). In one case #4, an overlapping traditional crib bumper pad was wrapped one-and-a-half times around the inside of a rocking bassinet occupied by twins. In another case #6, an "overly large" plastic bumper was placed inside an antique cradle, also occupied by twins. In case #18, a crib bumper pad was tied to the foot of a toddler bed (erroneously described as a daybed in EPIR), probably to keep the walking 11-month-old from climbing or falling out of the opening at the foot of the bed between the side rail and footboard. HS staff notes that although Thach et al., stated in the methods section of their paper that "Cases with evidence of non-traditional use of bumper pads were excluded," the six out-of- scope cases cited above are included in the "Results and Discussion" section and appear to conflict with the authors stated methodology. [30]

Two cases #s. 4 and 6, involved twins placed to sleep in the same bassinet/cradle. In addition to the hazard associated with a rocking/tilting cradle, the presence of two infants in a cradle can further reduce the sleeping space and increases the likelihood of an entrapment and suffocation hazard. Both cases were complicated further by the inappropriate placement of a crib bumper inside the cradles, increasing the existing entrapment and suffocation hazard of two infants placed together in the confined space. In case #6, the 11-day-old infant was found with her twin in an antique cradle (rocking type considered likely), with her face pressed against the crib pad surrounding the crib, which was also described as an "overly large plastic bumper."
In cases # 9 and 22, infants were found pressed up against or wedged between (depending on EPIR summary source) the padded lining of a wicker basket. The padded lining is not a crib bumper pad.

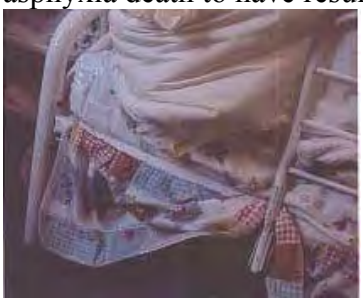
One case #10, involved a battery-powered rocking cradle/bassinet that came to rest in a tilted position, presumably due to the uneven weight distribution of the 2-month-old boy. (This cradle/bassinet did not rock from side to side but was "swung" from end to end by the battery-powered mechanism). He was found by his mother in the corner of the cradle with his head bent forward, and she stated that the baby died due to the tilt of the bassinet, and not the padding. The medical examiner ruled the death as "positional asphyxia," with manner of death accidental "awkward lie in cradle." It was noted that the baby's face was flattened. This is a recognized hazard in rocking cradles that fail to come to rest in a horizontal position.[31] Infants that slide to the downward tilted side/end are unable to extricate themselves from the compromised position. It is very likely that the infant scooted forward in the cradle so that the head end became maintained in a downward tilt causing the infant's body to be pushed against the padded lining of the cradle/bassinet. The lining of this product is not a crib bumper.

In case #18, the 11-month-old girl who could walk and climb out of her crib was found sitting on the floor, leaning forward with her neck caught by a crib bumper that had been used on a toddler

[30] Thach et. al., p.272. The authors report in the Methods section, "Files on these deaths and injuries were obtained and reviewed. Cases with evidence of non-traditional use of bumper pads were excluded. "

[31] *Ackerman J, Gilbert-Barness* E. Suspended rocking cradles, positional asphyxia, and sudden infant death. Arch Pediatr Adolesc Med. 1997; 151(6):573–5.; *Beal SM, Moore L, Collett M, Montgomery B, Sprod C, Beal A*.; The danger of freely rocking cradles. J Paediatr Child Health. 1995; 31(1):38–40. *Moore L, Bourne AJ, Beal S, Collett M, Byard RW*. Unexpected infant death in association with suspended rocking cradles. Am J Forensic Med Pathol. 1995; 16(2):177–80.

bed (erroneously described as a daybed in EPIR) to obstruct the gap at the foot of the bed between the side rail and footboard. She died when her lower body slid below the bumper, through the gap in the side of a toddler bed frame (near foot of bed), and her neck got caught by the top edge of crib bumper. Staff considers the medical examiner's conclusion of mechanical asphyxia death to have resulted specifically from a partial hanging strangulation.



In-Scope Cases:

Staff evaluated the 21 in-scope cases where crib bumpers were used inside a crib.
The authors included in their data search the time period in the mid-1980s, when a significant number of older cribs that did not meet the 1974 federal safety standards were still in use. As a result, there are a number of cases included that involve cribs with structural integrity issues, which create gaps that lead to entrapment hazards and bumper pads that did not meet voluntary standards for overly long ties. CPSC staff believes the hazards posed by the crib integrity issues are the primary hazard in these cases, and for many of the cases, believes that the infant would have died without the presence of the bumper in the crib.

In 10 of the 21 incidents (#s 1, 2, 7, 12 14, 20, 23, 25, 26, and 27), HS staff considers it was able to identify the actual cause (AC) of death.

- HS staff believes that three of the 10 crib deaths were attributed to overly long bumper ties (# 25, 26, and 27.) Staff acknowledges that the bumper ties likely caused these infants' deaths, which occurred in the 1985–1989 period. However, because this hazard was addressed by a change to the voluntary standard for crib bumpers in 2000 (which set a maximum tie length of nine inches), staff believes this hazard is not a concern for bumpers manufactured and marketed after the effective date of the standard.
- Two cases (#s 1 and 2) involved infant deaths that staff believes were likely due to faulty structural integrity of the crib, which created gaps where entrapment could occur. Large gaps between crib components or gaps caused by an ill-fitting mattress have been known to result in fatal entrapments. In one case (#1), a secondhand crib was missing most of its hardware, and the cause of death was reported as positional asphyxia. The infant in that case also had a history of sleep apnea, which staff considers a confounding factor. In the second incident (#2), the crib was missing a headboard and a mattress; pillows were used as an alternate headboard and alternate mattress. The 7-month-old girl was found lying supine with her head and neck hyper-extended into a 10-inch gap between the makeshift mattress and the pillow used as a headboard. A crib bumper was present and described as being "not secured

to the crib"; but there is no indication that it was involved in the death. Staff believes that the pillows used in the broken crib in place of the missing mattress and headboard, respectively, are the primary cause of this positional asphyxia death because they allowed a hazardous gap to form between them.

- In case #7, the child's mother reported having questioned the ME about the possible involvement of the bumper in her 13-month-old son's death. She quoted him as saying there was "no evidence of suffocation whatsoever," and she further reported that he told her the cause of death was attributed to a fatal cardiac arrhythmia related to his congenital heart defect, for which future corrective surgery was anticipated.

- One case (#12) involved a 4-month-old boy sleeping in a prone position with his twin sister. The bumper was not touching the victim's face; the narrative indicates that the infant was face down in the mattress, wedged between his sister and the bumper pad. Staff considers that this death resulted from wedge entrapment caused by multiple occupants in the crib. The presence of two infants in the relatively confined space of a crib created an entrapment hazard.

- One death (#14) was attributed to a mattress not set at the lowest position. This death was judged by staff to have occurred because the mattress was set too high for the height of the 10-month-old boy, reported to be large for his age. Thach considered that the bumper pad allowed the infant to climb from "a relatively safe environment" into a hazardous one. This conclusion, however, is not supported by the IDI, which indicates that the mattress platform was set at a position that allowed for only a 15-inch difference between the mattress surface and the top of the crib side rail. The projected height of an above average, 10-month-old is about 30 inches; and therefore, a 15-inch clearance would allow a child to fall or climb over the crib side rail, regardless of the presence of a crib bumper. The scene re-creation photograph shows the child was facing forward with his chin resting on the dresser; HS staff believes it is more likely that the child stepped out of the crib and fell in the space between the dresser and the crib.

- Case No. 20, related to multiple occupants and other confounders in the sleep setting, involved the death of a 2-month-old girl who was sharing the crib with a twin. The infant suffocated when she became entrapped face down on the crib mattress, in a 5–6 inch gap between a semi-rigid, homemade foam cushion and the crib side rail. The infants were each placed to sleep on separate foam cushions set on top of the crib mattress. Notably, the medical examiner told the state trooper to advise the mom "of the cause of death from the autopsy and to remove the cushions so the same problem wouldn't arise with the brother."

- In one case (No. 23, a 3-month-old girl was entrapped in a prone position by adult pillow(s) in her crib. The baby was originally placed to sleep on her side but was found on her stomach[32]. Despite the limited details, staff considers a pillow-related wedge entrapment to be the likely primary cause of this death because pillows are recognized as entrapment and/or suffocation hazards in a crib, regardless of the presence of a crib bumper.

In five cases (No's 5, 11, 15, 21, and 24) staff was able to identify the primary probable cause (PPC) of death.

- For case (No. 5), the IPII summary notes that the 14-month-old boy had his face pressed firmly against the bumper pad, but supplemental information includes an indistinct medical examiner's photo showing a baby face down on the mattress, with the top of his head touching the bumper. Moreover, the parents told police they found their son face down in the crib (or slightly turned to the left, according to the mom) with no objects close to his head. From a developmental perspective, HS staff believes that a healthy 14-month-old should be physically able to move his head if the airways became occluded, which suggests to staff that perhaps other confounders were involved. The boy was reported to have had a history of a prior severe respiratory infection that required extensive breathing treatment of an unspecified nature. HS staff believes it was more likely that preexisting respiratory issues (or other undocumented confounders) may have contributed to his death, because it is highly unlikely that the simple presence of a crib bumper could cause the death of a healthy 14-month-old child. Supplemental information received from the medical examiner on this case noted that this older boy had abnormal brain symmetry and had been recently diagnosed with reactive airways (asthma) and prescribed corticosteroid treatment, which was rejected by his parents. He had seen his doctor two days prior to death for congestion, so HS staff considers it quite likely that an acute asthma attack was involved in this unusual case of a 14-month-old child's crib death.

- In one case (No. 11) staff cannot rule out the bumper pad involvement, but consider it is not the primary cause due to multiple confounders such as soft bedding and co-sleeping in the same crib with her twin.

- Case No. 15 involved a pillow-related entrapment. Staff's initial opinion was based on the EPIR DTHS summary narrative, which indicated that the boy was found unresponsive in the crib and died from *positional asphyxia* due to being "*wedged between pillow and bumper pad.*" Despite limited details, and lack of information on the position of the infant's face, staff considered pillow-related wedge entrapment to be the primary cause of death because pillows are recognized as entrapment and/or suffocation hazards in a crib. Staff considers the

pillow caused this death and the crib bumper appears irrelevant as the primary cause. Staff's initial view is supported/confirmed by supplemental information in an autopsy and coroner's report, which confirmed that the baby was found lying face down in his crib. His head had been "resting on a pillow covered with a blanket .... the infant's head was sort of slipped off the pillow and his head was wedged between the pillow and the bumper inside the crib"; "Anatomic findings note: "Pattern of skin marks which matches the pillow cover is seen over the face"; Additional crib contents included, two baby blankets, a thick blanket used as a mattress pad, and a thick bumper pad surrounded the entire inside of the bed."

- In case No. 21), which occurred in the early 1990s, an 8-month-old girl was found on a waterbed mattress, face down into thick bedding (comforter, two thick blankets, two sheets, and a mattress pad). The medical examiner ruled this to be a SIDS case 20 years ago. Staff notes that current views are that SIDS deaths in healthy 8-month-old infants are rare. Staff considers that the older waterbed mattress, used with multiple layers of thick bedding between the baby's face and the mattress, presents a suffocation hazard that more likely explains the death of this prone, older infant. Other hazards present in the crib included two very large stuffed toys, one near the victim's head. The toys were used to brace the infant's head when the infant was younger. Given the bedding and other crib contents, staff considers that the bumper did not have a clear role, if any, in the death.
- Case No. 24, ruled a SIDS death by the medical examiner, involved a 2-month-old infant who was found face down in a thick quilt.

Unknown Cases (Unk):

- There were six cases where the existing case data were limited, unknown, inconsistent, ambiguous, or otherwise unclear, precluding staff's ability to make a reliable determination of the primary cause of death and the bumper's role (No's. 3, 8, 13, 16, 17 and 19).

- In one case (No. 3), a coroner ruled the death as positional asphyxiation several months after the incident. However, HS staff notes that confounding medical issues were likely involved in the infant's death because the 7-month-old was reported by first responders to have had blocked airways and locked jaws, and he was known to be on antibiotics for a respiratory infection. He was also reported to have bilateral lung hemorrhages at an autopsy conducted by a pathologist. The babysitter reported the infant was lying on his back with his face turned to the right side and his face was "up into the corner of the bumper pad." HS staff considers that this older child lying on his back should be developmentally capable of moving his head if his face is obstructed and believes that he may likely have died from a medical issue related to complications of a known respiratory infection. Supplemental information indicated that this supine child had a crease in his forehead and a denuded tracheal epithelium.

- Case (No. 8) involved a 3-month-old boy found lying prone. The mother stated that the bumper pad "was not close to the infant's face"; the medical examiner ruled the cause of death as probable SIDS.

- In case No. 13, multiple confounding factors were noted. For example, a sagging bumper pad and thick blankets were found in the crib. The father indicated to police that he found his 4-month-old son in a prone position and that he had his "arms up and his face into the soft padding." The bedding and prone position confounders make it unclear whether the bumper had a secondary role or acted as a secondary entrapment surface in this death.

- In three cases (Nos. 16, 17, and 19), the infant was reportedly found with its head wedged against the side of the mattress, wedged between the crib sides and the mattress, or entrapped between the crib side wall and the mattress edge, respectively. This is indicative of a problem either with the crib structure or mattress fit within the crib frame, which can result in a gap presenting an entrapment hazard. Staff notes that an excessive gap between the crib frame and mattress is a recognized hazard that can cause death by mechanical or positional asphyxia/suffocation (and even hanging strangulation if the gap is very large). In only one case (No. 17) was the baby's face reportedly contacting the crib bumper. Supplemental information in the medical examiner's investigation narrative specifies that he was found prone, face down, but does not actually specify whether his face (nose and mouth) was in contact with the bumper.

Discussion and Conclusion:

HS staff's findings and conclusions differ significantly from those published in the 2007 Thach paper. Staff believes the differences in interpretation were due in large part to the fact that the authors did not consider the full details for each case, including confounding factors in the death scenarios, which, in many of the cases, were considered by CPSC staff as the likely causative factors of the death. It also appears to HS staff that the different conclusions are due to Thach et al.,: (1) missing overlooking key information from some of the autopsy reports and death scene investigations; and (2) using only the limited information found in EPIR database case summaries (and in some cases omitting key EPIR summary details) to draw definitive conclusions. Ignore omit

Contrary to the conclusion of the Thach paper, the CPSC staff analysis of the 27 cases, with the exception of three cases,[33] showed that there was no conclusive evidence implicating crib bumper pads as a primary cause of death when the bumpers were properly used in an appropriate infant sleep setting. Furthermore, it appears that the authors viewed association or mention of a bumper as indicative of cause and effect, regardless of the presence of other likely risk factors. It is not clear to HS staff whether the authors had access to all source documents, IDIs, IPII, and

[33] The exception to this is three cases identified in the Thatch paper that involved strangulation of the infant on bumper ties that were too long. This hazard was subsequently addressed by a voluntary standard.

DTHS documents, although wording unique to these documents was incorporated into some of the Thach case summary narratives (as opposed to text from the EPIR summary). It is also not clear whether key information from the autopsy reports and death scene investigations was omitted or was not available to the authors. Although the authors stated that "Files on these deaths and injuries were obtained and reviewed,"[34] there is no record of such a request submitted to the CPSC Office of the Secretary under the Freedom of Information Act (FOIA). [35]

In large part, it appears that the authors failed to consider recognized risk factors related to: (1) the infant prone sleep position, a known high-risk factor for SIDS and suffocation in young infants between birth and 4 months; (2) the position of the infant's body, especially the infant's head and face, calling into question whether the infant's airway openings were blocked (*i.e.*, occlusion of the mouth and nose); and (3) premature infants and/or infants with preexisting medical conditions, particularly those with respiratory issues, at the time of the death. Infants who are premature or who have certain birth defects are at higher risk of suffocation because of developmental delays and compromised respiratory systems. It is unclear why this information was not considered by the authors because most of the cases presented strong evidence of confounding factors.

The death of an infant is a tragic event, no matter what the cause. Based on the weight of evidence, staff does not find a correctly installed and properly secured (*i.e.*, according to manufacturer's direction) crib bumper to present a primary risk of infant suffocation in a crib. Staff believes the Thach paper has reported an unsubstantiated risk attributed to crib bumper use and has resulted in subsequent well-intentioned, but misguided urgings by outside parties, including the AAP, recommending that bumpers should not be used in the infant sleep environment. It is clear from the case information that other serious hazards in the infant sleep environment existed that are of significantly greater concern than crib bumpers. These very real hazards of great concern to staff are:

- Prone Sleep Position—the prone sleep position is a known risk for SIDS; yet, young, particularly vulnerable infants are still placed in this position to sleep, as evidenced by the data HS staff reviewed.

- Pillows—pillows placed under or around an infant create hazardous suffocation and/or entrapment risks (according to CPSC data, about 38 deaths a year are attributed to pillows in the sleep environment[36]) compared to 27 deaths in 20 years reported in the Thach paper.

[34] Thach et. al., p.272. The authors report in the Methods section, "Files on these deaths and injuries were obtained and reviewed. Cases with evidence of non-traditional use of bumper pads were excluded" and went on to say in the Results discussion: "In 26 cases, a death scene investigation was to be conducted. In one case it was uncertain whether a formal investigation was made.

[35] There is no record of such a request submitted by authors to the Office of the Secretary under the Freedom of Information Act (FOIA). (only a search of case summaries from the CPSC clearing house.)

[36] 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 National Conference and Exhibition, San Francisco, CA, October 2-5, 2010. Section on Injury, Violence, and Poison Prevention Data, 1992–2010.

- Crib Integrity Issues—broken cribs, makeshift cribs, cribs missing hardware, improperly fitting mattresses or makeshift mattresses, all of which can create gaps that can lead to entrapment and suffocation and hanging strangulation risks.

- Other Objects in the Sleep Environment—anything that crowds the sleep environment for an infant can present a hazardous entrapment and/or suffocation hazard. This includes a sibling twin, adult size pillows, and specialized infant products, such as nursing pillow, carriers, and infant seats.

Link to Table A (spreadsheet file)

TAB F: Project Manager, Infant Suffocation Project (1992-1995) Memorandum

TAB F

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

Memorandum

Date: 5/15/2013

TO : Jonathan Midgett, Ph.D., Children's Hazard Team Coordinator
Office of Hazard Identification and Reduction

FROM : NJ Scheers,[†] Ph.D.
Project Manager, Infant Suffocation Project

SUBJECT : Analysis of Crib Bumper Deaths

The Juvenile Products Manufacturers Association (JPMA) petitioned the U.S. Consumer Product Safety Commission (CPSC) on May 9, 2012, requesting that the Commission adopt a rule to define and distinguish between hazardous pillow-like crib bumpers from nonhazardous traditional crib bumpers.[1] This memorandum reviews reports of fatalities related to crib bumpers that were identified by CPSC staff and identifies hazard patterns associated with the deaths.

BACKGROUND

Soft bedding can cause suffocation, entrapment, and strangulation in infants and young children. A number of studies have identified pillows, quilts, comforters, and other soft surfaces as particularly hazardous.[2,3,4,5,6,7] However, diagnosing suffocation as the cause of death is challenging and, with few exceptions, requires an autopsy to rule out other medical explanations for the death, including an investigation to review the death scene and the position of the infant in relationship to soft bedding when he or she was found unresponsive. Furthermore, suffocation and sudden infant death syndrome (SIDS) can be confused because these deaths are indistinguishable at autopsy. SIDS is a diagnosis of exclusion that remains unexplained after an autopsy, death scene investigation, and review of the infant's history find no other explanation for the death.[8] Recent studies found that while the rate of SIDS declined by more than 50 percent from the early 1990s, this rate has plateaued recently. With the increased use of death scene investigations for infant deaths, more deaths are being classified as "accidental suffocation and strangulation in bed." [9, 10, 11]

Crib bumpers are a form of soft bedding that received little attention until recently. Only one study of deaths attributed to crib bumpers has been published. This study consisted of a review of 27 crib bumper deaths from CPSC's data files.[12] Since the publication of that study, the American Academy of Pediatrics,[13,14] Health Canada,[15] and the National Institute of Child Health and Human Development,[16] among others,[17] have recommended against the use of crib bumpers, and two jurisdictions, the state of Maryland[18] and the city of Chicago,[19] have enacted a ban on the sale of crib bumpers.

[†] NJ Scheers was the project manager for the CPSC's Infant Suffocation Project, responsible for the design and implementation of a 3-year national study to determine if some infants diagnosed as SIDS actually suffocated unintentionally in soft bedding. Her work has been published in peer reviewed journals (endnotes 3, 4); she has presented at numerous conferences on safe sleep; and she has served as a consultant to the American Academy of Pediatrics task force to develop recommendations for safe sleep environments.

There are several hazards that may cause infants to suffocate in crib bumpers.[12] Wedging deaths occur when the infant's head becomes stuck between two surfaces and the infant cannot extricate itself.[20,21] Wedging prevents the infant from turning or lifting its head, and if wedged into a corner, the baby is entrapped and the baby's lack of motor skills may not allow the baby to back up. In some wedgings, the infant may be found face down between the two products, and it may not be clear what is covering the infant's face. However, in this scenario, the infant is in an enclosed space, a suffocating environment, which has the same effect as breathing into a paper bag. Note that while two surfaces are needed for a wedging to occur, if one surface is removed, such as the crib bumper, the wedging death will not occur. Wedging can occur with two different products; the same product, such as a pillow-like bumper that expands around the infant's head, or a product and a second infant.

Another hazard pattern occurs when infants are found with their face against the crib bumper without evidence of wedging. The mechanisms are likely rebreathing or nose and mouth compression, or both. Rebreathing is a suffocation hazard that is related to the capability of the infant to arouse from a suffocating environment.[22,23,24.25,26] Rebreathing can occur when the infant's face is against soft bedding, its expired air is trapped in the bedding, and the resulting microenvironment has low levels of oxygen and high levels of carbon dioxide. The infant rebreathes the carbon dioxide that accumulates in the bedding and suffocates. If an infant turns its head to get fresh air, the infant is unlikely to suffocate. However, studies have found that the part of the brain that regulates arousal may be defective in some infants so that they would be less likely to turn their heads to escape such a suffocating environment.[27, 28] Studies with experimental animals have shown this environment to be lethal and to cause hypercarbia and hypoxemia in living infants.[24, 29]

A third hazard is strangulation, where an infant becomes tangled in the ties used to attach the bumper to the crib. Long bumper ties are subject to a voluntary standard created many years ago and limited to nine inches in length so that they are capable of being tied to the end posts of a crib.[30] Since that time, CPSC staff is not aware of any fatalities caused by crib bumper ties, although incidents from loose bumper ties have been reported to the agency.

In reviewing the deaths in this series, the diagnoses by the medical examiners (MEs) and pathologists who were responsible for determining the cause and manner of death[31] were assumed to provide the best evidence for how the deaths occurred for several reasons: (1) medical examiners/pathologists are licensed physicians with specialized training in pathology and expert in diagnosing the cause and manner of death. (2) The ME's investigators, police departments, or other agencies are "on the spot," and conduct death scene investigations quickly when an infant dies, usually within hours of the infant's death, and provide this information to the MEs/pathologists. (3) Caregivers who found the infant are interviewed, and if emotionally capable, re-create how the infant was found by placing a doll or other facsimile.[32]

METHODOLOGY

Bumper-related suffocation deaths in cribs[33] were identified through a search of CPSC's databases[34, 35] for January 1, 1985 through October 31, 2012. A goal of the review was to assemble a core set of cases that had, at a minimum, an autopsy and death scene investigation, and where possible, photographs of the death scene. Therefore, additional information was requested from the states when this information was lacking in CPSC data files and collected for 50 percent of the cases. While attempts were made to obtain death certificates, an autopsy sufficed because the medical examiner or pathologist is responsible for determining the cause and manner of death for the medical part of the death certificate.[36] A total of 76 deaths in cribs, including 5 deaths from the 1980s and reported to CPSC during this time period, satisfied the search criteria (as below).

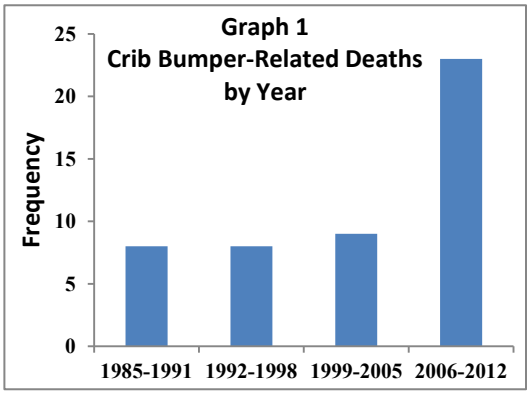
- There were 42 crib bumper-related suffocation deaths, as determined by the ME/pathologist (*e.g.*, positional asphyxia, asphyxia, suffocation) and noted on either the death certificate, in the autopsy, or in the investigation. In almost all cases, the narratives on the death certificate, autopsy, or investigation specifically attributed the death to a crib bumper (*e.g.*, "face wedged against pillow and bumper"). In two cases, the wording was less specific (Cases 4 "side rail padding," and 1988b "mattress and crib pad" causing the death).

- Five cases were diagnosed as sudden infant death syndrome (SIDS) and one case as a sudden unexplained infant death (SUID).[37] These were judged by the author as "likely" or "possible" to be bumper related. Three of these cases occurred in the early 1990s, when most sudden and unexpected deaths were diagnosed as SIDS. See Appendix A for a listing of the 48 cases with the official cause of death, autopsy findings, and investigation narratives.

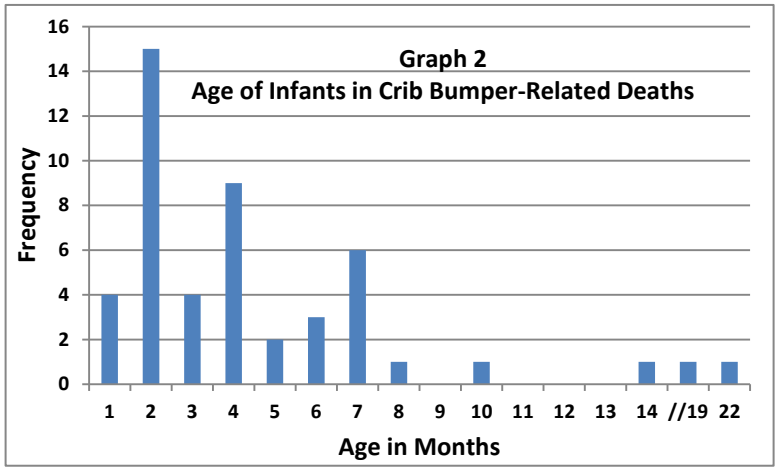
- Twenty-eight deaths were determined to be out of scope for this review because the deaths: were not related or incidental to crib bumpers; occurred outside the crib; or were diagnosed with a specific disease by ME/pathologist.

For the 48 bumper-related deaths, autopsies were available for 97.9 percent, death scenes and other investigations for 97.9 percent, death certificates for 75.0 percent, and photographs for 62.5 percent of the cases, including 17 reenactment photographs of how the infant was found unresponsive.

DATA ANALYSIS OF REPORTED CASES



Death Reports by Year. Crib bumper deaths were grouped by year in 7-year intervals. There were 23 reports of bumper-related deaths in 2006 through 2012, more than double the number of crib bumper deaths for each of the previous three intervals (Graph 1) and was significant with a one sample chi square test ($p<.004$).[38] This increase may represent a number of factors, such as an increase in reporting by the states, a diagnostic shift in cause of death diagnoses, or both, rather than an increase in crib bumper deaths. Thus, the number of crib bumper deaths in this study should be considered a minimum count.



Age at Death. Most infants who died with crib bumpers were very young. Almost 50 percent were 3 months old or younger, and 90 percent were 7 months old or younger. The spike in deaths at 2 months was primarily due to wedging deaths with crib bumpers (Graph 2).

There were three infants who were much older than the average. The oldest infant, who died at 22 months, had cerebral palsy. He was sleeping in a positioner and was found with his face against the crib bumper completely outside the positioner (Case 44). The next oldest, at 19 months old, had significant brain injury at birth (chronic anoxic encephalopathy due to meconium aspiration). She

was found with her face wedged between the bumper and the mattress; this was the first time she had rolled over (Case 34). However, the third oldest child, a 14-month-old, was healthy with a recent history of cold symptoms (Case 14).

Sleep position was available for 43 infants (Table 1). Most infants were placed prone or supine to sleep. All but one of the infants placed prone (13) were found prone (12). Of the 16 infants placed supine, 8 were found prone. Of the four infants placed on their side, two were found prone. The position placed to sleep was unknown for 13 infants; 7 of these were found prone.

Table 1
Position Placed to Sleep by Position Found

		Position Found				
		Prone	Side	Supine	Unknown	Total
Position Placed	Prone	13			1	14 (29.8%)
	Side	2	1		1	4 (08.5%)
	Supine	8	3	5		16 (34.0%)
	Unknown	7	2		4	13 (27.7%)
Total		30 (63.8%)	6 (12.8%)	5 (10.6%)	6 (12.8%)	47 (100%)

Hazard Patterns. There were three primary hazard patterns for infants who died with crib bumpers: (1) wedging between a crib bumper and another object; (2) face against the bumper with no wedging reported; and (3) strangulations. Most infants were found wedged between a crib bumper pad and another object and one infant was found wedged outside the crib (68.8 percent, n=33). Infants found with their face against a crib bumper with no wedging reported accounted for 25.0 percent of the deaths (n=12). Strangulation from bumper ties or strings represented 6.3 percent of the deaths (n=3). (Appendix A provides summaries of the 48 cases sorted by hazard pattern.)

The following sections are case reviews to provide some context to the Medical Examiners/pathologists' diagnoses of suffocation deaths from crib bumpers. A number of other factors were present in some of the deaths (*e.g.*, cluttered cribs, prone sleeping, incorrectly tied bumpers, minor or significant illness, positioning devices), as described in the investigation narratives. While important to consider, the MEs/pathologists are provided this information from the death scene investigations.

WEDGING DEATHS WITH CRIB BUMPERS

Thirty-three infant deaths were classified as wedgings, based on the narratives in the autopsy findings, death certificates, and investigations. Infants were found wedged between a crib bumper and: (A) a mattress (n=13); (B) a pillow or cushion (n=9); (C) with recliners (n=5); or (D) other objects and outside the crib (6).

Wedging deaths primarily involve the infant's face, and more specifically, the small area of the nose and mouth, and usually not the whole body. "… [I]nfants have bigger and heavier heads relative to their small body size and less developed neck muscles, making it easier for their heads to become trapped in and harder to extricate from a dangerous position."[39] The lack of motor development also plays a part for some infants who are unable to escape a suffocating environment.

A. Wedging between a crib bumper pad and a crib mattress. The death certificate, autopsy, or investigation narratives typically attributed the cause of these suffocation deaths to wedging between a mattress and crib bumper (#s 4, 8, 9, 14, 15, 21, 34, 49, 54, 58, 59,1988a, 1988b). However, for one death with limited information because records were no longer available (#1988b), the description of the

wedging, "mattress and crib pad causing suffocation," did not specify a crib bumper. This case was included as a crib bumper case because the phrase, "crib pad," has been used by medical examiners in the past as a synonym for a crib bumper. Two deaths that occurred in 1991 and 1992 were diagnosed as SIDS (Cases 4, 9), one with a death scene re-creation. The investigation narrative or scene photographs indicated that the baby was wedged.

There was no mention in the autopsies, death certificates, or investigations of a structural problem with a crib or an ill-fitting mattress contributing to these wedging deaths.

Below are examples of wedging deaths with crib bumpers, with photographs from the death scene.

Figure 1 (Case 59). A 1-month-old was placed to sleep in a sleep positioner. The parents used the positioner to prevent the infant from rolling over and from getting a flat head. The infant rolled *completely out* of the positioner and suffocated "… from the face being wedged between a crib bumper and a mattress." The father reported that the baby had a viral fever 2 weeks before his death and went to the hospital for 2 nights; however, the fever was gone within 24 hours. On the night of the death, the family, including the infant, had been experiencing flu-like symptoms.

Figure 2 (Case 21). A 4-month-old was placed to sleep prone because he would cry lying supine. The father found the baby on his stomach with his "arms up and his face into the soft padding." An indentation can be seen in the bumper and the ME attributed the death to "Asphyxia by suffocation, infant became wedged between the mattress and the bumper pad of his crib." There were two thick blankets in the crib, but they were not found between the infant's face and the bumper. The bumper appears to be installed incorrectly as it is sagging inward.

FIGURE 1

FIGURE 2

Figure 3 *(Case 9).* A 2-month-old was found unresponsive by his mother. He had been placed to sleep prone and was found prone. He was reported to be in good health and diagnosed as SIDS. In 1992, CPSC was conducting a special study to explore whether some infants diagnosed as SIDS had actually suffocated in soft bedding. CPSC investigators conducted an extensive on-site investigation and photographed the death scene re-created by the caregiver, who found the infant unresponsive. The infant was found with his face on top of a comforter and wedged in a corner in the bumper pad that did not allow him to lift or turn his head. The medical examiner was unaware of CPSC's investigation results when he conducted the autopsy on the day after the infant's death, and finding no medical reason for the death, diagnosed it as SIDS.

Figure 4 (Case 58). There was extensive information about the death of this 6-month-old infant. The grandmother bought the bumper before the birth because she thought it was part of what was required for caring for a child. The autopsy findings were, in part: "Suffocation in non-standard sleeping environment: (A) infant reportedly found face-down with face wedged between mattress and bumper pads of crib; (B) numerous pillows, blankets, and stuffed animals present within the crib."[40] The mother re-enacted how she found the baby and reported that the baby's left arm was over the pad, and he appeared to have been pulling the bumper pad toward his face. From photographs in the official documents, it appears that the bumper pad was not tied correctly to the corner post but had been tied to the slat next to the corner post, allowing the bumper to sag.

FIGURE 3

FIGURE 4

B. Wedging between a crib bumper and a pillow. Infants became trapped between a pillow and a crib bumper pad, if they were placed to sleep on top of pillows, or if pillows were placed in the crib with the sleeping infants. The death certificate or investigation narratives all listed the cause of death as wedging between a pillow and crib bumper (#s 6, 10, 13, 26, 46, 47, 61, 66, 71). Most of these deaths occurred with infants who were placed to sleep on top of pillows (#s 13, 46, 47, 61, 71), including a nursing pillow (# 66). It may be that caregivers were attempting to mitigate some health problems for their infants. One infant with a history of gastro esophageal reflux (acid reflux) could not sleep without the pillow (# 47). Another infant, who was sleeping prone, was taking over-the-counter medication for gas (#71). A third infant, born with a small hole in her heart and with poor weight gain, had a chronic cough (#13). A fourth infant, who had a stuffy nose, was taking antibiotics, and her caregiver used a sofa cushion to elevate her (Case 46). She was placed supine to sleep in a crib with two adult-size pillows at one end of the crib, a blanket, toys, mobile, and a jewelry box.

C. Wedging between a crib bumper and an infant recliner. Five deaths occurred in infant products that reclined but were not intended for use in a crib: four infant recliners from the same manufacturer and one 'bouncy chair," all with harnesses. The causes of death were diagnosed as: asphyxia (Cases 60, 64, 65), SIDS (Case 69) and Sudden Unexplained Infant Death (SUID, Case 70). Four of the five infants had been placed in the recliners unstrapped to their harnesses. For three deaths, the infants were found lying across the infant recliners with their heads tilted back and their faces against the crib bumpers.

The infant recliners were all used by caregivers to help prevent acid reflux. For example, in the case described below (Figure 5), the infant's mother described the acid reflux as "severe." For another infant (Figure 6), a "bouncy chair" was used in a modified crib to make it easier to breastfeed.

Figure 5 (Case 69). A 4-month-old was placed to sleep in an infant recliner. When found unresponsive, the infant was lying perpendicular to, and on top of, the recliner in his crib with his head hanging off the

recliner and his entire face pressed into the side crib bumpers. From birth, the baby suffered from "severe acid reflux," and his mother reported that he "always threw up half what he ate all the time." The mother bought the recliner after an Internet search found the infant recliner advertised (at that time) to help with reflux. The medical examiner diagnosed the cause of death as SIDS.

Figure 6 (Case 64). A 5-week-old 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 baby. A blanket was placed on top of the bouncer and another blanket was used to cover her. The crib's guard rail had been removed to allow the crib's mattress to be level with the bed, allowing easy access to the baby at night for breast feeding. The baby 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 cause of death was suffocation in an unsafe sleep environment.

FIGURE 5

FIGURE 6

One death diagnosed as SUID (Case 70) is included here because it a crib bumper-related death. In this case, a 7-month-old was placed in a reclining infant sleeper, with the cover and the harness missing, inside a full-size crib with a bumper pad. The mother found the infant 2 hours later, unresponsive 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. The baby's face was downward, and the mother reported that his head had not fallen all the way to the crib mattress surface. His head was up at the level of being near the top of the cushion, crib rail, and/or the bumper pad. The ME noted: "As the cause of death remains unknown with certainty and accidental asphyxia cannot be excluded, the manner of death also remains undetermined."

D. Wedging between a crib bumper and another object. Infants were also found wedged between crib bumpers and other surfaces, as well as one wedging outside the crib (Cases 16, 28, 35, 36, 43, 63). For example, three infants died when their arms became wedged under a bumper pad with their faces became pressed against the bumpers (Cases 36, 43, 63). For one of the infants, the bumper was tied to the corner posts incorrectly. Another infant, 4 months old, became wedged between his twin and a bumper pad (Case 28). He had a history of acid reflux, and his physician recommended that he be placed to sleep prone or on his side.

Figure 7 (Case 35). One wedging death occurred in a defective crib. The parents bought the crib at a thrift store and tried to fix it. The autopsy narrative noted "… the corners of the crib mattress were unsupported due to ill-fitted wood [support] slats. The infant was found in the corner of the crib with its face buried in a quilt and bumper pads." In this case, the bumper would contribute to the wedging by making it very difficult for the infant to raise her head and turn her face to the side to avoid suffocation.

Figure 8 (Case 16). One wedging death in this series occurred outside the crib and involved a 10-month-old boy. The infant was found "in an upright position with his chin resting on the edge of the dresser and the back of his head against the side rail of the crib," a scenario more likely to have occurred if he stood on bumper and fell facing the dresser," as noted by the ME's investigator. If he climbed over/rolled over/crawled over the bumper/crib rail, he would be more likely to fall parallel to the crib. While bumper involvement is somewhat speculative, it is a likely scenario of using a bumper to climb out of a crib.

FIGURE 7

FIGURE 8

FACE AGAINST THE BUMPER

There were 12 bumper-related deaths, where the primary description of the deaths from the ME/pathologist or investigation was that the infant suffocated with their face against a crib bumper pad. The mechanism of suffocation with these deaths is likely to be airway occlusion or failure to arouse with subsequent rebreathing. Infants were found with (A) their face into the corner of the bumper, or (B) along the side.

A. Face in Corner. It is not unusual for the death scene investigation to note that the infant was found with its face in the corner of the crib pressed against the crib bumper (Cases 20, 30, 37, 40, 42).

Figure 9 (Case 20). This 7-month-old child was found lying supine with his face in the corner of the crib and covered by the bumper pad. As reported in the autopsy: "this position "… would cause asphyxiation due to obstruction of airflow. A crease noted on the infant's forehead is consistent with an impression from the edge of the crib and further supports this conclusion." He had a respiratory illness, but neither his physician, nor the pathologist who conducted the autopsy, found that this illness played a part in his death.

FIGURE 9, TWO PHOTOGRAPHS

Figure 10 (Case 42). In another case, a 5- month-old was found with his face buried as if "snuggling" on top of the thick soft crib bumper padding in the corner of the crib. While the baby had been placed prone to sleep with thick bedding and stuffed toys in the crib, the police investigation reported that the position of soft bedding in relationship to the infant had minimal involvement. In the re-creation (Figure 10), the mother placed the bumper under the doll's nose and mouth. The autopsy opinion reported that the death was due to "positional asphyxia while laying (sic) face down in thick soft bumper padding bedding at the corner of the crib."

FIGURE 10

B. "Face Against" Bumper Side. For other suffocation deaths, infants were found with their heads against padded bumpers rather than in the corner of the crib (Cases 27, 32, 44, 56, 62), including two deaths diagnosed as SIDS from the early 1990s (Cases 2, 38). In one of these SIDS cases, a mother reported that the "infant had scooted up on the mattress and the right side of his face was against the side of the crib pad." The investigator noted that the mother "suspects he smothered or suffocated." For the second SIDS death, the infant was found "with face against plastic bumper" but with little additional information.

For two deaths described below, both had wet stains that intersect with the bumper and indicate that the infants were up against the bumper sides.

Figure 11 (Case 62). A 3-month-old was placed to sleep prone and was found "face down on the corner of a pillow with his head up against the padded bumpers," with the cause of death diagnosed as positional asphyxia. There was a wet spot on the pillow that goes to the edge of the bumper where the baby was found face down shown in the first photograph. Reenactment (with a bare crib) shows the baby up against the crib railing where the bumper would have been. While the investigator reported a cluttered crib, the clutter was not between the infant's face and the bumper.

Figure 12 (Case 56). A 2-month-old was placed prone to sleep as he was unable to sleep supine. The father who found the infant was not sure if the decedent's nose or mouth was obstructed but reported that his head/face was against a cloth bumper. He was too upset to do a doll reenactment. The investigator noted that 'where the bumper intersects with the mattress, there is a moderate sized wet area with bloody emesis in the center of the wet spot. This is reportedly the area where the decedent's head was located when he was found. The bumper also appeared to be slightly wet, but it was difficult to tell if there were any stains because it was patterned."

FIGURE 11, TWO PHOTOGRAPHS

FIGURE 12

Two of these deaths occurred in cribs with structural integrity problems (Cases 27, 32 shown in Figure 13). For the first case (Case 27), the crib was missing the headboard and mattress, and there were several large pillows used as a mattress and for the headboard. The ME determined that the death was due to "pressure against an overstuffed crib bumper during sleep," and the investigation reported that lividity[41] markings were consistent with the baby lying supine with her head extended into the gap between the crib bumper and the pillow.

Figure 13 (Case 32). With this death, the ME described the infant as found "with his neck extended and face buried in a bumper pad. His nose and mouth were completely blocked by the pad, confirmed by the lividity pattern on the decedent's face … and indicates an inability to breathe due to body position (positional asphyxia)." The photograph of the bumper shows an indentation where the baby's face was found, while the reenactment photograph is limited because the rigidity of the doll prevents the reenactment from showing the neck extended. The missing hardware did not seem to affect the crib bumper, which was securely fastened to the crib slats with no sagging.

FIGURE 13, THREE PHOTOGRAPHS

The last case in this category is a death of a 22-month- old child with cerebral palsy placed to sleep in a sleep positioner (Case 44, described previously). The child was developmentally delayed and had little muscle control, although he no longer had seizures of any kind. He slept in a sleep position to support him through the night. His father found him at the end of the crib "his face pressed against the crib bumper pad" along the side of the crib. Although the father re-created the death scene, photographs of the recreation were not available.

STRANGULATIONS

Three deaths (Cases 1985, 1987, 1989) from the 1980s were caused by bumper ties becoming wrapped around an infant's neck. In one case, an infant apparently placed her head through a loop that formed by the bumper ties and strangled. Since that time, this hazard of excessive bumper tie length has been addressed by a voluntary standard.[30]

SUMMARY AND DISCUSSION

There were 48 deaths in this series that were either causally related or associated with crib bumpers. Of these, the author identified 42 deaths as bumper related and 6 deaths as "likely" or "possibly" bumper related (5 diagnosed as SIDS and 1 as a SUID). With few exceptions, the diagnosis of the ME or pathologist specifically attributed the deaths to asphyxia with crib bumpers. It is problematic to reach a different diagnosis than the ME/pathologists who: had the benefit of first-hand knowledge in diagnosing these cases; have the legal responsibility to determine the manner and cause of death; and who, with few exceptions, clearly stated the cause of death on the autopsy or death certificate in the reported cases.

Deaths from crib bumpers are rare, but they do occur and are likely to be underreported to CPSC. The National Fatality Review Board (NFRB) has reports of 32 crib bumper-related deaths from 2008 to 2011, from 37 states. For this same time period, CPSC has 13 reports of crib bumper deaths from 26 states, with only 3 that match with the NFRB cases.[42] Also, because CPSC does not have a product code for crib bumpers, it is challenging for staff to identify bumper deaths from wording on the death certificates. Often synonyms are used (*e.g.*, "crib rail padding," "padded crib wall") and only through manual searches are bumper-related cases identified and then verified through collecting additional information from the states. Finally, some MEs/pathologists continue to diagnose such deaths as SIDS, to spare caregivers from the grief that they may have been able to prevent their infant's death.

A number of "risk factors" were present in the deaths (*e.g.*, cluttered cribs, minor or significant illness, incorrectly tied bumpers, prone sleeping, positioning devices).[43] The MEs/pathologists likely knew and considered these factors during the investigations as they made their final diagnoses. As risk factors, these conditions may be associated with suffocation deaths for a population, but are not necessarily the cause of death in a specific case. With the exception of illness, these factors can be thought of as "foreseeable misuse" by consumers with a very vulnerable population. The CPSC has addressed "foreseeable" misuse with other consumer products and in its regulation.[44] The language in CPSC's FHSA statute and the legislative history note that reasonably foreseeable misuse (underline in original) of a product can also give rise to a mechanical hazard and that "the Commission has in the past taken regulatory action with respect to products where the hazard resulted from reasonably foreseeable consumer misuse."[45]

Clutter in the Crib. The descriptions from some of the investigations noted a cluttered crib filled with pillows, blankets, comforters, adult pillows and stuffed toys. These conditions may or may not be part of what "caused" the death. While CPSC and others advise against clutter in the crib, objects in the cribs that were not in physical contact with the infant's face would not be considered contributory in any way, but are reported to provide a complete description of the death scene. The important question to ask is "what is the exact cause of death at that moment in time?" If there is nothing against the infant's nose and mouth except the bumper, or if the baby is wedged between a bumper and another product, the fact that the clutter is elsewhere in the crib was judged by the MEs/pathologists as not relevant to the death.

Medical Issues. In three cases (Cases 13, 34, 44) there were significant medical issues: one infant with cerebral palsy, another with significant brain damage, and a third was born with a small hole in her heart. In all three cases, the medical examiners were well aware of the medical issues and determined that the deaths were due to asphyxia by the crib bumper. For example, the ME's conclusion for the child with cerebral palsy was: "It is my opinion that [name], a 22 month old white male with severe cerebral palsy died as a result of asphyxia due to obstruction of the nose and mouth by the crib bumper pad when he maneuvered into a position while sleeping from which he could not extricate himself." While the three very ill infants may have been susceptible to suffocation, in the final analysis they died because of wedging with a crib bumper and may have lived if the bumper was not in the crib. Investigators also queried caregivers about minor illness such as respiratory illnesses (colds, flu). These minor illnesses were all ruled out as the cause of death at the autopsy.

Bumper Ties. There were five cases identified in the series with bumper installation problems. In some cases, bumpers were tied incorrectly. They were not tied to the corner posts but to the side slats or not all the bumper ties were used, allowing the bumper to sag. Installing a crib bumper would appear to be a simple task for a caregiver and some may not understand the difference between tying the bumper to the corner post rather than to the next slat.

Prone sleeping. In 1994, National Institute of Child Health and Human Development conducted a *Back to Sleep* campaign and recommended against prone sleeping.[46] Since then, supine sleep positioning in the United States dramatically increased from 13 percent in 1992, to 74 percent in 2009.[47] Prone sleeping with soft bedding poses a suffocation risk, particularly for those infants turning into the facedown position with nose and mouth covered.[3,24,28,48,49] One sleep study of living infants in their own beds showed they spontaneously positioned their faces so that their external airways were covered.[50] Another study found that infants who are inexperienced in prone sleeping had a decreased ability to escape from an asphyxiating sleep environment when placed prone.[51]

Infants may also roll from a nonprone position to a prone position during sleep. For example, one study found that for infants who were ≥24 weeks of age, 14 percent who were placed supine were found prone, and 18 percent placed on their side were found prone.[52] In this series of 48 crib bumper-related deaths, 10 infants placed to sleep in a nonprone position were found prone. Because of the concern that infants may roll to the prone position, the AAP recommends: "To prevent suffocation or entrapment if the infant rolls, soft or loose bedding should continue to be removed from the infant's sleep environment," and also recommend against the use of crib bumpers.[14]

Infant Sleeping Products. Two infants died after completely rolling out of infant sleep positioners, and five infants rolled out of an infant recliner, including a "bouncy chair," and died with their faces up against a crib bumper. The Food and Drug Administration (FDA) and CPSC jointly recommended that caregivers stop using sleep positioners, unless specifically prescribed by their pediatricians for the management of gastro esophageal reflux or plagiocephaly.[53] CPSC has also recalled and taken action against a manufacturer of infant recliners.[54]

This review found that despite public health campaigns by government agencies and leading organizations warning against the use of soft bedding, including crib bumpers, some caregivers continue to use soft bedding with their infants. Caregivers report that they use soft bedding for comfort, safety, and aesthetics.[55] The media also continue to show unsafe sleeping environments and feature celebrity parents and their infants. A study of "Infant Sleep Environments Depicted in Magazines Targeted to Women of Childbearing Age" found that bumper pads appeared in 69 (85 percent) of the 81 pictures of cribs.[56]

Because crib bumper deaths are likely an addressable hazard, the Commission may want to consider directing the staff to study a range of options for mitigating the hazard, including a performance standard for bumpers that limits the propensity for wedging, airway occlusion, and/or rebreathing; a ban of "non-mesh sided" bumpers, but not "vertical bumpers," as currently enacted by the state of Maryland[17] and the city of Chicago,[19] and continued outreach to caregivers to warn about crib bumper use.

References

[1] JPMA "Petition Requesting a Performance Standard 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." Online at http://www.cpsc.gov/library/foia/foia12/petition/JPMAbumper.pdf (Accessed 8/8/2012).

[2] 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 Morality Study. Pediatrics, 2003;111:1207-14.

[3] Scheers, NJ, Dayton CM, Kemp JS. Sudden infant death and external airways covered. Case comparison study of 206 deaths in the United States. Arch Pediatr Adoles Med, 1998;152:540-547.

[4] Scheers, NJ, Rutherford, GW, Kemp, JS. Where should infants sleep? A comparison of risk for suffocation of infants sleeping in cribs, adult beds, and other sleeping locations. Pediatrics 2003;112:883-9.

[5] Ponsonby A-L, Dwyer T, Couper D, Cochrne J. Association between use of a quilt and sudden infant death syndrome: case-control study. BMJ 1998;316:195-6.

[6] Kemp JS, Unger B, Wilkins D, et. al. Unsafe sleep practices and an analysis of bed sharing among infants dying suddenly and unexpectedly: results of a four-year, population-based, death-scene investigation study of sudden infant death syndrome and related deaths. Pediatrics 2000;106:E41.

[7] Pasquale-Styles,MA, Tackitt PL, Schmidt CJ. Infant death scene investigations and the assessment of potential risk factors for asphyxia: a review of 209 sudden unexpected infant deaths. J Forensic Sci 2007;52:924-929.

[8] Willinger M, James LS, Catz C. Defining the sudden infant death syndrome. Pediatr Pathol. 1991;11:677-684.

[9] Shapiro-Mendoza CK, Kimball M, Tomashek KM, Anderson RN, Blanding S. U.S. infant mortality trends attributable to accidental suffocation and strangulation in bed from 1984 through 2004: Are rates increasing? Pediatrics 2009;123:533-9.

[10] Shapiro-Mendoza CK, Tomashek KM, Anderson RN, Wingo J. Recent national trends in sudden, unexpected infant deaths: more evidence supporting a change in classification or reporting. Am J Epidemiol 2006; 163:762-769.

[11] Mitchell E, Krous HF, Donald T et. al. Changing trends in the diagnosis of sudden infant death. Am J Forensic Med Pathol. 2000;21:311-314.

[12] Thach BT, Rutherford GW and Harris K. Deaths and Injuries Attributed to Infant Crib Bumper Pads. J Pediatr 2007; 151:271-4.

[13] Moon RY, American Academy of Pediatrics, Task Force on Sudden Infant Death Syndrome. Technical report—SIDS and other sleep-related infant deaths: expansion of recommendations for a safe infant sleeping environment. *Pediatrics*. 2011:128(5). Available at: www.pediatrics.org/cgi/content/full/128/5/e1341.

[14] American Academy of Pediatrics, "SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendation for a Safe Infant Sleeping Environment." Online at http://pediatrics.aappublications.org/content/128/5/e1341.full, see section on issues related to sleep position. (Accessed 8/8/2012).

[15] Health Canada. Policy Statement for Bumper Pads. August 2005. Online at: http://www.hc-sc.gc.ca/cps-spc/legislation/pol/bumper-bordure-eng.php. (Accessed 4/3/2013).

[16] NIH News, NIH statement on the new crib safety standards, June 27, 2011, on line at: http://www.nih.gov/news/health/jun2011/nichd-27.htm (Accessed 4/3/2013).

[17] Moon RY. And things that go bump in the night: nothing to fear? J Pediatr 2007; 151(3):237-238.

[18] Prohibition of Sale of Baby Bumper Pads. Department of Health and Mental Hygiene, Subtitle 11 Maternal and Child Health, online at http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.11.07. (Accessed 8/3/2013.)

[19] City of Chicago Ban of Crib Bumper Pads. Amendment of Chapter 7-36 of Municipal Code by adding new Section 112 by adding crib bumper pads, final action date 9/8/2011. Online at: http://chicago.legistar.com/LegislationDetail.aspx?ID=923695&GUID=AF2C04B0-6D16-4B2D-8618-8E894C09B951&Options=Advanced&Search=. (Accessed 4/3/2013.)

[20] Drago DA, Dannenberg AL. Infant mechanical suffocation deaths in the United States, 1980-1997. Pediatrics 1999;103 (5). Available at: www.Pediatrics.org/cgi/content/full/103/5/e59.

[21] Abramson H. Accidental mechanical suffocation in infants. Journal of Pediatrics 1944; 25(5);404-413.

[22] Carleton JN, Donoghue AM, Porter WK. Mechanical model testing of rebreathing potential in infant bedding materials. Arch Dis Child 1998;78:323-328.

[23] Kemp JS, Thach, BT. Sudden death in infants sleeping on polystyrene-filled cushions. N Engl J Med 1991; 324:1858-1864.

[24] Choidini BA, Thach BT. Impaired ventilation in infants sleeping facedown: potential significance for sudden infant death syndrome. J Pediatr 1993;123:686-92.

[25] Kemp JS, Nelson VE, Thach BT. Physical properties of bedding that may increase risk of sudden infant death syndrome in prone-sleeping infants. Pediatr Res 1994;36:7-11.

[26] Sakai J, Kanetake J, Takahashi S, Kanawaku Y, Funayama M. Gas dispersal potential of bedding as a cause for sudden infant death. Forensic Sci Int 2008:180:93-7.

[27] NIH News."SIDS Linked to Low Levels of Serotonin." Online at: http://www.nichd.nih.gov/news/releases/020310-SIDS-linked-serotonin.cfm (Accessed 8/8/2012).

[28] Kinney HC, Thach BT. The Sudden Infant Death Syndrome. N Engl J Med 2009; 36:795-805. See section "Asphyxia-Related Sudden Deaths."

[29] Galland BC, Bolton DPG, Taylor BJ, et.al. Ventilatory sensitivity to mild asphyxia. Prone versus supine sleep. Arch Dis Child. 2000;83:423-428.

[30] ASTM International. ASTM F 1917 – 12: Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories, published August 2012.

[31] There are five categories for manner of death: natural, accident, suicide, homicide and undetermined.

[32] Hanzlick RL, Jentzen, JM, Clark SC. Infant Death Investigation: Guidelines for the Scene Investigator. Atlanta, GA: Centers for Disease Control and Prevention: January 2007. Online at: https://netforum.avectra.com/temp/ClientImages/NAME/2ee9fad8-9102-464d-bd05-255cb833a35a.pdf. (Accessed 4/3/2013.)

[33] CPSC also has reports of bumper-related deaths in other sleep products such as bassinettes, play yards, toddler beds, and cradles.

[34] Four CPSC database files were searched. The DTHS file includes information from death certificates purchased by the CPSC from all 50 states and the District of Columbia. The IPII file contains data on consumer product-related incidents from consumer complaints, as reported to the CPSC through letters and telephone calls, and other sources such as media articles and medical examiner reports. The INDP file contains data from follow-up investigations by CPSC staff. The NEISS database is a probability sample of U.S. hospitals with emergency departments that contains information primarily on product-related injuries associated with consumer products and occasionally some deaths.

[35] Because CPSC does not have a product code that identifies crib bumpers, the data search used product codes for infant sleep products with which bumper pads might be used: code 1542 -"Baby mattresses or pads (excluding mattress covers or mattress pads)," code 1543 -"Cribs (excluding portable cribs)," code 1545 -"Cribs, not specified," and code 1529 -"Portable cribs," as well as a search for "bump" or "pad" or both and "bumper" AND "pad" in the report narratives of the records.

[36] Medical Examiners' and Coroners' Handbook on Death Registration and Fetal Death Reporting, Centers for Disease Control and Prevention, on line at: http://www.cdc.gov/nchs/data/misc/hb_me.pdf. (Accessed 3/29/2013).

[37] SUID is the sudden and unexpected death of an infant in which the manner and cause of death are not immediately obvious prior to investigation. SUID can be caused by metabolic disorders, hypothermia or hyperthermia, neglect or homicide, poisoning, or accidental suffocation. On line at: http://www.sidscenter.org/definitions.html. (Accessed 4/21/2013).

[38] One sample $\chi^2 = 13.5$, df = 3, p<.000.

[39] Yeh ES, Rochette LM, McKenzie LB, Smith GA. Injuries associated with cribs, playpens and bassinets among young children in the US, 1990-2008. Pediatrics 2011;127:479-485, p484.

[40] Personal communication with the ME who conducted the autopsy. She reported that: (1) their Medical Examiner Office defines a standard sleeping environment as a mattress covered by a fitted sheet; and (2) the death was caused by wedging between the bumper pad and the mattress.

[41] Lividity is a purple coloration of dependent parts, except in areas of contact pressure, appearing within 30 minutes to 2 hours after death, as a result of gravitational movement of blood within the vessels. Definition online at: http://medical-dictionary.thefreedictionary.com/postmortem+lividity. (Accessed 4/8/2013).

[42] Personal communication, Director NFRB.

[43] 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. Bethesda, MD: U.S. Consumer Product Safety Commission; 2010 July.

[44] 16 CFR 1115.4(d)

[45] Petition requesting ban of baby bath seats and rings, March 30, 2001.

[46] NICHD/NIH. Back to Sleep Campaign. Available online at: https://www.nichd.nih.gov/SIDS/Pages/sids.aspx (Accessed 4/3/2013).

[47] National Infant Sleep Position Study website, 2004, online at: http://dccwww.bumc.bu.edu/ChimeNisp/Tables_in_PDF/NISP%201992-2009%20The%20usual%20sleep%20position.pdf. (Accessed 4/3/2013).

[48] Patel AL, Paluszynska D, Harris KA, Thach BT. Occurrence and mechanisms of sudden oxygen desaturation in infants who sleep face down. Pediatrics 2003; 111:e328-e332.

[49] Kemp JS, Sucre J, Thach BT. "Sudden Infant Death Syndrome and Apparent Life-Threatening Events", in Kendig and Chernick's Disorders of the Respiratory Track in Children (8th ed.). Elsevier, 2012, 1046-1066. For a comprehensive review, see sections "Abnormal arousal and the impact of sleep position;" "Abnormalities in ventilatory response and threats within the sleep environment;" and "Soft bedding as an effect modifier: physiologic implications."

[50] Walters KA, Gonzalez A, Jean C, et. al. Face-straight-down and face-near-straight-down in healthy, prone-sleeping infants. J Pediatr 1996; 128:616-625.

[51] Paluszynska DA, Harris KA, Thach BT. Influence of sleep position experience on ability of prone-sleeping infants to escape from asphyxiating microenvironments by changing head position. Pediatrics 2004; 114(6):1634-1639.

[52] Willinger M, Ko CW, Hoffman HJ, Kessler RC, Corwin MJ. Factors associated with caregivers' choice of infant sleep position, 1994 -1998: the National Infant Sleep Position Study. *JAMA*. 2000;283(16):2135–2142.

[53] Centers for Disease Control and Prevention, Suffocation deaths associated with use of infant sleep positioners – United States, 1997-2011. MMWR Morb Mortal Wkly Rep. November 23, 2012; 61(46):933-937.

[54] Five Infant Deaths Prompt CPSC to Sue Manufacturer of Nap Nanny and Chill Infant Recliners. http://www.cpsc.gov/en/Newsroom/News-Releases/2013/Five-Infant-Deaths-Prompt-CPSC-to-Sue-Manufacturer-of-Nap-Nanny-and-Chill-Infant-Recliners/. (Accessed 4/24/2013).

[55] Ajao TI, Oden RP, Joyner BL, Moon RY. Decisions of Black Parents about Infant Bedding and Sleep Surfaces: A Qualitative Study. Pediatrics 2011;128 (3):494-502.

[56] Joyner BL, Gill-Bailey C, Moon RY. Infant Sleep Environments Depicted in Magazines Targeted to Women of Childbearing age. Pediatrics 2009;124;e416, online at: http://pediatrics.aappublications.org/content/124/3/e416.full.html (Accessed 4/3/2013).

APPENDIX A:
NARRATIVES FROM CASE REPORTS (DEATH CERTIFICATE, AUTOPSY, INVESTIGATIONS) AND INFANT CHARACTERISTICS

SORTED BY HAZARD PATTERN

Case	*Hazard Pattern*	*DTH CERTIFICATE narrative*	*AUTOPSY Narrative*	*INVESTIGATION Narrative*	*Date of death*	*Age (mths)*	*Sex*
4	A. Wedging with Bumper (Mattress)	Sudden Infant Death Syndrome	Sudden Infant Death Syndrome	Police investigation and coroner's official reports note the father found infant "pushed up tight against the **side rail padding** and between the mattress and side rail padding" in a waterbed crib. She was face down and arms up. The initial cause of death was "accidental asphyxiation in crib." There were pressure marks about the left forehead, nose and left cheek regions. The Coroner's report further noted that the "decedent was found in the crib with her head down in the corner between the mattress and rail cover. The mother felt the decedent had 'suffocated'." In the early 1990s, SIDS was the diagnosis of choice. **CRIB BUMBER PADS** WERE IN THE CRIB, AS WELL AS STUFFED TOYS AND A LOOSE BLANKET.	1991	8	F
8	A. Wedging with Bumper (Mattress)	BABY BECAME WEDGED BETWEEN CRIB AND MATTRESS AT HOME SUFFOCATION	Hospital shut down and when reopened, records not available	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. Note: no mention in any of the documents of a gap, an ill-fitting mattress or a structurally defective crib.	1991	7	F
9	A. Wedging with Bumper (Mattress)	Sudden Infant Death Syndrome	Sudden Infant Death Syndrome	An infant placed prone to sleep was found prone and unresponsive by his mother. He was reported to be in good health. In 1992, CPSC was conducting a special study to explore whether some infants diagnosed as SIDS had actually suffocated in soft bedding. CPSC investigators conducted an extensive on-site investigation and photographed the death scene recreated by the caregiver who found the infant unresponsive. The infant was found with his face on top of a comforter and wedged in a corner in the **bumper pad** that did not allow him to lift or turn his head. The medical examiner was unaware of CPSC's investigation results when he conducted the autopsy on the day after the infant's death, and finding no medical reason for the death, diagnosed it as SIDS.	1992	2	M

Case	Hazard Pattern	DTH CERTIFICATE narrative	AUTOPSY Narrative	INVESTIGATION Narrative	Date of death	Age (mths)	Sex
14	A. Wedging with Bumper (Mattress)	Not Available	Positional Asphyxia, accident. Opinion: "…was discovered on his abdomen in his crib with his face pressed against a **bumper pad.** He had a history of recent cold symptoms."	An infant was found by his mother "facedown in his crib. He was laying on the left side of his face with his face in between the mattress pad and the **bumper pad**." Father reported that there were some stuffed animals and books in the crib but that none were close to his son's head and nothing under his son's head. The baby was treated weeks ago for a head and chest cold with extensive breathing treatment. The family reported that Infant had a recent respiratory condition and treated for a few days with medication. On the night of his death, he was slightly congested but not on medication and had no severe distress of any kind.	1996	14	M
15	A. Wedging with Bumper (Mattress)	**SUFFOCATED** IN CRIB - PROBABLE **SUFFOCATION** -	Opinion: "…died of probably suffocation when he became entrapped within his crib between the side wall of the crib and the edge of the mattress."	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. Note: no mention in any of the documents of a gap, an ill-fitting mattress or a structurally defective crib.	1997	2	M
21	A. Wedging with Bumper (Mattress)	Not Available	Asphyxia by suffocation. "Infant became wedged between the mattress and the **bumper pad** of his crib."	Infant placed to sleep prone because he would cry lying supine. Father found the baby on his stomach in his crib with his "arms up and his face into the soft padding" surrounding the inside of the crib. An indentation can be seen in the **bumper** in the black and white police photos taken at the death scene. These also show a sagging bumper and thick blankets that were present in the crib.	2000	4	M
34	A. Wedging with Bumper (Mattress)	Asphyxia due to suffocation by obstruction of nose and mouth.	Cause of Death: Asphyxia due to suffocation by obstruction of the nose and mouth. Found unresponsive in crib with face wedged between mattress and **bumper.** Other Significant Findings: Chronic anoxic encephalopathy due to meconium aspiration at birth (significant brain injury at birth)	Mother found the infant unresponsive lying prone with her face wedged between the crib **bumper** and the mattress. This was the first time the baby had rolled over. There was no bedding on the mattress with just the plastic cover present.	2004	19	F

Case	Hazard Pattern	DTH CERTIFICATE narrative	AUTOPSY Narrative	INVESTIGATION Narrative	Date of death	Age (mths)	Sex
49	A. Wedging with Bumper (Mattress)	Probable Asphyxia, obstruction of nose and mouth. Face wedged against **bumper** and mattress of crib.	Probable asphyxia due to obstruction of the nose and mouth. [The infant] was found unresponsive lying with his face wedged against the **bumper** of his crib and the mattress.	Infant was placed to sleep for nap supine on top of a large C-shaped nursing pillow. Police reports say the father found the baby had "flipped over, crawled up over the [nursing pillow] and his face was against the padded **bumper** and mattress that were in the crib" with his "mouth up against the bumper almost wedged between the mattress and the bumper." No mention in the case report (investigation, autopsy, death certificate) that nursing pillow was involved in the death. Other objects in crib included quilts, blankets, toy bottle, book, wall clock.	2008	2	M
54	A. Wedging with Bumper (Mattress)	Suffocation due to or as a consequence of SIDS.	Asphyxia with pulmonary (A) edema, (B) focal pulmonary hemorrhage. Opinion: [Name] died of position asphyxia. She was found in a crib facing the mattress **bumper.** There are no physical injuries or natural diseases contributing to her death.	Mother reported that the baby was placed prone to sleep covered by a blanket. She was found prone 12 hours later turned 180 degrees and "wedged face down between the mattress and the **crib padding**." The top of her head was resting against a stuffed toy. There was a CT scan to look for evidence of a basilar skull fracture or subdural hematoma ("shaken baby"). The forensic pathologist believed the CT scan was misread and concluded that [name] died from positional asphyxia.	2010	4	M
58	A. Wedging with Bumper (Mattress)	A 6 MOM DECEDENT FOUND IN CRIB WITH FACE BETWEEN **BUMPER PAD** AND MATTRESS. SUFFOCATION IN NON-STANDARD SLEEPING ENVIRONMENT.	Findings: Suffocation in non-standard sleeping environment: (A) infant reportedly found face-down with face wedged between mattress and **bumper pads** of crib; (B) numerous pillows, blankets and stuffed animals present within the 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. In recreating the scene, the mother reported that the baby's left arm was over the pad and he appeared to have been pulling the bumper pad toward his face. Pathologist in consultation with others discounted "shaken baby" hypothesis of hospital doctor. Bumper pad incorrectly tied to crib.	2010	6	M
59	A. Wedging with Bumper (Mattress)	Asphyxia; wedging of face in mattress.	The cause of death is attributed to asphyxia from the face being wedged between a **crib bumper** and mattress. The baby reportedly rolled over a positioner and was found in the above described position.	A seven-week-old male victim died when he rolled completely out of a sleep positioner and became stuck at the corner of the **bumper pad.** The victim was found by his father turned on his stomach with his face against the bumper pad and mattress. No mention in any of the official documents that the sleep positioner was involved in the wedging. Father reported baby had a viral fever 2 weeks before death, went to the hospital for 2 nights, and put on antibiotic. Fever gone in 24 hours. Family and infant had been ill with flu like symptoms and vomiting on the night of the infant's death. Diagnosed with infant asthma, but autopsy found no evidence of asthma. Parent used the positioner to prevent the baby from rolling over and also getting a flat head.	2010	2	M

Case	Hazard Pattern	DTH CERTIFICATE narrative	AUTOPSY Narrative	INVESTIGATION Narrative	Date of death	Age (mths)	Sex
1988a	A. Wedging with Bumper (Mattress)	BABY **WEDGE**D BETWEEN MATTRESS AND SIDES - MECHANICAL ASPHYXIA; BEING **WEDGE**D BETWEEN CRIB MATTRESS AND **BUMPER PADS**	"The cause of death is mechanical asphyxia secondary to being wedged between the crib mattress and sides."	A two month old male child was found by his mother dead in his crib. The mother found the infant "face down in his crib with his face between the mattress and the **bumper pads.** "Not ill prior to this and appeared to have been thriving." Note: no mention in any of the documents of a gap, an ill-fitting mattress or a structurally defective crib.	1988	2	M
1988b	A. Wedging with Bumper (Mattress)	MATTRESS & CRIB PAD CAUSING SUFFOCATION - PULMONARY EDEMA & CONGESTION OF LUNGS -	Records not available before 1989	**Mattress and crib pad** causing suffocation - pulmonary edema and congestion of lungs - autopsy yes. Note that "crib pad" is often used by ME to describe a crib bumper.	1988	2	F
6	A. Wedging with Bumper (Pillow)	FACE WEDGED IN CRIB BETWEEN PILLOW, MATTRESS & **BUMPER ASPHYXIA;** EXTERNAL FACIAL COMPRESSION (SUFFOCATION)	Diagnosis: Asphyxia due to external suffocation (compression of nostril and mouth when infant became wedged between bed cushion and crib **bumper**).	A 2 month old female died from suffocation as a result of external facial compression. The victim became trapped face down between the **side rail of her crib** and a thick semi rigid homemade cushion in the crib. The victim fell between the cushion in the side rail with her face coming to rest on the crib's mattress. Placed on pillow to sleep, believed to have rolled off. Co-sleeping with twin.	1992	2	F
10	A. Wedging with Bumper (Pillow)	FOUND UNRESPONSIVE WEDGED BETWEEN PILLOW AND **BUMPER PAD** POSITIONAL ASPHYXIA	Circumstantial Summary: the mother found "the deceased face down in the crib, with the head wedged between a pillow that was covered with a blanket and the **bumper pad** on the inside of the crib."	Found unresponsive wedged between pillow and **bumper pad.** Mother found infant lying face down in his crib. She reported that "his head had sort of slipped or at least to have slipped off the edge of the pillow. His head was sort of wedged between the pillow and bumper pads inside the bed." The investigator reported that "inside the bed were a pillow covered with a blanket, two baby blankets and a thick blanket used as a mattress pad and thick bumper pads surrounded the entire inside of the bed. There were toys, diapers, medicine for diaper rash and a small plastic bag in the bed. Some of these items were not in direct contact with the baby." The infant's face had a "pattern of skin marks [that] matches the pillow cover."	1993	1	M
13	A. Wedging with Bumper (Pillow)	BABY'S HEAD WENT BETWEEN PILLOW AND **PADDED CRIB WALL**, FACE DOWN IN SOFT BEDDING - ASPHYXIA; SUFFOCATION-FACE DOWN IN SOFT BEDDING	Autopsy: "Asphyxia: suffocation - face down in soft bedding."	ME investigation report: baby was placed to sleep prone on a full size pillow. "Found her torso and legs still on the pillow but her head and neck were between the **crib bumper pad** and the pillow in a 4 inch area. Her full face was into the mattress." Born with ventricle septal defect – small hole in the heart. She had poor weight gain and a chronic cough.	1996	2	F

Case	Hazard Pattern	DTH CERTIFICATE narrative	AUTOPSY Narrative	INVESTIGATION Narrative	Date of death	Age (mths)	Sex
26	A. Wedging with Bumper (Pillow)	FOUND DEAD WEDGED IN CRIB - ASPHYXIA; WEDGED BETWEEN PILLOW AND **CRIB BUMPER -**	Asphyxia: wedged between pillow and crib **bumper**	Infant found lying prone and "wedged between adult pillows and a **crib bumper."**	2001	3	F
46	A. Wedging with Bumper (Pillow)	DECEDENT PLACED IN UNSAFE CRIB. POSTIONAL **ASPHYXIA** IN CRIB.	Positional Asphyxia in crib: Contributing factor: Chronic Interstitial Pneumonitis.	An infant with a stuffy nose was placed to sleep supine on top of a sofa cushion with her head slightly elevated. The baby was found deceased the next morning by her father "prone on top of a sofa pillow in her crib with her face wedged between the pillow and **bumper pad**." Numerous other items and pillows were in the crib.	2008	2	F
47	A. Wedging with Bumper (Pillow)	**Death Certificate:** WEDGED BETWEEN **BUMPER GUARD** AND PILLOW. POSITIONAL ASPHYXIA.	Positional Asphyxia: dec found with face, nose and mouth in mattress and pillow.	This premature infant usually sleeps on top of a pillow because she was unable to sleep without it. Father found infant wedged between the pillow, mattress and edge of the crib rail with her right face down. The infant was premature and had a history of acid reflux.	2008	3	F
61	A. Wedging with Bumper (Pillow)	Cause Redacted	Probable positional asphyxia.	Forensic investigator on scene and took photos (not available for review). Child placed to sleep on top of an adult pillow and found with his face wedged between the pillow and a **thin cloth bumper pad** in the crib.	2010	1	M
66	A. Wedging with Bumper (Pillow)	Positional Asphyxia (Wedging). Positional Asphyxia sustained when became wedged between **crib pads** and pillow.	Positional asphyxia (wedging). Infant found with face between pillow and **crib bumper**.	An infant was placed to sleep supine with his head and torso resting on a nursing pillow. Underneath the pillow were a baby blanket and a quilt that was covering the infant's feet. His mother found him face down with his head tilted to the left, wedged between the nursing pillow and the **bumper** on the crib.	2010	4	M
71	A. Wedging with Bumper (Pillow)	Not Available	Suffocation by bedding. Became wedged between **crib padding** and adult pillow.	Baby placed prone to sleep on top of a full size adult pillow. The contents of the crib included the adult pillow, bedding, a baby blanket, a stuffed animal and **bumper pads**. Child was not on medication but took an over-the-counter supplement for gas. Decedent was found unresponsive by his father wedged between crib pads and full size adult pillow.	2012	1	M

Case	Hazard Pattern	DTH CERTIFICATE narrative	AUTOPSY Narrative	INVESTIGATION Narrative	Date of death	Age (mths)	Sex
60	A. Wedging with Bumper (Infant Recliner)	Probably positional asphyxia. Sleeping in crib with [infant recliner] became wedged between device and **bumper.**	Probable positional asphyxia. Case Summary: The decent was found unresponsive in her crib lying between a padded **crib bumper** and an [infant recliner]. Autopsy did not reveal any evidence of trauma, congenital anomaly or disease to account for her death.	A six-month-old female victim was found unresponsive in her crib lying between a nursery product and a bumper pad. She "somehow fell sideways on the [infant recliner] and her head fell back in such a way that her face was pressed between the [infant product] and the **baby bumper** and she smothered to death." The caregivers did not use the harness because the baby did not normally move around a lot on the seat. The caregivers used the infant recliner to prevent acid reflux.	2010	6	F
64	A. Wedging with Bumper (Infant Recliner)	Suffocation due to an unsafe sleep environment. Infant wedged between **crib bumper** and pillow holding a bouncy chair.	Suffocation in an unsafe sleep environment. Conclusion: The infant was reportedly sleeping unstrapped in a bouncy chair placed on a pillow in her crib and found later unresponsive wedged between the **bumper pad** of the crib and the pillow holding the bouncy chair.	An infant was placed unstrapped in a baby bouncer inside her crib to sleep. The bouncy chair had been propped up on the bottom with a pillow to level it so that it would be horizontal rather than on an incline. A blanket was placed on top of the bouncer and another blanket was used to cover her. The crib's guard rail had been removed to allow the crib's mattress to be level with the bed when they were placed along each other so the mother could have easy access to the baby at night when she needed to breast feed. The infant 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.	2010	1	F
65	A. Wedging with Bumper (Infant Recliner)	Position/Compression asphyxia. Entrapped between a [infant recliner] and **bumper pads in crib.**	Died of position/compression asphyxia sustained when she was entrapped between a [infant recliner] and **bumper pads** in the crib.	A 4-month-old female infant was placed to sleep in a harnessed infant recliner 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 recliner. He went into the bedroom and found the victim not breathing, still harnessed in the infant recliner with her head hanging off and tilted back with the neck hyper-extended and her face in the **bumper pad** of the crib. The mother bought the item because the infant had projectile vomiting 1-2 times a day and she wanted to prevent acid reflux.	2010	4	F
69	A. Wedging with Bumper (Infant Recliner)	Sudden Infant Death Syndrome	Sudden Infant Death Syndrome.	A 4 month-old male was found unresponsive, lying perpendicular to and on top of a foam baby recliner installed in his crib. 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 death scene was recreated by the mother who found the infant. The infant had severe acid reflux and the caregivers used the infant recliner to prevent acid reflux.	2011	4	M

Case	Hazard Pattern	DTH CERTIFICATE narrative	AUTOPSY Narrative	INVESTIGATION Narrative	Date of death	Age (mths)	Sex
70	A. Wedging with Bumper (Infant Recliner)	Not available.	Sudden Unexplained Infant Death (SUID). [Victim] was found face down in bed with his face into his bedding, suggesting possible asphyxia as a cause of death but this is not conclusive. As the cause of death remains unknown with certainty and accidental asphyxia cannot be excluded, the manner of death also remains undetermined.	A seven-month-old male was placed in an infant recliner with the cover and the harness missing. The infant recliner 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 infant recliner and the crib wall and/or the top of the **bumper pad.** The Mother reported that the victim's face was downward and that it had not fallen all the way to the crib mattress surface. His head was up at the level of being near the top of the cushion, crib rail and/or the bumper pad. The caregivers used the infant recliner to prevent acid reflux.	2012	7	M
16	A. Wedging with Bumper (Other)	**ASPHYXIA** BY COMPRESSION OF UPPER NECK WHILE **WEDGE**D BETWEEN FURNITURE AND CRIB	External Exam by ME: Asphyxia by wedging. Abrasions, nose, anterior and posterior back.	A 10 month old male died of positional asphyxia, wedged between his crib railing and a dresser six inches away. Investigator noted that the child probably stood atop the **bumper pad** and climbed over the railing and became wedged. The infant was found "in an upright position with his chin resting on the edge of the dresser and the back of his head against the side rail of the crib," a scenario more likely to have occurred if he stood on bumper and fell facing the dresser. If he climbed over/ rolled over/crawled over the bumper/crib rail, he would be more likely to fall parallel to the crib. The crib support was in the second from lowest position and the distance from the top of the mattress to the top of the side rail was 15 inches. The bumper was 12 inches high. The infant measured 29 inches in length.	1997	10	M
28	A. Wedging with Bumper (Other)	Asphyxia; positional crib accident. Baby found face down in crib, pinned between **bumper pad** and sibling sister.	Consistent with positional asphyxiation. Reportedly found face down, wedged against crib side.	An infant placed prone for a nap in a crib was found wedged between the **bumper** pad and his twin sister. Cause of death asphyxia due to positional crib accident. History of acid reflux - doctor recommended to place prone or on side to sleep.	2002	4	M
35	A. Wedging with Bumper (Other)	FOUND UNRESPONSIVE IN DEFECTIVE CRIB - **POSITIONAL ASPHYXIA** - **AUTOPSY YES**.	According to the scene investigation, the corners of the crib mattress were unsupported due to ill fitted wood slats. The infant was found in a corner of the crib with its face buried in a quilt and **bumper pads.**	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 (as shown with re-creations photographs). Note: the bumper would contribute to wedging making it very difficult for the infant to raise her head and turn her face to the side to avoid suffocating.	2004	4	F

Case	Hazard Pattern	DTH CERTIFICATE narrative	AUTOPSY Narrative	INVESTIGATION Narrative	Date of death	Age (mths)	Sex
36	A. Wedging with Bumper (Other)	HEAD COMPRESSED AGAINST CRIB **BUMPER** WITH ARM **WEDGE**D BETWEEN CRIB AND MATTRESS - **ASPHYXIA** DUE TO COMPRESSION OF HEAD AGAINST CRIB **BUMPER** -	Cause: Asphyxia due to compression of the head against **crib bumper.** Manner: Accident (head compressed against crib bumper with arm wedged between crib and mattress)*	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. Her arm was wedged between the crib and the mattress according to the ME autopsy report and the death certificate. Note: no mention in any of the documents of a gap, an ill-fitting mattress or a structurally defective crib.	2005	4	F
43	A. Wedging with Bumper (Other)	FOUND UNRESPONSIVE IN CRIB. SEQUELAE OF **SUFFOCATION**. **ENTRAPMENT**.	ME Opinion: "The decedent's body and face were pressed against the **padding of the crib** and one arm was entrapped between the padding and the rail sides. Based on all the information available to me at this time… [the baby] died as a result of suffocation due to entrapment."	An infant 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 herself up to breathe. The police photos seem to show that the bumper was not tied correctly to corner post. Police report a cluttered crib.	2007	2	F
63	A. Wedging with Bumper (Other)	Positional asphyxia: infant in prone position with face against **crib bumpers**.	Positional asphyxia consistent with wedging.	Baby placed to sleep prone with her arm sticking through the slats of the crib. She was placed prone because she slept better that way. She shared the crib with her twin sister. The crib had a thin cotton sheet covering the mattress and a cotton blanket to cover the twins. Mother reported she found the baby face down with one arm positioned between the crib's **bumper padding** and the mattress. Coroner advised the Sheriff's department that [Name's] face was pressed against one of the soft bed bumpers while CPSC's investigator reported that the coroner stated asphyxiation was due to her face being against the crib mattress.	2010	2	F
20	B. Face Against Bumper (Corner)	POSITIONAL ASPHYXIATION	Summary: "The scene photographs of the crib...show the infant's face to have been in a corner of the crib and **covered by a pad along the edge of the crib,** which would cause asphyxiation due to obstruction of airflow. A crease noted on the infant's forehead is consistent with an impression from the edge of the crib and further supports this conclusion."	Infant placed to sleep supine in the middle of the crib and found supine unresponsive. The babysitter stated that the baby's "face appeared to be buried in the corner of the **bumper pad.**" Pallor around nose and mouth and indentation in the bumper shows that the baby's face was pressed into the bumper. The Infant treated for respiratory problems but his physician who treated him stated this "did not seem severe enough to cause his death." The autopsy also did list any infection as a contributory cause to the death.	1998	7	M

Case	Hazard Pattern	DTH CERTIFICATE narrative	AUTOPSY Narrative	INVESTIGATION Narrative	Date of death	Age (mths)	Sex
30	B. Face Against Bumper (Corner)	BABY SUFFOCATED AT HOME IN THE CORNER OF THE CRIB AGAINST THE **CRIB BUMPER.** SUFFOCATION - ACCIDENTAL.	Decedent was found dead in a crib with her face into a **bumper pad.**	Grandmother is the legal guardian of the twins who were co-sleeping. She found the victim "with her face against the **bumper pad** in the corner of the crib,' and reported that "the impression on [the victim's] face indicated she was in the corner of the crib." The investigation noted that the bumper was sagging inward and the crib contained a padded comforter, a crocheted afghan and a blanket over the crib mattress. The grandmother stated that the crib mattress is very firm and the babies weren't accustomed to it, so she put the blankets over the mattress for extra comfort. She also stated that" both babies were accustomed to sleeping on their stomachs and couldn't get to sleep on their backs."	2003	3	F
37	B. Face Against Bumper (Corner)	TRAPPED FACE-DOWN AGAINST PADDING IN THE CORNER OF THE CRIB - PENDING, POSITION **ASPHYXIA**	Positional Asphyxia; accident. Opinion: "…died as a result of position asphyxia, trapped face down against the **padding in the corner of the crib."**	"Nanny found baby had rolled from her original position to the other side of the crib with her face up against the side rail **bumper pad.**" Re-enactment was completed but photos not available.	2006	5	F
40	B. Face Against Bumper (Corner)	Not Available	Positional asphyxia - found prone in corner of crib with cheeks abutting mattress/blanket and **bumper pad.**	Infant placed to sleep supine and 40 minutes later found prone and unresponsive with her face between the railing and round mat. There was a stain on the mattress that corresponds to where the decedent's nose and mouth would have been. The cheek/temple area would also have been in contact with the **bumper pad**. Re-creation photographs show a blanket on top of the mattress and two blankets bundled up at the foot of the crib.	2007	4	F
42	B. Face Against Bumper (Corner)	POSITIONAL ASPHYXIA. LYING FACE DOWN IN **CRIB BUMPER** BEDDING.	Death is "due to positional asphyxia while laying (sic) face down in thick soft **crib bumper** padding bedding at the corner of the crib."	The victim was found by his babysitter face down with his face on a **bumper pad** that "was pulled down like he was snuggling with it." She re-created the death scene with a doll showing the bumper under the doll's mouth and nose. The victim "always sleeps on his stomach, this is the only way he sleeps." The infant currently had an untreated ear infection and was on medication for oral thrush. Other bedding in the crib was a large blanket hanging over the north side of the crib and a portion of the blanket under the victim's head. A small thin blue blanket was in the crib and a corner on the victim's right knee. A toy was located across the south end of the crib on the interior. The crib bumper does not appear to be correctly tied.	2007	5	M
2	B. Face Against Bumper (Side)	Sudden Infant Death Syndrome	Dec'd found in crib with face against the **plastic bumper."**	A 2 month old preemie presents with cardiac arrest. Mom went in to check baby in crib found him with **face against plastic bumper**	1990	2	M

Case	Hazard Pattern	DTH CERTIFICATE narrative	AUTOPSY Narrative	INVESTIGATION Narrative	Date of death	Age (mths)	Sex
27	B. Face Against Bumper (Side)	FACE AGAINST OVERSTUFFED **CRIB BUMPER** - ASPHYXIATION	Asphyxiation caused by pressure against an overstuffed **crib bumper** during sleep.	An infant was placed supine in a crib that did not have a mattress or a headboard. She was found unresponsive by her mother with her face extended backwards into the gap between the **crib bumper** and pillow. A makeshift mattress consisted of a thick blanket wrapped in a sheet and pillows used for the headboard. Several pillows were placed on their sides at the head and both sides of the crib. A crib bumper was not secured to the crib. The baby had a habit of arching her back in order to move.	2002	7	F
32	B. Face Against Bumper (Side)	FACE DESTRUCTED (sic) BY **CRIB BUMPER PAD** - POSITIONAL ASPHYXIA	The decedent was found dead in a crib with his neck extended and face buried in a **bumper pad.** His nose and mouth were completely blocked by the pad, confirmed by the lividity pattern on the decedent's face.	Infant found with his face against a **bumper pad** in his crib at home by his mother. The crib was bought at a garage sale and had "most of the hardware missing." Re-creation photographs show the missing crib hardware does not appear to have an effect on the bumper, which is secured to the crib with no sagging. The indentation in the bumper shows where the infant's face was buried in the bumper pad.	2003	2	M
38	B. Face Against Bumper (Side)	Sudden Infant Death Syndrome	SIDS; Medical Examiner Reporting Form states "victim's face was up against the crib's **bumper pad** when found."	A male infant, age 4 months, died when he was found unresponsive in his crib by his mother. The mother reported that the “infant had scooted up on the mattress and the right side of his face was against the side of the crib pad. “ His face was up against the crib's **bumper pad** when found. She suspects he smothered or suffocated.	2006	4	M
44	B. Face Against Bumper (Side)	FACE BECAME PRESSED AGAINST **CRIB BUMPER PAD** WHILE SLEEPING - ASPHYXIA; SUFFOCATION	Opinion: …"22 month old male with severe cerebral palsy died as a result of asphyxia due to obstruction of the nose and mouth by the crib **bumper pad** when he maneuvered into a position while sleeping from which he could not extricate himself"	Infant was placed to sleep in an infant sleep positioner and was found by his father at the end of his crib with his face pressed against crib **bumper pad**. Infant had severe cerebral palsy and was developmentally delayed with "little muscle control." The father recreated the death scene but the photograph is not available.	2007	22	M

Case	Hazard Pattern	DTH CERTIFICATE narrative	AUTOPSY Narrative	INVESTIGATION Narrative	Date of death	Age (mths)	Sex
56	B. Face Against Bumper (Side)	2-MONTH-OLD MALE DECEDENT **ASPHYXIA**TED IN CRIB AT HIS RESIDENCE. CAUSE OF DEATH: **SUFFOCATION**.	Suffocation, history that the decedent was found unresponsive, prone in his crib against/near a soft fabric **bumper**	An infant was placed prone to sleep because he could not sleep supine and was found unresponsive in a crib with his face against a **crib bumper.** The ME's investigator reports that the father was not sure if the decedent's nose or mouth was obstructed but that the baby's head/face was against a cloth bumper inside the crib. "There is a moderate size wet spot and reddish colored stain on the fitted sheet. The stain was located near where the bumper and the mattress intersect on the side of the crib...the bumper also appeared to be wet but it was difficult to tell if it was stained due to the pattern on the bumper." There was a fitted sheet on top of a mattress and a comforter bunched up against the inside of the crib. Father was too emotional to reconstruct the death scene.	2009	2	M
62	B. Face Against Bumper (Side)	Positional Asphyxia,	Positional Asphyxia, accident.	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. There was a wet spot on the pillow that goes to the edge of the bumper where the baby was found face down (see photographs). In the crib were a pillow, 2 comforters, a blue towel, a dinosaur toy.	2010	3	M
1985	C. Strangulation (Bumper Tie)	Not Available	[Infant]... died due to asphyxia due to compression of the neck by cord.	A father who went to his seven month old son's bedroom to awaken him found him strangled on a loose **bumper** pad tie.	1985	**7**	M
1987	C. Strangulation (Bumper Tie)	TIE O**F** **BUMPER PAD** BECAME TANGLED AROUND NECK - CEREBRAL ANOXEMIA AND ANOXIA; LIGATURE COMPRESSION OF NECK VESSELS	Cerebral Anoxemia and Anoxia, Minutes, due to ligature compression of the neck vessels, Minutes.	A 7-month-old child died from anoxia in her crib when a crib **bumper pad** tie wrapped around her neck.	1987	**7**	F
1989	C. Strangulation (Bumper Tie)	Not Available	[Redacted} one of a twin, 6 month old, female infant died due to asphyxia due to compression of the neck by cord. The manner of death is classified as accidental	On morning of 5/9/89 a six-month old female died from asphyxia due to strangulation after she apparently placed her head through a loop formed by tied fabric attachment strings of a **bumper pad** in a full- size crib in which she was placed for a nap. Apparently, victim could not extricate her head from the loop and the string tightened around her neck. Accident occurred at home of victim's grandmother, who had been babysitting victim & her twin sister for more than four months before the accident.	1989	6	F

TAB G: Advice from Other Agencies

T
A
B

G

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: May 15, 2013

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Kenneth R. Hinson, Executive Director

FROM: DeWane Ray, Assistant Executive Director
Office of Hazard Identification and Reduction

Jonathan Midgett, PhD, Children's Hazards Team Leader
Office of Hazard Identification and Reduction

SUBJECT: Crib Bumpers: Advice from Other Organizations

In January 2011, staff surveyed public advice for creating safe sleep settings for infants. At that time, the National Institutes of Child Health and Human Development (NICHD) said to avoid pillow-like bumpers, but the most recent recommendation is to avoid any bumpers:

Organization	Previous Recommendation	Most Recent Recommendation
NICHD	**Keep soft objects, toys, and loose bedding out of your baby's sleep area.** Don't use pillows, blankets, quilts, sheepskins, or pillow-like crib bumpers in your baby's sleep area, and keep all objects away from your baby's face. http://www.nichd.nih.gov/publications/pubs/upload/Safe_Sleep_2009_Eng.pdf (accessed 1/2011)	***Why shouldn't I use bumpers in my child's crib? Current research shows that crib bumper pads or padded bassinets can cause injury or death to infants.***[2] Before crib safety was regulated, the spacing between the slats of the crib sides could be any width, which posed a danger to infants if they were too wide. Parents and caregivers used padded crib bumpers to protect infants. Now that cribs must meet safety standards, the slats don't pose the same dangers. As a result, the bumpers are no longer needed. Evidence does not support using crib bumpers to prevent injuries. In addition, evidence shows that crib bumpers can cause serious injuries and death. Keeping them out of an infant's sleep area is the best way to avoid these dangers. http://www.nichd.nih.gov/health/topics/sids/conditioninfo/pages/faqs.aspx#bumpers (accessed 2/2013)

Similarly, the American Academy of Pediatrics website changed its 2011 discussion of the correct use of bumper pads to a recommendation in 2012 that bumper pads not be used at all:

Organization	Previous Recommendation	Most Recent Recommendation
AAP	If bumper pads are used, remove them when the baby begins to stand so that they can't be used as steps. http://www.healthychildren.org/english/safety-prevention/at-home/Pages/Choosing-a-Crib.aspx (accessed 1/2011)	Do not use pillows, bumper pads, quilts, comforters, sheepskins, stuffed toys, other soft products, or any objects that could increase the risk of suffocation or strangulation. http://www.healthychildren.org/english/safety-prevention/at-home/Pages/Choosing-a-Crib.aspx (accessed 2/2013)
AAP	Baby Bedding, Bumpers, and Blankets If you come to find that the excitement you feel about having a new baby is wrapped up in the buying of a fancy baby bedding set complete with bumper and quilted blanket, then don't let us stop you. After all, we couldn't resist the parental urge to splurge either—at least not the first time around. For those of you who are interested in taking a more minimalist approach, now is the time for us to point out that as cute as it may be to walk into the nursery and see the lamp match the wallpaper border match the blanket match the diaper holder…you get the picture, you really don't need any of it. For safety's sake, those big crib quilts should be kept out of your baby's sleeping environment, and you should remove the bumper padding as soon as your baby starts moving around to make sure she doesn't stand a chance of getting tangled in it. The receiving blanket(s) and/or pajamas you use to wrap your baby in should be enough for warmth. If you're really set on using a baby blanket, we suggest using a small, thin, lightweight one instead of anything thick or fluffy. http://www.healthychildren.org/English/ages-stages/baby/sleep/Pages/Suitable-Sleeping-Sites.aspx (accessed 1/2011)	**Baby Bedding, Bumpers, and Blankets** If you come to find that the excitement you feel about having a new baby is wrapped up in the buying of a fancy baby bedding set complete with bumper and quilted blanket, then don't let us stop you. After all, we couldn't resist the parental urge to splurge either—at least not the first time around. For those of you who are interested in taking a more minimalist approach, now is the time for us to point out that as cute as it may be to walk into the nursery and see the lamp match the wallpaper border match the blanket match the diaper holder…you get the picture, you really don't need any of it. **For safety's sake, keep soft objects or loose bedding out of the crib. This includes pillows, blankets, and bumper pads. Bumper pads should not be used in cribs. There is no evidence that bumper pads prevent injuries, and there is a potential risk of suffocation, strangulation or entrapment. The receiving blanket(s) and/or pajamas you use to wrap your baby in should be enough for warmth.** http://www.healthychildren.org/English/ages-stages/baby/sleep/Pages/Suitable-Sleeping-Sites.aspx (accessed 2/2013)

The SIDS advocacy group, First Candle, recently changed its website advice as well. In 2011, the website said to avoid "soft or pillow-like bumpers," but their most recent advice is to avoid the use of any bumpers:

Organization	Previous Recommendation	Most Recent Recommendation
First Candle	Soft or pillow-like bumpers, wedges and positioners should never be used in your baby's sleep area. http://www.firstcandle.org/new-expectant-parents/bedtime-basics-for-babies/create-a-safe-sleep-zone/ (accessed 1/2011)	Crib bumpers, wedges and positioners should never be used in your baby's sleep area. http://www.firstcandle.org/new-expectant-parents/bedtime-basics-for-babies/create-a-safe-sleep-zone/ (accessed 2/2013)

Health Canada gives guidance on the manufacture of bumpers, such as minimum tie lengths and recommendations on tie location and lock stitching. Health Canada's conclusion is that bumpers can be a risk, but bumpers are not banned in Canada. They just recommend against their use:

> Manufacturers, distributers, and retailers of bumper pads should ensure that the following minimum safety specifications are met:
>
> Bumper pads should be capable of being secured along their top and bottom edges at all corners, as well as at the midpoints of the long sides of the crib.
>
> Ribbons, strings, or ties on bumper pads should not exceed 23 cm (9 inches).[2]
>
> Lock-stitching should be used in the production of bumper pads.
>
> A permanent conspicuous label should be attached to the bumper pad that provides a warning which conveys the following:
>
> "To prevent entanglement or strangulation, position ties to outside of crib and be sure they are secure. Remove bumper pads when child can sit up unaided"

Conclusion

> The use of bumper pads may expose young children to the hazards of entanglement, entrapment, strangulation, and suffocation.
>
> Accordingly, it is the position of Health Canada that bumper pads compromise the safety of children with negligible perceived benefits. Therefore, Health Canada recommends that the Canadian public discontinue the use of these products. Bumper pads that continue to be bought and sold on the Canadian market should meet the minimum safety recommendations outlined in this policy.

http://www.hc-sc.gc.ca/cps-spc/legislation/pol/bumper-bordure-eng.php (accessed 2/2013)

The evolution of these messages illustrates how prominent, respected child safety organizations and agencies have strengthened their recommendations about the use of crib bumpers in the last few years. The former, popular message was to avoid "pillow-like" bumpers. The most recent advice is to avoid any bumpers. Given the long history of bumper use in the United States and the recent changes in the public advice of prominent safety advocates, staff believes that consumers have faced some confusion about the construction of a proper sleep setting for their infants. The need for child health and safety advocates to speak with a consistent voice is important, especially given the potentially confusing or potentially contradictory change in advice that has occurred.

March 2013 Case No	Thach et al Table 1	Age (mths) (not in Thach)	Sex (red font not in Thach)	Thach Table 1 Case Narratives Reported as "Medical Examiners' summaries of deaths" : blue = EPIR DCRT narrative by coder: Purple = EPIR IDI synopsis from investigator: red = EPIR IPII narrative by coder; green = Unique info only found in a source document pdf (or Authors note italic font)	IDI narrative - verbatim EPIR text	DTHS narrative - verbatim EPIR text	IPII narrative - verbatim EPIR text	Available documents (updated April 2013)	Staff's overview of all available case details highlighting key facts and opinion as to whether the bumper played a primary role in the death (clear, unclear, confounded, irrelevant or confounded) and whether could still have occurred without a bumper being present *(Oct 2012 - New Information Added to HS Initial view from April 2012)*	Thach Classification* (FA; WB; BT)	Bumper Clearly the Primary Cause?	Any role for bumper? (1º or 2º [primary or	Staff Classification** AC, PPC, UNK, OOS	Staff's View of Actual or Most Probable Primary Cause(***	HS View of Key Summary Case Details
32	1	2	M	"Face obstructed by crib bumper pad-positional asphyxia. 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." **(Thach narrative is a combination of the full verbatim EPIR DTHS narrative plus the full verbatim EPIR IPII-MECAP narrative)**		FACE DESTRUCTED BY CRIB BUMPER PAD - POSITIONAL ASPHYXIA - AUTOPSY YES	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. 03-09004	IPII-MECAP (2 pages); DTHS (1 page); suppl IPII (12 pages autopsy, photos)	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, acccident, 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 considers the crib bumper appears irrelevant as primary cause in this death. - Note 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.***	FA	N	Y-2º	AC	SIC	SIC- entrapment death in a secondhand crib missing its hardware - this resulted in crib frame failure and creation of a hazardous gap.
27	2	7	F	**"Died of asphyxiation caused by pressure against an overstuffed crib bumper during sleep.** A 7-month old female was found unresponsive in her crib by her mother. The victim was placed on her back in the crib." **(Thach narrative is the EPIR IDI narrative which has been selectively truncated to omit key facts that the crib was missing its mattress and contained pillows).**	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.***	FACE AGAINST OVERSTUFFED CRIB BUMPER - ASPHYXIATION - AUTOPSY YES		IDI (30 pages); DTHS (1 page)	This case involves a 7 month-old girl found dead in her crib. Although the autopsy report and the DCRT documents both note the ME's findings as *"asphyxia"* with injury caused by *"face against an overstuffed crib bumper",* the ME report does not convey the full facts evident in the police report. The police report has death scene photos and officers' statements that clearly show the baby was found dead in a broken crib that was missing its mattress and head board. The crib was filled with thick bedding; several large pillows/ thick blankets were used as a makeshift mattress and a pillow was used as a makeshift headboard. The girl was found on her back with her head tipped backwards and downwards below her shoulder level. Her neck was hyperextended into a 10-inch gap between the pillow/blankets used as a mattress and the pillow used as the headboard. Her inverted face was pressed against the pillow used as the headboard. Although an untied manufactured crib bumper was present in the crib, it was not involved in her death. ***Staff considers the primary cause of death to be the broken crib (missing mattress and headboard) coupled with use of multiple pillows in the crib. Staff believes these crib defects directly lead to a positional asphyxia type death involving neck hyperextension plus occlusion of the mouth and nostrils of the baby's inverted head. The unsecured crib bumper appears irrelevant and uninvolved in this death.***	FA	N	N	AC	SIC	SIC- broken crib missing mattress, headboard- makeshift pillows used as substitutes. Entrapment death due to neck hypertension, head inversion, face into pillow used as headboard

March 2013 Case No	Thach et al Table 1	Age (mths) (not in Thach)	Sex (red font not in Thach)	Thach Table 1 Case Narratives Reported as "Medical Examiners' summaries of deaths" : blue = EPIR DCRT narrative by coder: Purple = EPIR IDI synopsis from investigator: red = EPIR IPII narrative by coder; green = Unique info only found in a source document pdf (or Authors note italic font)	IDI narrative - verbatim EPIR text	DTHS narrative - verbatim EPIR text	IPII narrative - verbatim EPIR text	Available documents (updated April 2013)	Staff's overview of all available case details highlighting key facts and opinion as to whether the bumper played a primary role in the death (clear, unclear, confounded, irrelevant or confounded) and whether could still have occurred without a bumper being present *(Oct 2012 - New Information Added to HS Initial view from April 2012)*	Thach Classification* (FA; WB; BT)	Bumper Clearly the Primary Cause?	Any role for bumper? (1° or 2° [primary or	Staff Classification** AC, PPC, UNK, OOS	Staff's View of Actual or Most Probable Primary Cause(***	HS View of Key Summary Case Details
20	3	7	M	"A coroner determined a 7-month-old male infant died in a crib due to positional asphyxiation—face in corner of crib against bumper pad. **Victim was on his back with head turned to right, and his face was up into the corner of the bumper pad."** **(Thach narrative first sentence is the verbatim EPIR IDI narrative Second sentence is a "near verbatim sentence" from the police report text in the IDI)**	A CORONER DETERMINED A 7 MONTH MALE INFANT DIED IN A CRIB DUE TO POSITIONAL ASPHYXIATION - FACE IN CORNER OF CRIB AGAINST BUMPER PAD.	INFANT'S FACE IN CORNER OF CRIB - POSITIONAL ASPHYXIATION - AUTOPSY NO		IDI (30 pages); DTHS (1 page); suppl IPII (5 pages-MD autopsy)	This case involves a 7 month-old boy found not breathing, in his crib, by his babysitter who called 911. She said he was lying on his back with his face turned toward his right side and his face was *"up into the corner of the bumper pad".* The baby had had a respiratory infection (5 days on an antibiotic) and the police responders noted that they had difficulty attempting artificial respiration because his airways appeared blocked and his jaw appeared locked even though he was still warm (not in rigor). Paramedics transported the baby to the ER where he was pronounced dead. Contrary to the DTHS EPIR narrative, the police report clearly states that an autopsy was conducted in their presence. The police report contains officer's notes on the autopsy indicating that the MD 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. He apparently 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 (staff has no notes on microscopic findings or lab culture tests). It is unclear why the DCRT, signed more than 3 months later, ruled the cause to be "*positional asphyxia"* as a result of *"infant's face in corner of crib".* Strangely, it appears to be signed by a non-MD coroner (funeral home employee) and has conflicting information as to whether an autopsy was done saying NO (box 25a), Yes (box 25b). The EPIR DTHS summary narrative incorrectly states AUTOPSY NO; whereas police records clearly indicate an autopsy was done in their presence. ***Although full autopsy findings are not available, staff considers that an older child, lying supine, is developmentally capable of moving his head if his face is obstructed and that this boy likely died from a medical issue related to complications of a known respiratory infection. Staff finds that the crib bumper appears confounded (unlikely) as the primary cause of death.*** *Supplemental information - supine - strange finding crease on forehead? denuded tracheal epithelium? - consult with forensic pathologist Dr Mary Case - Dr Thach co-author- troubling interpretation*	FA	N	?	UNK	MI	Unclear - ruled positional asphyxia by ME. Ambiguous information in autopsy re likely respiratory infections/MI and crease on forehead of supine child, plus unusual finding of denuded tracheal epithelium seems overlooked? NOTE: paramedics reported the boy appeared to have locked jaws and blocked airways, making artificial respiration difficult (he was stll warm i.e., not rigor)

March 2013 Case No	Thach et al Table 1	Age (mths) (not in Thach)	Sex (red font not in Thach)	Thach Table 1 Case Narratives Reported as "Medical Examiners' summaries of deaths" : blue = EPIR DCRT narrative by coder: Purple = EPIR IDI synopsis from investigator: red = EPIR IPII narrative by coder; green = Unique info only found in a source document pdf (or Authors note italic font)	IDI narrative - verbatim EPIR text	DTHS narrative - verbatim EPIR text	IPII narrative - verbatim EPIR text	Available documents (updated April 2013)	Staff's overview of all available case details highlighting key facts and opinion as to whether the bumper played a primary role in the death (clear, unclear, confounded, irrelevant or confounded) and whether could still have occurred without a bumper being present *(Oct 2012 - New Information Added to HS Initial view from April 2012)*	Thach Classification* (FA; WB; BT)	Bumper Clearly the Primary Cause?	Any role for bumper? (1° or 2° [primary or	Staff Classification** AC, PPC, UNK, OOS	Staff's View of Actual or Most Probable Primary Cause(***	HS View of Key Summary Case Details
Not included in Epi data search 2013	4	4	M	"This incident involved the death of a 4-month-old infant due to positional asphyxia. The infant was found unresponsive by his mother. **He had crawled face first into the corner of his crib with his nose and mouth pressed against the protective bumpers."** **(Thach narrative is a combination of the first one and a half verbatim sentences in the EPIR IDI narrative (selectively truncated to omit key fact that the case involved a bassinet). The last part is a verbatim selected sentence from an IDI support attachment i.e., MD's (coroner) autopsy opinion, which mistakenly used "crib" to describe what elsewhere in the IDI is clearly reported (text and photos) to be a rocking -type wood bassinet in which the prone victim and his twin brother were sleeping).**	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.***	CHILD TRAPPED IN CORNER OF CRIB - ACUTE CARDIORESPIRATORY FAILURE; SUFFOCATION; POSITIONAL ASPHYXIA - AUTOPSY YES		IDI (38 pages); DTHS (1 page)	NOTE: The EPIR summary narrratives (IDI or DTHS) do not indicate that this case involves an at risk 4 month-old preemie twin boy who was born 3 months early (only~1m by gestational age) and who was sleeping with his twin brother. The EPIR DTHS record (and Thach narrative) incorrectly states that he died in a crib, whereas the IDI report and coroner's photos clearly show that the twins were sleeping together in a rocking wooden bassinet, in which a full size cloth bumper was being used (it wrapped a1.5 times around the crib perimeter). The victim had a history of mild bronchopulmonary and renal dysplasia, mild focal heart pathology and corrective surgery for bilateral hernias; he was also taking medications for lung congestion and constipation. The twins were placed prone at opposite ends of the bassinet. At ~5am, the mom removed one twin for a feed, then found the victim unresponsive in the corner of the bassinet. He somehow had become trapped with *"his face up against"* the bassinet side wall, in the area where the overlapping bumper was double thick. The autopsy MD noted blanching of the forehead and nostrils, which also had a *"slightly pushed up appearance and show some pressure artifact."* He opined that death was due to *"positional asphyxia"* noting the baby*" had crawled face first into the corner of his crib (sic) with his nose and mouth pressed against the protective bumpers"* Staff considers this death was more likely due to uneven weight distribution of the multiple occupants in the rocking bassinet, coupled with misuse of the full-size bumper. It appears probable that this caused the bassinet to become fixed in a tilted position resulting in the victim's face being forcefully maintained against the double thick, overlapping section of the misused (too long) crib bumper, until his twin was removed for feeding. ***Although the baby ultimately suffocated because his face was reportedly pressed against the misused full-sized crib bumper, staff considers the crib bumper only played a secondary role in this death. Furthermore, staff notes that positional asphyxia deaths can occur in any rocking type bassinet/cradle that gets stuck in a fixed tilt, regardless of the presence of a crib bumper, and that this risk is enhanced by multiple occupancy, particularly for vulnerable young infants, preemies and twins. Staff considers the combination of multiple occupants in a rocking bassinet to be the primary cause of this vulnerable preemie twin's death.***	FA	N	Y-2º	OOS-bassinet	CSS-with twin	Postiional asphyxia -sleeping in rocking bassinet with twin - found with nose and mouth pressed against overlong (full crib size) bumper pad. Nostrils had pushed up appearance consistent with a pressure artifact, suggesting baby was likely trapped against bassinet side, by twin, probably due to their uneven weight distribution causing the rocking bassinet to come to lie at a fixed tilt.

March 2013 Case No	Thach et al Table 1	Age (mths) (not in Thach)	Sex (red font not in Thach)	Thach Table 1 Case Narratives Reported as "Medical Examiners' summaries of deaths" : blue = EPIR DCRT narrative by coder: Purple = EPIR IDI synopsis from investigator: red = EPIR IPII narrative by coder; green = Unique info only found in a source document pdf (or Authors note italic font)	IDI narrative - verbatim EPIR text	DTHS narrative - verbatim EPIR text	IPII narrative - verbatim EPIR text	Available documents (updated April 2013)	Staff's overview of all available case details highlighting key facts and opinion as to whether the bumper played a primary role in the death (clear, unclear, confounded, irrelevant or confounded) and whether could still have occurred without a bumper being present (Oct 2012 - New Information Added to HS Initial view from April 2012)	Thach Classification* (FA; WB; BT)	Bumper Clearly the Primary Cause?	Any role for bumper? (1º or 2º [primary or	Staff Classification** AC, PPC, UNK, OOS	Staff's View of Actual or Most Probable Primary Cause(***	HS View of Key Summary Case Details
14	5	14	M	"A 14-month-old baby boy died sleeping in a crib with his face pressed firmly against a bumper pad." (Thach narrative is verbatim first sentence of the EPIR IPII-MECAP narrative. It selectively omits the second (last) sentence which states: "Baby was treated weeks ago for a head and chest cold with extensive breathing treatment").			A 14 MONTHL 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.	IPII-MECAP missing - Limited to EPIR IPII narrative: Suppl IPII-traced 95 page full ME investigation, autopsy, police report, med. records	Limited information. The only record for this case of the death of a 14 month-old boy is an IPII-MECAP report, but the original document is missing from archives (personal communication from Clearinghouse staff). Staff's opinion is based on the limited information provided in the EPIR IPII summary narrative which states the *"14 month-old baby boy died sleeping in a crib with his face firmly pressed against a bumper pad. Baby was treated weeks ago for a head and chest cold with extensive breathing treatment"* . Staff assumes that an otherwise healthy 14 month-old boy is developmentally capable of moving his head if his face simply became pressed against a bumper pad. The boy's reported history of a prior respiratory infection that required extensive breathing treatment suggests some respiratory medical issue could be the most likely primary cause of death, perhaps asthma? ***Despite limited information, staff considers it unlikely that the crib bumper is relevant as the primary cause of death.*** ***Supplemental information notes this older boy had abnormal brain symmetry (cerebellum cerebellar peduncle 40% smaller but normal histology) and a history of serious breathing issues. He had recently been diagnosed with reactive airways, and had prior and ongoing infections - his father had refused MD recommended Prelone steroid treatment, and he saw him again just 2 days before death for ongoing congestion. These findings appear to support staff's views. Note: although the father specified no objects were close to his head when found, the death scene description somehow evolved to face pressed against bumper pad in the MEs report of positional asphyxia accidental? The autopsy reads "discovered face down on his stomach with his face pressed against a bumper pad" "pressure marks, nose"(see indistinct ME's photo showing a baby face down on mattress, with top of head simply touching the bumper); both mum and dad say he was lying face down in the crib between the mattress pad and the bumper pad and no objects were near him - he had been very sick)***	FA	N	N	PPC	MI	MI - history of serious breathing, reactive airways, ongoing illness issues, abnormal brain symmetry at autopsy. Note: at the scene, both parents specified to police that they found their son face down in crib (or slightly turned to left mum) with no objects close to his head; indistinct ME's photo (what/where/when?) appears to show a prone baby face down in the crib with the top of his head touching the bumper. In the final diagnosis of positional asphyxia, the ME's ambiguous statement in the autopsy report *"discovered face down on his stomach with his face pressed against a bumper pad"* appears to have evolved erroneously into *"baby's face was pressed into the bumper"*
Predates Epi 2013 search range	6	11 day	F	"Baby got face into plastic bumper pad of cradle. Crib pad was much too large for this size of bed. Night was very hot, and it was felt that the crib pad adhered to the victim due to the heat. Baby got face into plastic bumper pad. Anoxia consistent with accidental suffocation. (Thach narrative is reordered, near verbatim text from the first and last two sentences of the EPIR DTHS narrative. The second and third sentences are near-verbatim text lifted from the IDI report).	THIS INVESTIGATION INITIATED FROM A DEATH CERTIFICATE WHICH REPORTED THE DEATH OF AN ELEVEN DAY OLD INFANT. THE COUNTY CORONER INVOLVED IN THE INVESTIGATION STATED THAT IT IS FELT THAT DEATH WAS DUE TO SUFFOCATION OF THE INFANT WHEN HER FACE WAS PUSHED INTO THE CRIB PAD WHICH SURROUNDED THE CRADLE DURING SLEEP. THE CRADLE WAS BEING USED BY THE MOTHER FOR 2 TWIN INFANTS. IT WAS AN ANTIQUE CRADLE. THE CRIB PAD WAS TOO LARGE FOR THE SIZE OF THE CRADLE.	FACE INTO PLASTIC BUMPER PAD OF CRADLE - ANOXIA CONSISTANT WITH ACCIDENTAL SUFFOCATION; BABY GOT FACE INTO PLASTIC BUMPER PAD; RESTLESSNESS DUE TO TEMPERATURE AND HUMIDITY - CONGESTION, BILATERAL, MODERATE - AUTOPSY YES		IDI (4 pages); DTHS (1 page)	Limited details: This case involves the death of an 11 day-old twin girl in antique cradle (>100 years-old) where she was sleeping overnight with her twin. An overly large plastic bumper was in the cradle and the victim was found the next morning with *"her face pressed tight against the crib pad" (*i.e the plastic bumper). The handwritten DCRT(part illegible) was completed by the local coroner (school teacher, not an MD) and indicates that no autopsy was done. The IDI indicates the coroner would not release her full report without further investigation by an MD, pathologist. Assuming the antique cradle to be a rocking type cradle (as was typical 100 years ago), staff considers this death was more likely due to uneven weight distribution of the multiple occupants in the cradle, coupled with misuse of the overly large plastic bumper. It appears probable that the cradle became fixed in a tilted position, resulting in the newborn victim's face being forcefully maintained against the large plastic bumper. Although the baby ultimately suffocated because her face was reportedly pressed tight into the overly long bumper, staff considers the bumper played only a secondary role in this death. ***Furthermore, staff notes that positional asphyxia deaths can occur in any rocking type bassinet/cradle that gets stuck in a fixed tilt, regardless of the presence of a crib bumper, and that this risk is enhanced by multiple occupancy, particularly for vulnerable young infants, preemies and twins. Staff considers the combination of multiple occupants in a rocking bassinet to be the primary cause of this vulnerable preemie twin's death.*** NOTE: the EPIR DTHS record has the victim's age entered incorrectly as 4 months instead of 11 days; also the summary DTHS records notes that an autopsy was done, but no autopsy was checked on the actual DCRT source document.	FA	N	Y-2º	OOS-bassinet	CSS-with twin	Suffocation death of newborn in antique cradle (bassinet) with twin - found face pressed against "overly" large plastic bumper- note coroner is local teacher not an MD! Unclear if cradle becanme unalanced in fixed tilt

March 2013 Case No	Thach et al Table 1	Age (mths) (not in Thach)	Sex (red font not in Thach)	Thach Table 1 Case Narratives Reported as "Medical Examiners' summaries of deaths" : blue = EPIR DCRT narrative by coder: Purple = EPIR IDI synopsis from investigator: red = EPIR IPII narrative by coder; green = Unique info only found in a source document pdf (or Authors note italic font)	IDI narrative - verbatim EPIR text	DTHS narrative - verbatim EPIR text	IPII narrative - verbatim EPIR text	Available documents (updated April 2013)	Staff's overview of all available case details highlighting key facts and opinion as to whether the bumper played a primary role in the death (clear, unclear, confounded, irrelevant or confounded) and whether could still have occurred without a bumper being present *(Oct 2012 - New Information Added to HS Initial view from April 2012)*	Thach Classification* (FA; WB; BT)	Bumper Clearly the Primary Cause?	Any role for bumper? (1° or 2° [primary or	Staff Classification** AC, PPC, UNK, OOS	Staff's View of Actual or Most Probable Primary Cause(***	HS View of Key Summary Case Details
Predates Epi 2013 search range	7	13	M	"A 13-month-old male was found dead in his crib while he and his mother were visiting at his grandmother's house. The infants face was resting against a properly installed plastic bumper pad." **(Thach narrative is verbatim text of complete EPIR IDI investigator's narrative, which is based on a telephone interview with the victim's mother).**	A 13 MONTH OLD MALE WAS FOUND DEAD IN HIS CRIB WHILE HE AND HIS MOTHER WERE VISITING AT HIS GRANDMOTHER'S HOUSE. THE INFANTS FACE WAS RESTING AGAINST A PROPERLY INSTALLED PLASTIC BUMPER PAD.		10 MO. OLD BOY SUFFICATED IN CRIB BUMPER PAD.	IDI (2 pages); IPII-Hotline-consumer (missing)	Limited information This case involves the death of a 13 month-old boy who was found lifeless in his crib with *"his face turned into the bumper"*. His mom initially had called the CPSC hotline about a potential suffocation hazard presented by the bumper. The short IDI report notes that she was withdrawing her complaint having specifically questioned the autopsy MD about her bumper theory. Apparently, he had completely refuted this and told her that he attributed the death to a "*congenital arterial(sic should be atrial) septum defect*", and his diagnosis was that her son died due to a *"cardiac arrhthymia brought on by his defective heart"* with *"no evidence of suffocation whatsoever."* (This is not evident in the EPIR IDI synopsis). The victim was older than typical crib death suffocation victims and was known to have an atrial septum birth defect (hole-in- the-heart baby); with corrective surgery anticipated at about 4-5 years of age. ***Despite the limited information, staff believes a pre-existing medical congenital defect to be the clear cause of this older child's death and so considers the crib bumper is irrelevant as primary cause.*** *Supplemental information requested - not received (as of Nov 2012).*	FA	N	N	AC	MI	Autopsy MD refuted any role for the bumper and attributed death to the 13 month old boy's congenital heart defect (atrial septal wall) for which future corrective surgery was known to be needed
3	8	3	M	"A 3-month-old male died of SIDS in his crib with his face against the bumper pad." **(Thach narrative is verbatim complete EPIR IPII narrative).**	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.		A 3 MONTH OLD MALE DIED OF SIDS IN HIS CRIB WITH HIS FACE AGAINST THE BUMPER PAD.	IDI (21 pages): IPII (1 page)	The IDI of this 3 month-old boy's crib death is based on an interview with the baby's mom and an autopsy report. It was prompted by a Congressman's letter (EPIR pdf not legible; HS obtained a legible copy from archives). The mom reported her husband was caring for the baby while she was out and that he had placed the baby prone in his crib at ~6:45 pm. The boy apparently cried extensively for nearly 2 hours, then at ~9 pm, the dad found him unresponsive, lying prone near the upper left crib corner, with his face turned to the left toward, but not touching, the crib bumper. The mom did not get home until 9:30 pm when she found her husband holding the baby "attempting to call 911." (Strange ~30 minute delay before dad tried to call 911?) The boy was pronounced DOA at the ER. The ME's autopsy report opined the cause of death as SIDS, and noted diffuse lung congestion and slight edema, with thin watery mucus in the airways; cultures and lab tests were pending. The mom reported the autopsy found evidence of an early CMV (cytomegalo virus) respiratory infection, which did not did not explain the death, but would likely have caused pneumonia or infection after 7-10 days (mum or MD's opinion?). In noting that the baby's ***"nose and mouth were not completely covered by the bumper pad"*** the mom seems to discount bumper pad involvment in this crib death. ***Staff agrees with the ME's ruling of a SIDS death, which is consistent with the young infant's prone position; the only other potential risk factor is a possible early respiratory virus. Staff considers the presence of the crib bumper to be incidental and irrelevant in this death.***	FA	N	N	UNK	MI	SIDS per ME, in prone baby - face was not touching the bumper as found by father
Predates Epi 2013 search range	9	2	F	"A 2-month-old female was found dead in her wicker infant basket for a nap after being fed at noon. She was found on her stomach, head turning to the left with face pressed slightly against the padded basket liner. The medical examiner found no anatomic cause and attributed the death to probable suffocation." **(Thach narrative is near-verbatim text lifted from IDI narrative).**	AT APPROX. 4:40 PM, A TWO MONTH OLD FEMALE WAS FOUND DEAD IN HER WICKER INFANT BASKET. SHE HAD BEEN PLACED IN THE BASKET FOR A NAP AFTER BEING FED AT NOON. SHE WAS FOUND ON HER STOMACH, HEAD TURNED TO THE LEFT WITH FACE PRESSED SLIGHTLY AGAINST THE PADDED BASKET LINER. THE MEDICAL EXAMINER FOUND NO ANATOMIC CAUSE AND ATTRIBUTED THE DEATH TO PROBABLE SUFFOCATION.		2 MONTH OLD FEMALE DIED WHEN SHE BECAME WEDGED INTO PADS OF BASKET TH AT WAS USED AS ABASSINETTE.	No documents available	Limited details: No source documents are available for the IPII-MECAP and the IDI record (specific requests from Archives have not been fulfilled so staff has only the EPIR database summary narratives) The ME apparently ruled the death of a 2 month-old girl, found dead in a wicker infant basket/bassinet as a probable suffocation. She was reportedly found unresponsive, lying prone, with her face slightly pressed into the basket's padded liner but staff notes that the IPII-MECAP summary does indicate she was wedged into the pads (entrapment). Based on the limited available information, staff suggests the ME's reported findings of suffocation might also involve wedging entrapment. ***This case does not involve a crib bumper or a crib, and therefore is considered out of scope of the current staff CPSC staff crib bumper review.***	FA	N	N	OOS-basket	LI	Limited details - death of prone 2m girl iin a basket, wedged between basket's padding lining. Does NOT involve a traditional crib bumper

March 2013 Case No	Thach et al Table 1	Age (mths) (not in Thach)	Sex (red font not in Thach)	Thach Table 1 Case Narratives Reported as "Medical Examiners' summaries of deaths" : blue = EPIR DCRT narrative by coder: Purple = EPIR IDI synopsis from investigator: red = EPIR IPII narrative by coder; green = Unique info only found in a source document pdf (or Authors note italic font)	IDI narrative - verbatim EPIR text	DTHS narrative - verbatim EPIR text	IPII narrative - verbatim EPIR text	Available documents (updated April 2013)	Staff's overview of all available case details highlighting key facts and opinion as to whether the bumper played a primary role in the death (clear, unclear, confounded, irrelevant or confounded) and whether could still have occurred without a bumper being present (Oct 2012 - New Information Added to HS Initial view from April 2012)	Thach Classification* (FA; WB; BT)	Bumper Clearly the Primary Cause?	Any role for bumper? (1° or 2° [primary or	Staff Classification** AC, PPC, UNK, OOS	Staff's View of Actual or Most Probable Primary Cause(***	HS View of Key Summary Case Details
Not included in Epi data search 2013	10	2	M	"A 2-month-old male died of anoxia when he was sleeping and his face was pressed against the bumper of the 'bassinet/carrier' (cradle). The victim was dead on arrival. ***Note: Mother stated that the baby died due to the tilt of the bassinet/carrier."*** ***(Thach narrative is verbatim text lift of full IDI narrative plus an additional authors' note indicating awareness of non-EPIR summary detail that mom reported death was due to a tilted sleep surface - latter appears to be derived from verbatim text strings in the IDI report).***	A 2 MONTH OLD MALE DIED OF ANOXIA WHEN HE WAS SLEEPING AND HIS FACE WAS PRESSED AGAINST THE BUMPER OF THE "BASSINET/CARRIER" (CRADLE). THE VICTIM WAS DEAD ON ARRIVAL.		A 2 MONTH OLD MALE DIED SLEEPING IN A BASSINET/CRADLE/SWING WITH HIS FACE COMPRESSED AGAINST A PILLOW.	IDI (37 pages); IPII-MECAP (8 pages - in IDI)	This case involves the death of a 2 month-old boy in the bassinet/cradle component of a convertible 4-in-1 combination infant product. (The infant bassinet/portable carry bed and infant carrier seat components convert to a swinging bassinet-cradle and a swinging seat, respectively, when attached to a battery-powered swing mechanism). The mom had placed the baby in a prone position, with his face to one side, in the bassinet/portable bed, which was attached to the swing frame. She set the swing on low speed and left the room. On her return, she found him *"crowded into the bottom corner of the rocking bassinet" "with his head bent forward"* and his "face pressed against" the plastic bumper of the tilted bassinet. Following autopsy, the ME ruled the death as *"positional asphyxia, accident"* due to *"awkward lie in cradle".* The mom reported that her son's death was due to the "tilt of the bassinet" and his location against the bumper; she also noted that *"his face was flattened"* when found. The IPII-MECAP report notes that the boy was found *"lying with his long axis along the short axis of the cradle. The cradle was tipped with all its weight toward one end"* and the "*the child's back was arched and the child's face was compressed against the pillows".* ***Although the baby ultimately asphyxiated because his face was pressed against the bassinet bumper, staff considers the bassinet bumper played only a secondary role in this death. Furthermore, staff notes that positional asphyxia deaths can occur in any rocking type bassinet/cradle that gets stuck in a fixed tilt, regardless of the presence of a bumper. Staff considers the fixed tilt of the rocking bassinet to be the primary cause of this 2 month-old boys death. This case does not involve a crib bumper or a crib, and therefore is considered out of scope of the current staff CPSC staff crib bumper review.***	FA	N	Y-2º	OOS-bassinet	SIP	Positiional asphyxia was in a convertible multi product - battery powered rocking bassinet, cradle, swing seat - found with nose and mouth pressed against the plastic padding at one end of the tilted bassinet which had become unbalanced (product design defect). "his face was flattened". This case DID NOT involve a traditional crib bumper.
30	11	**2.75**	**F**	"Baby suffocated at home in the corner of the crib against the crib bumper. Suffocation—accidental." **(Thach narrative is complet verbatim EPIR DTHS narrative).**		BABY SUFFOCATED AT HOME IN THE CORNER OF THE CRIB AGAINST THE CRIB BUMPER. SUFFOCATION - ACCIDENTAL. AUTOPSY - YES.		DTHS-poorly legible DCRT (1page); suppl IPII (19 page autopsy,investigation, coroner rpt)	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 DTHS 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)***	FA	N	Y-2º	PPC	CSS	**Suffocation in corner of the crib against bumper pad per ME. Coroner's report noted - CSS-cosleeping with twin - soft bedding under babies (blanket over mattress, afghan, padded comforter and bumper that sagged inwards in corner where baby was found)**
28	12	4	M	"Baby found face down in crib, pinned between bumper pad and sibling sister. A male infant, age 4 months, placed for a nap in a crib with a twin sister was found wedged between the bumper pad and his sister. Cause of death asphyxia due to positional crib accident." **(Thach narrative is a combination of the partial verbatim text from the EPIR DTHS narrative followed by the full verbatim EPIR IPII-MECAP narrative).**		BABY FOUND FACE DOWN IN CRIB, PINNED BETWEEN BUMPER PAD AND SIBLING SISTER - ASPHYXIA; POSITIONAL CRIB ACCIDENT - AUTOPSY YES	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. 02-0634.	IPII-MECAP (1page); DTHS (1 page)	Limited information: Despite the limited information, the death certificate clearly notes that this 4 month-old boy died as a result of *positional asphyxia* when he was found *"face down in crib, pinned between bumper pad and sibling sister".* The IPII-MECAP report further clarifies that the sister was his twin. ***Staff considers this death resulted from wedge entrapment in a prone position caused by multiple occupants in the crib. The bumper was not touching the victim's face and staff considers death could have resulted under similar circumstances, even if the bumper was not present. Despite limited details, staff considers the crib bumper to be irrelevant as the primary cause in this death.***	WB	N	Y-2º	AC	CSS	CSS- prone boy found wedged face down between bumper/crib side and twin

March 2013 Case No	Thach et al Table 1	Age (mths) (not in Thach)	Sex (red font not in Thach)	Thach Table 1 Case Narratives Reported as "Medical Examiners' summaries of deaths" : blue = EPIR DCRT narrative by coder: Purple = EPIR IDI synopsis from investigator: red = EPIR IPII narrative by coder; green = Unique info only found in a source document pdf (or Authors note italic font)	IDI narrative - verbatim EPIR text	DTHS narrative - verbatim EPIR text	IPII narrative - verbatim EPIR text	Available documents (updated April 2013)	Staff's overview of all available case details highlighting key facts and opinion as to whether the bumper played a primary role in the death (clear, unclear, confounded, irrelevant or confounded) and whether could still have occurred without a bumper being present (Oct 2012 - New Information Added to HS Initial view from April 2012)	Thach Classification* (FA; WB; BT)	Bumper Clearly the Primary Cause?	Any role for bumper? (1° or 2° [primary or	Staff Classification** AC, PPC, UNK, OOS	Staff's View of Actual or Most Probable Primary Cause(***	HS View of Key Summary Case Details
21	13	4	M	"A 4-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." **(Thach narrative is verbatim complete verbatim EPIR IDI narrative).**	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.		4 MONTH OLD MALE DIED DUE TO ASPHYXIA BY SUFFOCATION AFTER HE WAS WEDGED BETWEEN THE MATTRESS AND THE BUMPER PAD OF THE CRIB. 00-0319.	IDI (34 pages); IPII-MECAP (4 pages)	According to the initial IPII-MECAP report (a 4-page autopsy report), the death of this 4 month-male resulted from *"asphyxia by suffocation, accidental"* associated with *"a history of being found wedged in bed clothing (crib bumper)"*. The full IDI contains a full police report with death scene photos and statement given by the father. He reportedly found his son prone in the crib with *"arms up and his face into the soft padding."* Contrary to the autopsy MECAP report, there is no mention of any kind of ***wedging*** in police report or father's report which simply notes "an apparent indentation in the soft padding where the baby's face was." An indent can be seen bumper in the black and white police photos taken at the death scene. These also show a sagging bumper and thick blankets were present in the crib. This case is confounded by the inconsistency between the ME and police reports regarding "wedging", plus the infant's prone position, and the thick blankets in the crib. ***Due to these multiple confounders, it is unclear whether the crib bumper had a primary role in this death.***	WB	N	?	UNK	CSS-MC-LI	Multiple confounders and inconsistencies in death of prone child in CSS - thick blankets and sagging bumper
16	14	10	M	"A 10-month-old male died of positional asphyxia, wedged between his crib railing and a dresser 6 inches away. He apparently stood on the crib bumper pads and climbed over the crib railing." ***Author's note: This case indicates yet another hazard of bumper use. The bumper allowed the infant to climb from a relatively safe environment into a hazardous one.*** **(Thach narrative is verbatim text of complete EPIR IDI narrative. It also includes an authors' note concerning an unwitnessed event that HS staff considers unobjective bias).**	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.	WEDGED BETWEEN CRIB AND FURNITURE - ASPHYXIA BY COMPRESSION OF UPPER NECK WHILE WEDGED BETWEEN FURNITURE AND CRIB - AUTOPSY NO		IDI (19 pages); DTHS (1 page); Suppl IPII-(5 pages-ME autopsy + recreation photos)	This case involves a 10 month-old boy who somehow climbed out or fell out of his crib. His body got caught in a gap between the external crib sides and a nearby dresser, with his chin resting on the edge of the dresser. The death was ruled as "*asphyxia by compression of upper neck while wedged between furniture and crib*" on the DCRT (signed by MD), which notes that no autopsy was done. It was an Coroner's Investigator's opinion that the boy ***probably*** stood on the bumper pad and climbed over the crib railing (as is also opined by Thach et al.,) Staff notes that the victim was reportedly a "larger than average" child and that he was likely much too tall for a mattress set only 15" below the side rail. Projected anthropomorphic data for this child suggests a height exceeding >28.5" and center of gravity of about 15.7" which suggests he could easily have climbed over or fallen over the 15" side rail when standing on the mattress. There is no mention of the crib bumper in the DCRT, police report, or death scene investigator's report. Staff views Author's note/opinion as an ill-considered unobjective biased view not supported by case facts. ***Staff considers this death was caused by a mattress set too high which allowed the large child to fall/climb out of the crib leading to his partial hanging strangulation while caught between furniture and the exterior crib frame; the crib bumper appears irrelevant as the primary cause of death.*** ***Supplemental information does note indicate whether the reconstruction photos, using a doll, were taken in the involved crib/at the scene - but importantly, the photos confirm the boy's head and body were facing away from the crib and previous information reported by HS notes the rail was low enough for the large child to easily get out of the crib without turning his body to climb over the rail. Furthermore, the bumper is not mentioned in the autopsy findings on the cause and manner of death.***	WB	N	N	AC	Mattress not set at lowest position	Asphyxia by compression of upper neck while wedged between furntiture and crib per ME - consequence of falling/climbing over crib rail only 15 inches above the mattress, set at its uppermost position (too high for 10 month old boy)

March 2013 Case No	Thach et al Table 1	*Age (mths) (not in Thach)*	*Sex (red font not in Thach)*	**Thach Table 1 Case Narratives Reported as "Medical Examiners' summaries of deaths"** : blue = EPIR DCRT narrative by coder: Purple = EPIR IDI synopsis from investigator: red = EPIR IPII narrative by coder; **green = Unique info only found in a source document pdf (*or Authors note italic font)***	**IDI narrative - verbatim EPIR text**	**DTHS narrative - verbatim EPIR text**	**IPII narrative - verbatim EPIR text**	**Available documents (updated April 2013)**	**Staff's overview of all available case details highlighting key facts and opinion as to whether the bumper played a primary role in the death (clear, unclear, confounded, irrelevant or confounded) and whether could still have occurred without a bumper being present** ***(Oct 2012 - New Information Added to HS Initial view from April 2012)***	**Thach Classification* (FA; WB; BT)**	**Bumper Clearly the Primary Cause?**	**Any role for bumper? (1º or 2º [primary or**	**Staff Classification** AC, PPC, UNK, OOS**	**Staff's View of Actual or Most Probable Primary Cause(***	**HS View of Key Summary Case Details**
10	15	**1**	M	"Found unresponsive wedged between pillow and bumper pad. Positional asphyxia. **Note: Mother reported the baby's head had slipped off the edge of the pillow. His head was wedged between the pillow and the bumper pads inside the bed."** **(Thach narrative is combination of the verbatim EPIR DCRT narrative and an unknown source's details in the authors' note that the baby's head was wedged between the pillow and bumper pads - that recent supplemental IPII information identified as a cororner's report).**		FOUND UNRESPONSIVE WEDGED BETWEEN PILLOW AND BUMPER PAD POSITIONAL ASPHYXIA - AUTOPSY YES		DTHS - destroyed; Suppl IPII- (20 pages include Dcert, autopsy, coroner's rpt)	Limited information. The only record for this case of the death of a 1 month-old boy is a DTHS report, but the original document is no longer available from archives, having now been destroyed by the Federal Records Center (personal communication from Clearinghouse staff). Staff's initial opinion was based on the EPIR DTHS summary narrative, which indicated that the boy was found unresponsive in crib, and died from *positional asphyxia* due to being *"wedged between pillow and bumper pad"* . ***Despite limited details, and lack of information on the position of the infant's face, staff considered pillow-related wedge entrapment to be the primary cause of death because pillows are recognized as entrapment and/or suffocation hazards in a crib, and can cause an infant death even if a bumper is not present. Staff considers the pillow caused this death and the crib bumper appears irrelevant as primary cause.*** ***Staff's initial view is supported/confirmed by supplemental information in an autopsy and coroner's report which confirmed that the baby was found lying face down in his crib. His head had been "resting on a pillow covered with a blanket.....the infant's head was sort of slipped off the pillow and his head was wedged between the pillow and the bumper inside the crib";"Anatomic findings note 3) Pattern of skin marks which matches the pillow cover is seen over the face"; Additional crib contents, 2 baby blankets and a thick blanket used as a mattress pad and a thick bumper pads surrounded the entire inside of the bed"***	WB	N	Y-2º	PPC	CSS	CSS -coroner's report says found prone, face down on blanket-covered pillow, facial marks matched blanket, but also reports head was wedged between the pillow and crib bumper (ambiguous); plus thick blanket used as mattress pad.
8	16	7	F	"Seven-month-old girl was placed in her crib for a 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 hospital." **(Thach narrative is verbatim text of complete EPIR IDI narrative).**	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 **WEDGE**D BETWEEN THE MATTRESS AND THE BUMPER PAD ATTACHED TO SIDE SLATS. CHILD WAS PRONOUNCED DEAD ON ARRIVAL AT THE HOSPITAL.	BABY BECAME WEDGED BETWEEN CRIB AND MATTRESS AT HOME SUFFOCATION - AUTOPSY NO		IDI (6 pages); DTHS (1page)	Staff notes the death of this 7 month old girl occurred in 1991 (per DTHS record) not 1992 (per INDP record). The baby was reportedly found by her mother with "*her head wedged between the side of the mattress and the bumper pad attached to the crib slats.* " She brought the cold, unresponsive baby to the police department for assistance because she had no phone and the nearest hospital was 12 miles away. CPSC staff requested the full police report but it was never received. The fact that the mother reported the baby's head was **wedged against the side of the mattress** suggests her head had become entrapped in an excessive side gap resulting from either a structurally defective crib and/or an ill-fitting mattress. ***Although the surface contacting the baby's face is not specified, 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. Staff considers that the crib bumper appears irrelevant as the primary cause of death.*** ***Supplemental information requested - not received (as of Nov 2012).***	WB	N	?	UNK	LI-SIC?	Limited information - head "wedged against side of mattress" suggests excessive mattress side gap but information is ambiguous and not clear cut

March 2013 Case No	Thach et al Table 1	*Age (mths) (not in Thach)*	*Sex (red font not in Thach)*	**Thach Table 1 Case Narratives Reported as "Medical Examiners' summaries of deaths"** : blue = EPIR DCRT narrative by coder: Purple = EPIR IDI synopsis from investigator: red = EPIR IPII narrative by coder; **green = Unique info only found in a source document pdf (*or Authors note italic font)***	**IDI narrative - verbatim EPIR text**	**DTHS narrative - verbatim EPIR text**	**IPII narrative - verbatim EPIR text**	**Available documents (updated April 2013)**	**Staff's overview of all available case details highlighting key facts and opinion as to whether the bumper played a primary role in the death (clear, unclear, confounded, irrelevant or confounded) and whether could still have occurred without a bumper being present** ***(Oct 2012 - New Information Added to HS Initial view from April 2012)***	**Thach Classification* (FA; WB; BT)**	**Bumper Clearly the Primary Cause?**	**Any role for bumper? (1^{0} or 2^{0} [primary or**	**Staff Classification** AC, PPC, UNK, OOS**	**Staff's View of Actual or Most Probable Primary Cause(***	**HS View of Key Summary Case Details**
Predates Epi 2013 search range	17	2	M	"Found by mother with face **wedged** between crib mattress and bumper pads. COD: asphyxia." **(Thach narrative seems to be the authors' reconstructed combination of text word strings from both the EPIR DTHS and IDI narratives (does not appear to be ME quote)**	A TWO MONTH OLD MALE CHILD WAS FOUND BY HIS MOTHER DEAD IN HIS CRIB. THE MOTHER FOUND THE CHILD'S FACE BETWEEN THE MATTRESS AND THE BUMPER PADS. THE CHILD'S DEATH IS LISTED BY THE MEDICAL EXAMINER AS "ACCIDENTAL" WITH THE CAUSE OF DEATH "ASPHYXIA."	BABY WEDGED BETWEEN MATTRESS AND SIDES - MECHANICAL ASPHYXIA; BEING WEDGED BETWEEN CRIB MATTRESS AND BUMPER PADS AUTOPSY YES		IDI (4 page); DTHS (1 page); suppl IPII 8 pg (6 new) autopsy+ME summary	This case has ambiguous information in the EPIR summary narratives for the DTHS record and the short 4 page IDI (from archives). The DCRT document (completed by an MD) reports that the immediate cause of death of the 2 month-old boy was *"mechanical asphyxia"* which was due to *"being wedged between crib mattress and bumper pads"* and in describing how the fatal injury occurred, further notes *"baby wedged between mattress and crib sides"*. The CPSC investigator's brief IDI report text notes that no death investigation was done by the ME's office or the police and states that the ME's report lacked any *"information or details on either the crib or mattress or the accident itself. There is no mention of the position of the child's body in the crib."* The IDI EPIR summary narrative simply describes the death as asphyxia (omits "mechanical" descriptor). Based on the ME's use of the term ***mechanical asphyxia*** and note that the baby was ***wedged between the crib sides and the mattress*** , staff interprets this case as likely indicative that the baby was wedge-entrapped in an excessive gap between the crib sides and the mattress. An excessive side gap can result from either a structurally defective crib and/or an ill-fitting mattress and is a recognized entrapment hazard that can cause death by positional asphyxia/suffocation regardless of the presence of a crib bumper. ***Although the baby's face was reportedly contacting the crib bumper, presumably occluding the nose and mouth, staff considers that the crib bumper appears to have played a secondary role, with an excessive side gap likely being the primary cause of death.*** ***Supplemental information includes the autopsy and ME's hand written case narrative report specifying death due to mechanical asphyxia due to being wedged between crib mattress and sides.- Accident. Mom reported her son was well at 1am, then at 7:45 am, she found him"face down in his crib with his face between the bumper pads and mattress."" He was apneic, cold and stiff" The ME's case narrative (p8) specifies the baby was found prone, face down, but does not actually specify whether the baby's face (nose and mouth) was in contact with the bumper. It also does not clarify if death resulted from entrapment (body or head) in a hazardous side gap between the crib frame and the mattress, as suggested by use of "mechanical asphyxia." The MEs information about the primary cause of this asphyxial death is ambiguous and is revised to asphyxia of uncertain unclear primary cause.***	WB	N	?	UNK	LI-SIC?	Mechanical asphyxia in prone position- circumstances unclear because the ME's information is ambiguous. The baby reportedly was found by mom, prone, cold and stiff, face down between bumper pads and mattress. ME's case summary reads" found wedged between his mattress and the side of crib" but notes "cause of death is mechanical asphyxia secondary to being wedged between the crib mattress and sides". No scene investigation, crib was not examined, so there is no clear information to determine whether the ME intentionallly used the descriptor m*echanical asphyxia* as it is commonly used to describe asphyxia due to chest compression/body entrapment (excessive side gap?) as opposed to asphyxia due to occlusion of airway openings, which is more commonly described as suffocation.
25	18	11	F	"An 11-month-old female slid off a day bed mattress. The crib bumper pad is believed to have become caught around the victim's neck, and as she slid forward and she was unable to breathe and suffocated. The cause of death is mechanical asphyxia, the manner of death is considered accidental." **(Thach narrative is near-verbatim text from the EPIR IDI narrative but omits the following text from the end of the first sentence and beginning of second sentence which distorts the incident scenario).**	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 BREATH AND SUFFOCATED. THE CAUSE OF DEATH IS MECHANICAL ASPHYXIA. THE MANNER OF DEATH IS CONSIDERED ACCIDENTAL.	ENTANGLED WITHIN CRIB BUMPER - MECHANICAL ASPHYXIATION - AUTOPSY YES	AN 11 MONTH OLD GIRL DIED AFTER SHE SLID OFF HER DAYBED BETWEEN THE MATTRESS AND A CRIB BUMPER PAD. THE PAD WRAPPED AROUND HER NECK AND SUFFOCATED HER.	IDI (14 pages); IPII-(2 newsclips) : DTHS: (1 page)	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. This case does not involve a crib bumper used on a crib, and therefore, is considered out of scope of the current staff CPSC staff crib bumper review.*** **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.**	WB	NA	NA	OOS	OOS	death in a toddler bed

March 2013 Case No	Thach et al Table 1	*Age (mths) (not in Thach)*	*Sex (red font not in Thach)*	**Thach Table 1 Case Narratives Reported as "Medical Examiners' summaries of deaths"** : blue = EPIR DCRT narrative by coder: Purple = EPIR IDI synopsis from investigator: red = EPIR IPII narrative by coder; **green = Unique info only found in a source document pdf (*or Authors note italic font)***	**IDI narrative - verbatim EPIR text**	**DTHS narrative - verbatim EPIR text**	**IPII narrative - verbatim EPIR text**	**Available documents (updated April 2013)**	**Staff's overview of all available case details highlighting key facts and opinion as to whether the bumper played a primary role in the death (clear, unclear, confounded, irrelevant or confounded) and whether could still have occurred without a bumper being present** ***(Oct 2012 - New Information Added to HS Initial view from April 2012)***	**Thach Classification* (FA; WB; BT)**	**Bumper Clearly the Primary Cause?**	**Any role for bumper? (1º or 2º [primary or**	**Staff Classification** AC, PPC, UNK, OOS**	**Staff's View of Actual or Most Probable Primary Cause(***	**HS View of Key Summary Case Details**
15	19	2.5	M	"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 pads in his crib. He was pronounced dead at the scene." **(Thach narrative is verbatim text of complete EPIR IDI narrative).**	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.	SUFFOCATED IN CRIB - PROBABLE SUFFOCATION - AUTOPSY YES		IDI (13 pages); DTHS (1 page)	A 2 month-old boy was put to sleep in his crib at 10 pm and was found by his mother at ~5 am prone and unresponsive. He was declared dead at the scene by the ME and coroner and his death was investigated by the local child death review committee. The full autopsy found nothing suspicious and opined his death was accidental likely due to "*probable suffocation when he became entrapped within his crib between the side wall of the crib and the edge of a mattress.*" The CPSC IDI was conducted almost a year later and contains conflicting information, reportedly based on verbal input from an investigator in the Sheriff's department who said the baby's head got caught between a baby blanket and the bumper pad in his crib. There is no supporting documentation for this opinion in the official police report and no mention of crib bumper in the official autopsy, DCRT, or review committee report, prepared within 2 months of the death. Based on the ME's report of ***entrapment between the crib side wall and mattress edge*** , staff considers it likely that the baby somehow became wedged entrapped in an excessive side gap resulting from either a structurally defective crib and/or an ill-fitting mattress. ***Although the surface contacting the baby's face is not specified, 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. Staff considers that the crib bumper appears irrelevant as the primary cause of death.***	WB	N	?	UNK	LI-SIC?	Limited information: "entrapment between the crib side wall and the edge of the mattress" (ME) suggests excessive mattress side gap but verbal input collected 1 year later during IDI noted "head got caught between a baby blanket and the bumper pad" (sheriff dept). Ambiguous - not clear cut
6	20	**2**	**F**	"Face wedged in crib between pillow, mattress, and bumpers, external facial compression (suffocation)." **(Thach narrative is verbatim text of near complete EPIR DTHS narrative).**	A 2 MONTH OLD FEMALE DIED FROM SUFFOCATION AS A RESULT OF EXTERNAL FACIAL COMPRESSION. THE VICTIM BECAME TRAPPED FACE DOWN BETWEEN THE SIDE RAIL OF HER CRIB AND A THICK SEMIRIGID HOMEMADE CUSHION IN THE CRIB. THE VICTIM FELL BETWEEN THE CUSHION IN THE SIDE RAIL WITH HER FACE COMING TO REST ON THE CRIB'S MATTRESS. THE ACCIDENT OCCURRED IN THE VICTIM'S HOME.	FACE WEDGED IN CRIB BETWEEN PILLOW, MATTRESS & BUMPER ASPHYXIA; EXTERNAL FACIAL COMPRESSION (SUFFOCATION) - AUTOPSY YES	A 2 MONTH OLD FEMALE DIED SLEEPING ON CUSHIONS (BUMPER PADS & CRIB MA TTRESS) IN HER CRIB.	IDI (8 pages); IPII-MECAP (1 page); DTHS (1 page); Suppl IPII-ME (autopsy 3pg)	NOTE: The EPIR summary narrratives (IDI, IPII-MECAP or DTHS) do not indicate that this case involves a 2 month-old preemie twin girl sleeping in the same crib as her twin brother. This is reported in the IPII-MECAP report and full IDI, based mainly on telephone interviews with the mom and the responding paramedic (also a State Trooper). The twins were born 3 weeks early and had been placed at opposite ends of a full sized crib. The paramedic/trooper clearly reported that each twin slept on similar homemade cushions (4" thick, adult pillow-sized pieces of semi-rigid foam covered by a pillow case) that created a 5-6" gap with the crib sides. He reported that the mom said "*she found the victim in the crib wedged between the foam cushion and the side rail of the crib. The victim's face was against the mattress of the crib."* Lividity patterns were consistent with the prone victim's head being immobilized.in this gap, in a face down position. The DCRT notes the death resulted from *"asphyxia, due to external facial compression (suffocation) - accident"* with *"face wedged in crib between pillow, mattress and bumper"*. The IPII-MECAP reports notes the ME told the state trooper to advise the mom *"of the cause of death from autopsy and to remove cushions so same problem wouldn't arise with brother."* It is unclear why the mom told the CPSC investigator that only the surviving twin boy slept on a homemade cushion. ***Staff considers this death resulted from wedge entrapment-related suffocation of a vulnerable young preemie twin in a prone position. The physical restriction due to use of the large, semi-rigid foam cushion in the crib, rather than multiple occupants or a crib bumper, is considered the primary cause of death. Staff considers death could have resulted under similar circumstances, even if a bumper was not present so considers the crib bumper to be irrelevant as the primary cause of death.*** (NOTE: the IPII record says death occurred on 6/3/93 but it is really 6/3/92 which explains why it is not linked to the DCRT and IDI EPIR records) ***Supplemental autopsy confirmed Asphyxia due to external suffocation (compression of nostrils and mouth when infant became wedged between the bed cushion and crib bumper); OPINION: death "is due to asphyxia related to facial compression when the infant rolled off of a bed cushion and became wedged face-down in the corner of a crib. The manner of death is accident."***	WB	N	Y-2º	AC	CSS	CSS - a twin entrapped face down into mattress between semi-rigid pillow-sized foam cushion and bumper covered crib side - note the ME told the state trooper to advise the mom "of the cause of death from autopsy and to remove cushions so same problem wouldn't arise with brother."

March 2013 Case No	Thach et al Table 1	Age (mths) (not in Thach)	Sex (red font not in Thach)	Thach Table 1 Case Narratives Reported as "Medical Examiners' summaries of deaths" : blue = EPIR DCRT narrative by coder: Purple = EPIR IDI synopsis from investigator: red = EPIR IPII narrative by coder; green = Unique info only found in a source document pdf (or Authors note italic font)	IDI narrative - verbatim EPIR text	DTHS narrative - verbatim EPIR text	IPII narrative - verbatim EPIR text	Available documents (updated April 2013)	Staff's overview of all available case details highlighting key facts and opinion as to whether the bumper played a primary role in the death (clear, unclear, confounded, irrelevant or confounded) and whether could still have occurred without a bumper being present *(Oct 2012 - New Information Added to HS Initial view from April 2012)*	Thach Classification* (FA; WB; BT)	Bumper Clearly the Primary Cause?	Any role for bumper? (1° or 2° [primary or	Staff Classification** AC, PPC, UNK, OOS	Staff's View of Actual or Most Probable Primary Cause(***	HS View of Key Summary Case Details
4	21	8	F	"An 8-month-old female died after being trapped tight against a side rail padding and mattress in her crib." **(Thach narrative is verbatim text of the IPII EPIR narrative (which appear based on findings of an investigator from the ME's dept (not MD) findings).**	AN 8 MONTH OLD FEMALE WAS FOUND IN HER CRIB UNRESPONSIVE. CPRAND 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 BUMBER PADSWERE IN THE CRIB, AS WELL AS STUFFED TOYS AND A LOOSE BLANKET.		A 8 MONTH OLD FEMALE DIED AFTER BEING TRAPPED TIGHT AGAINEST THE SIDE RAIL PADDING AND MATTRESS IN HER CRIB.	IDI (45 pages); IPII-MECAP (5 pages in IDI)	A 8 month-old girl was placed on her back in the middle of her crib and was found unresponsive the next morning, after having rolled onto her stomach. She was *"found face down with her arms up" "at the edge of the crib waterbed mattress, next to the crib bumper"*. The mom reported to the IDI investigator that the baby was not trapped on entangled in anything. Neither parent reported that the baby's face was in contact with the crib bumper to the police or CPSC investigator. As noted by the mom (and partly shown in police death scene photos), the waterbed mattress was *"covered by a mattress pad and two thick blankets. A fitted sheet, regular sheet, and a comforter were then placed over the mattress. All mattress coverings were tucked in at the sides"*. Two very large stuffed toys, that the parents had previously used to brace the child's head when she was younger, were also in the crib (seen in photos), and one was one within a foot of the victim's head when she was found. The ME's investigative report (and IPII EPIR summary) conflicts with the CPSC IDI and police reports in noting that the father reported finding the baby *"pushed up tight against the side rail padding and between the mattress and side rail padding."* and inexplicably reporting that *"No toys or other items were in the bed"*. In 1991, a month after initally considering a possible asphyxiation death, the ME ruled this a SIDS death noting *"the reported circumstances and autopsy findings were consistent with natural death due to SIDS".* ***Staff notes that 20 years later, current views are that SIDS deaths in healthy 8 month-old babies are rare. Staff considers that the older waterbed mattress used with multiple layers of thick bedding between the baby's face and mattress presents a suffocation hazard that more likely explains the death of this prone, 8 month-old baby. Given the reported inconsistencies on the baby's position when found, and crib contents, staff considers that the crib bumper did not have a clear role, if any, in this death.***	WB	N	N	PPC	CSS	SIDS per ME - CSS-older baby (8 month) prone on waterbed mattress, on multiple layers of thick bedding, with large stuffed toys in crib
Predates Epi' 2013 search range	22	6 day	F	"A 6-day-old female was found not responsive in her infant basket. She was on her stomach with her head turned to one side. Her face was pressed into the crevice between the basket mattress and padded sideliner. After an autopsy was preformed, the medical examiner ruled that death was caused by probable suffocation due to an external airway obstruction." **(Thach narrative is verbatim text of complete IDI narrative).**	AT APPROX. 5:30AM, A 6 DAY OLD FEMALE WAS FOUND NOT RESPONSIVE IN HER INFANT BASKET. SHE WAS ON HER STOMACH WITH HER HEAD TURNED TO ONE SIDE. HER FACE WAS PRESSED INTO THE CREVICE BETWEEN THE BASKET MATTRESS AND PADDED SIDE LINER. AFTER AN AUTOPSY WAS PERFORMED, THE MEDICAL EXAMINER RULED THAT DEATH WAS CAUSED BY PROBABLE SUFFOCATION DUE TO AN EXTERNAL AIRWAY OBSTRUCTION.		A 1-MONTH OLD GIRL DIED AFTER BECOMING WEDGED INTO THE PADS OF A WICK ER BASKET.	No documents available	Limited details: No source documents are available for the IPII-MECAP and IDI records (specific requests from Archives have not been fulfilled), only the EPIR database summary narratives. The ME reportedly ruled this death of a 6 day-old girl, found dead in a wicker infant basket/bassinet, as a "probable suffocation due to external airway obstruction". She was reportedly found unresponsive, lying prone, with her head turned to one side, and her face pressed into the crevice between the basket's mattress and padded side liner. ***Staff considers the descriptors "pressed" and "wedged" in the EPIR summaries suggest possible wedge entrapment-related suffocation in the basket padding. This case does not involve a crib bumper or a crib, and therefore, is considered out of scope of the current staff CPSC staff crib bumper review.***	WB	N	N	OOS-basket	LI	Limited details - death of prone, 6 day old girl iin a basket, heard turned to one side and pressed (wedged?) between basket's padding mattress and side lining. Does NOT involve a traditional crib bumper

March 2013 Case No	Thach et al Table 1	*Age (mths) (not in Thach)*	*Sex (red font not in Thach)*	**Thach Table 1 Case Narratives Reported as "Medical Examiners' summaries of deaths"** : blue = EPIR DCRT narrative by coder: Purple = EPIR IDI synopsis from investigator: red = EPIR IPII narrative by coder; **green = Unique info only found in a source document pdf (*or Authors note italic font)***	**IDI narrative - verbatim EPIR text**	**DTHS narrative - verbatim EPIR text**	**IPII narrative - verbatim EPIR text**	**Available documents (updated April 2013)**	**Staff's overview of all available case details highlighting key facts and opinion as to whether the bumper played a primary role in the death (clear, unclear, confounded, irrelevant or confounded) and whether could still have occurred without a bumper being present** ***(Oct 2012 - New Information Added to HS Initial view from April 2012)***	**Thach Classification* (FA; WB; BT)**	**Bumper Clearly the Primary Cause?**	**Any role for bumper? (1º or 2º [primary or**	**Staff Classification** AC, PPC, UNK, OOS**	**Staff's View of Actual or Most Probable Primary Cause(***	**HS View of Key Summary Case Details**
26	23	**3**	F	**The baby was found wedged between adult pillows and crib bumper. The baby had originally been placed on her side and was found on her stomach." (Thach narrative initially looks as though it was derived from the rearranged EPIR IPII narrative but is actually verbatim text lifted from the body of the IPII-MECAP report).**		FOUND DEAD WEDGED IN CRIB - ASPHYXIA; WEDGED BETWEEN PILLOW AND CRIB BUMPER - AUTOPSY YES	A FEMALE INFANT, AGE 3 MONTH, WHO WAS FOUND WEDGED BETWEEN ADULT PILLOWS AND CRIB BUMPER ON AN ADULT BED DIED FROM ASPHYXIA. 01-6784. ***STAFF NOTE EPIR CODER ERROR IN A CRIB NOT ADULT BED***	IPII-MECAP (5 pages); DTHS (2 pages); suppl IPII -(11 pages autopsy)	Limited information: The 5 page IPII-MECAP report notes that a 3 month-old girl was placed on her side in her crib at ~7:45 pm and was heard crying about 90 minutes before being found unresponsive at ~10:45pm. It indicates that she was found lying prone and *"wedged between adult pillows and a crib bumper";* elsewhere it notes that after review, the ME's initial view of SIDS as the pending possible cause was amended to *"asphyxia, wedged between pillow and crib bumper, accident".* Whether one or more pillows was present is not clear and the item(s) in contact with the baby's face were not specified. ***Despite the limited details, staff considers pillow-related wedge entrapment to be the primary cause of this death because pillows are recognized as entrapment and/or suffocation hazards in a crib, regardless of the presence of a crib bumper. Staff considers the pillow caused this death and the crib bumper appears irrelevant as the primary cause.*** NOTE: THIS DEATH OCCURED IN A CRIB AND NOT IN AN ADULT BED AS SPECIFIED IN THE EPIR -IPII SUMMARY NARRATIVE (CODER"S ERROR) ***Supplemental Information in the autopsy report is that the baby was put to bed in the crib with an adult pillow and was found wedged between the pillow and the bumper on her stomach. it is not specified whether the pillow or bumper was in contact with her mouth/nose.***	WB	N	Y-2º	AC	CSS	CSS-pillow (adult pillow related - prone wedging)
9	24	2	M	A 2-month-old male was found dead in his crib. **Autopsy examination revealed no cause of death, but findings frequently seen in sudden infant death syndrome. Based on circumstances surrounding the death as currently known, this death meets the criteria for sudden infant death syndrome." *Author's note: The original death scene investigation makes no mention of infant's head position at death, and so the medical examiner lacked this important information. A subsequent CPSC death scene investigation (Figure 2) indicated that the baby's face was covered by a comforter, and his head was wedged between the mattress and the bumper pads .* (First part of Thach narrative is verbatim text from non-consecutive sentences lifted from the ME's opinion in full autopsy report in IDI The author's note, that the baby's head was covered by a comforter and wedged between the bumper pads, is attributed to information from CPSC's on-site IDI and death scene photo reconstruction (Thach Fig 2))**	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***.	A 2 MONTH OLD MALE DIED OF SIDS SLEEPING IN A CRIB.		IDI (42 pages); IPII-MECAP (6 pages in IDI)	A 2 month-old boy was found lying prone with his head in the crib corner and his face pressing down into an underlying thick quilt. The ME diagnosed the death as meeting the criteria for SIDS. Contrary to the Thach narrative interpretation, the CPSC IDI does not clearly report that the baby's head was wedged in the crib corner by bumpers (no pressure markings seen on head at autopsy, and *close proximity of the bumper to the infant's face was ruled out by the parent 's responses to the CPSC special investigation questionnaire* . Staff disagrees with Thach et al's statement that the baby's *face* was *"covered"* by a comforter; staff interprets *"face covered"* as meaning something lying on top of the face, as opposed lying on top of the back or side of the head, and staff would not describe a face pressing s*traight down into a quilted comforter* (as the mom clearly reports for this case) as the face being covered. Reconstruction photos show the shiny quilt edging (not bumper!) lightly touching the right side/rear of the baby's head, not his face but it unclear if this was representative of the death scene since the IDI noted *"The fringe of the quilt may have covered his head"* presumably based on the mom's input. ***Staff considers the prone position, young developmental age and thick quilt beneath the baby's face heightened the risk of the SIDS for this 2 month-old boy who was born 2 weeks early. Staff does not consider the crib bumper is relevant as the primary cause of death. No new information in supplemental information provided in 2012***	WB	N	N	PPC	CSS	SIDS per ME, baby found prone in CSS -face down into thick quilt, face not touching bumper, head partially covered by quilt edge

March 2013 Case No	Thach et al Table 1	Age (mths) (not in Thach)	Sex (red font not in Thach)	Thach Table 1 Case Narratives Reported as "Medical Examiners' summaries of deaths" : blue = EPIR DCRT narrative by coder: Purple = EPIR IDI synopsis from investigator: red = EPIR IPII narrative by coder; green = Unique info only found in a source document pdf (or Authors note italic font)	IDI narrative - verbatim EPIR text	DTHS narrative - verbatim EPIR text	IPII narrative - verbatim EPIR text	Available documents (updated April 2013)	Staff's overview of all available case details highlighting key facts and opinion as to whether the bumper played a primary role in the death (clear, unclear, confounded, irrelevant or confounded) and whether could still have occurred without a bumper being present *(Oct 2012 - New Information Added to HS Initial view from April 2012)*	Thach Classification* (FA; WB; BT)	Bumper Clearly the Primary Cause?	Any role for bumper? (1^0 or 2^0 [primary or	Staff Classification** AC, PPC, UNK, OOS	Staff's View of Actual or Most Probable Primary Cause(***	HS View of Key Summary Case Details
Predates Epi 2013 search range	25	6	F	A 6-month-old female was strangled by the strings of her bumper pads while sleeping in her full size crib. She **had** placed her head through a loop formed by the tied fabric attachment strings of the bumper pad." **(Thach narrative is a combination of the full EPIR IPII narrative with added text "in her full size crib" lifted verbatim from the EPIR IDI narrative. "**	ON MORNING OF 5/9/89 A SIX-MONTH OLD FEMALE DIED FROM ASPHYXIA DUE TO STRANGULATION AFTER SHE APPARENTLY PLACED HER HEAD THROUGH A LOOP FORMED BY TIED FABRIC ATTACHMENT STRINGS OF A BUMPER PAD IN A FULL- SIZE CRIB IN WHICH SHE WAS PLACED FOR A NAP. APPARENTLY, VICTIM COULD NOT EXTRICATE HER HEAD FROM THE LOOP AND THE STRING TIGHTENED AROUND HER NECK. ACCIDENT OCCURRED AT HOME OF VICTIM'S GRANDMOTHER, WHO HAD BEEN BABYSITTING VICTIM & HER TWIN SISTER FOR MORE THAN FOUR MONTHS BEFORE THE ACCIDENT.		6 MONTH OLD GIRL WAS STRANGLED BY THE STRINGS OF HER BUMPER PADS WHIL E SLEEPING.	IDI (49 pages) includes IPII (10 pages)	**NOTE: UNCLEAR IF THIS IDI IS RESTRICTED?)** Staff notes this IDI (which was obtained by HS from archives) was triggered by the bumper manufacturer reporting to CPSC (IPII) that the firm had first become aware of their bumper's alleged role in the death of a 6 month-old girl when contacted by an attorney representing the victim's mother. The 6 month-old girl was a twin who was placed alone in a crib for nap at ~ 9:30 am. Her grandmother (babysitter) found her unresponsive ~90 minutes later. Apparently, the baby had somehow managed to get her neck caught in a loop formed by the single ties at each end of the bumper pad. The grandmother reported that she had to untie the bumper pad ties in order to remove the baby from the crib. Paramedics transported the girl to the local hospital where she was later pronounced dead. The bumper's two single end ties were 10.5" and 11" long (ties in other pairs were each 9.25" to 11.25" long). It is unclear exactly how the baby could insert her head into the bumper tie loop if the bumper was correctly tied to the crib frame, which possibly suggests that the bumper ties had loosened or been incorrectly tied to the crib frame. ***Regardless, staff considers the long bumper ties were the cause of this 1989 strangulation death. Staff notes that the excessive bumper tie length hazard has since been addressed by a voluntary standard.***	BTS	Y	Y-1^0	AC	Bumper Tie	Pre-1990 case of strangulation involving longer bumper tie length (>10").
Predates Epi 2013 search range	26	**7**	M	Asphyxiation by string-ligature. **Father noted the string around baby's neck. He pulled baby from crib, pulling the string from the bumper pad in the process. Police surmise that the baby had grasped the loosened tie in his hand then rolled over pulling the tie across the front of his neck. A mark was made." (Thach narrative first sentence is part of the EPIR DTHS narrative. The rest is near-verbatim IDI unique report text strings extracted and combined from one paragraph) .**	A FATHER WHO WENT TO HIS SEVEN MONTH OLD SON'S BEDROOM TO AWAKEN HIM FOUND HIM STRANGLED ON A LOOSE BUMPER PAD TIE.	BUMPER STRING-IN-CRIB-CAUGHT-AROUND NECK - ASPHYXIATION-BY STRING-LIGATURE - AUTOPSY YES		IDI (21 pages: DTHS (I page in IDI)	After an overnight sleep, a 7 month-old boy was found at ~7:40 am by his father, lying prone with head turned to left. The father then realized that the 20" bumper ties were wrapped around the baby's neck. In pulling the boy from the crib, the father reportedly pulled the ties from the bumper pad. The responding police officer's report notes that the lifeless child was already in rigor mortis. The DCRT reports *"asphyxiation by string ligature - bumper string in crib caught around neck - accident"* and the autopsy report notes the cause of death to be *"asphyxiation due to accidental strangulation"*. ***Staff considers the long bumper ties were the cause of this 1987 strangulation death. Staff notes that the excessive bumper tie length hazard has since been addressed by a voluntary standard.***	BTS	Y	Y-1^0	AC	Bumper Tie	Pre-1990 case of strangulation involving longer tie length (20").
Predates Epi 2013 search range	27	**7**	**F**	Tie of bumper pad became tangled around neck. Cerebral anoxemia and anoxia; ligature compression of vessels." **(Thach narrative is verbatim text of EPIR DTHS narrative).**	A 7-MONTH-OLD CHILD DIED FROM ANOXIA IN HER CRIB WHEN A CRIB BUMPER PAD TIE WRAPPED AROUND HER NECK.	TIE OF BUMPER PAD BECAME TANGLED AROUND NECK - CEREBRAL ANOXEMIA AND ANOXIA; LIGATURE COMPRESSION OF NECK VESSELS - AUTOPSY YES	8 MO. OLD GIRL SUFFOCATED AFTER BECOMING TANGLED IN CRIBS BUMPER PAD.	IDI (15 pages); DTHS (I page); IPII-MECAP (1 page)	A mother placed her 7 month-old girl in a crib for a morning nap. Later, her older daughter was also put in the same room for a nap. Both girls were seen awake by the mom ~90 minutes before she found the baby unresponsive in her crib. The mom reported two bumper ties (10" and 10.25") from a hand-crafted crib bumper were wrapped around the baby's neck. The mom recalled, but was not certain, that the ties were wrapped in opposite directions. The bumper was received as a gift from a church group and the ties were described as being ribbons. The DCRT and autopsy notes the cause of death as *"cerebral anoxemia and anoxia, minutes, due to ligature compression of neck vessels, minutes"* The pathologist and police theory, that the baby self-strangled by rolling and tightening the ties around her neck, does not agree with the mom's recalled position of the bumper ties. Staff cannot rule out possible involvement of the older sister (age?) who the mom said *"was known to like to go to the crib to play with the infant and occasionally was known to untie the bumper ties."* ***Staff considers the long bumper ties were the cause of this 1987 strangulation death. Staff notes that the excessive bumper tie length hazard has since been addressed by a voluntary standard.***	BTS	Y	Y-1^0	AC	Bumper Tie	Pre-1990 case of strangulation involving longer tie length (>10") -on homecrafted crib bumper (gift) with "ribbon tie"; unclear if older sibling had any role.

Thach Appendix - Table A

March 2013 Case No	Thach et al Table 1	*Age (mths) (not in Thach)*	*Sex (red font not in Thach)*	**Thach Table 1 Case Narratives Reported as "Medical Examiners' summaries of deaths"** : blue = EPIR DCRT narrative by coder: Purple = EPIR IDI synopsis from investigator: red = EPIR IPII narrative by coder; **green = Unique info only found in a source document pdf (*or Authors note italic font)***	**IDI narrative - verbatim EPIR text**	**DTHS narrative - verbatim EPIR text**	**IPII narrative - verbatim EPIR text**	**Available documents (updated April 2013)**	**Staff's overview of all available case details highlighting key facts and opinion as to whether the bumper played a primary role in the death (clear, unclear, confounded, irrelevant or confounded) and whether could still have occurred without a bumper being present** *(Oct 2012 - New Information Added to HS Initial view from April 2012)*	**Thach Classification* (FA; WB; BT)**	**Bumper Clearly the Primary Cause?**	**Any role for bumper? (1^{0} or 2^{0} [primary or**	**Staff Classification** AC, PPC, UNK, OOS**	**Staff's View of Actual or Most Probable Primary Cause(***	**HS View of Key Summary Case Details**
	Note: Thach case narratives vary from being a complete verbatim EPIR case narrative from a single source (e.g., 1, 8, 11) , to combinations of two EPIR narratives (e.g., cases 1, 12) or an EPIR narrative plus text string from a source document (e.g. case 4) , to more extreme cases where a complete EPIR narrative is truncated in mid sentence to provide an uniformed reader with a completely different understanding of the circumstancesof the death and the role played by the crib bumper (eg. cases 2, and 4, 5) .													
	*Likely Thach Case Type (FA = face against; WB = wedged between; BTS = bumper tie strangulation)													
	**Staff Classification: AC (actual cause); PPC (probable primary cause); UNK (unknown); OOS (out of scope)													
	***Staff details on primary cause of death: SIC (structural integrity of crib); CSS (confounded sleep setting); SIP (specialized infant product); MI (medical issue); LI (limited information)													

March 2013 Case No	Thach et al Case No	**HS Table 1 – Detailed Case Summaries** **Staff's overview of all available case details highlighting key facts and opinion as to whether the bumper played a primary role in the death (clear, unclear, confounded, irrelevant or confounded) and whether could still have occurred without a bumper being present** ***(Oct 2012 - New Information Added to HS Initial view from April 2012 review)***
1		This IDI was obtained from archives. The case was ruled *Out of Scope* by staff because it did not involve either a traditional bumper and did not occur in a full size crib. Rather, the 11 month old boy fell out through a hole in the wall of a portable crib, known to be broken, and strangled on a piece of plastic cord that formed part of the framing between the base of the crib and its mesh walls. Text in the coroner's report and investigative summary further clarify that the death, which was ruled, asphyxia, accident, due to compression of neck, occurred as a result of accidental hanging" - Of note, the word crib bumper does not appear in any of the source documents, - only in the CPSC investigator's narrative. ***Staff considers this case Out of Scope in terms of traditional crib bumpers.***
2		Limited information: The 2 line NEISS narrative for this 1990 case states *"a 2 month-old preemie presents with cardiac arrest: mom went in to check baby in crib, found him with face against plastic bumper"* Despite an assignment, no IDI was ever completed for this case. ***The minimal details suggest possible preemie-related health issues, but that is not totally clear, and though it is considered unlikely, staff cannot categorically rule out the possible involvement of the plastic bumper.*** ***Supplemental information in an IPII-MECAP with autopsy notes that this small 7lb 8oz baby was being monitored by a NICU-type apnea monitor that did not alarm when he stopped breathing. His postmortem report noted 1. SIDS, 2 right inguinal hernia, but did not mention Crip bumper. Also, findings of 20 cc of turbid peritoneal fluid suggest possible leakage of gut contents/local sepsis? Importantly, the plastic bumper is mentioned only incidentally, per the mother's reported "as found" position.***
3	8	The IDI of this 3 month-old boy's crib death is based on an interview with the baby's mom and an autopsy report. It was prompted by a Congressman's letter (EPIR pdf not legible; HS obtained a legible copy from archives). The mom reported her husband was caring for the baby while she was out and that he had placed the baby prone in his crib at ~6:45 pm. The boy apparently cried extensively for nearly 2 hours, then at ~9 pm, the dad found him unresponsive, lying prone near the upper left crib corner, with his face turned to the left toward, but not touching, the crib bumper. The mom did not get home until 9:30 pm when she found her husband holding the baby "attempting to call 911." (Strange ~30 minute delay before dad tried to call 911?) The boy was pronounced DOA at the ER. The ME's autopsy report opined the cause of death as SIDS, and noted diffuse lung congestion and slight edema, with thin watery mucus in the airways; cultures and lab tests were pending. The mom reported the autopsy found evidence of an early CMV (cytomegalo virus) respiratory infection, which did not did not explain the death, but would likely have caused pneumonia or infection after 7-10 days (mum or MD's opinion?). In noting that the baby's ***"nose and mouth were not completely covered by the bumper pad"*** the mom seems to discount bumper pad involvement in this crib death. ***Staff agrees with the ME's ruling of a SIDS death, which is consistent with the young infant's prone position; the only other potential risk factor is a possible early respiratory virus. Staff considers the presence of the crib bumper to be incidental and irrelevant in this death.***

4	21	A 8 month-old girl was placed on her back in the middle of her crib and was found unresponsive the next morning, after having rolled onto her stomach. She was "found face down with her arms up" "at the edge of the crib waterbed mattress, next to the crib bumper". The mom reported to the IDI investigator that the baby was not trapped on entangled in anything. Neither parent reported that the baby's face was in contact with the crib bumper to the police or CPSC investigator. As noted by the mom (and partly shown in police death scene photos), the waterbed mattress was "covered by a mattress pad and two thick blankets. A fitted sheet, regular sheet, and a comforter were then placed over the mattress. All mattress coverings were tucked in at the sides". Two very large stuffed toys, that the parents had previously used to brace the child's head when she was younger, were also in the crib (seen in photos), and one was one within a foot of the victim's head when she was found. The ME's investigative report (and IPII EPIR summary) conflicts with the CPSC IDI and police reports in noting that the father reported finding the baby "pushed up tight against the side rail padding and between the mattress and side rail padding." and inexplicably reporting that "No toys or other items were in the bed". In 1991, a month after initially considering a possible asphyxiation death, the ME ruled this a SIDS death noting "the reported circumstances and autopsy findings were consistent with natural death due to SIDS". Staff notes that 20 years later, current views are that SIDS deaths in healthy 8 month-old babies are rare. Staff considers that the older waterbed mattress used with multiple layers of thick bedding between the baby's face and mattress presents a suffocation hazard that more likely explains the death of this prone, 8 month-old baby. Given the reported inconsistencies on the baby's position when found, and crib contents, staff considers that the crib bumper did not have a clear role, if any, in this death.
5		A 3 month-old twin, born 6 weeks prematurely, was placed prone in her crib at ~3:30 am. At 8:45 am, she was found unresponsive, almost exactly as she had been placed (prone, with her face turned to the left and with nothing touching her face). She was pronounced DOA at the ER. She had a prolonged history of colic/spitting up, and also had a dry, non-productive cough a week before death. The ME investigator also noted that nothing was near her face, and mentioned a baby pillow and 4 stuffed toys were in the crib. The ME autopsy report ruled the death as *SIDS due to natural causes*. NOTE: It is not stated in the ME's report whether or not the victim's twin sister was present in the crib; the CPSC investigator's report text (p2-4) is not readable in the EPIR IDI pdf. ***Staff agrees with the ME's ruling of a SIDS death, which, given the finding of nothing being in contact with the girl's face, is consistent with the young at-risk preemie twin girl's prone position. Even the presence of a pillow (a recognized suffocation/entrapment hazard in a crib) is discounted as being involved in this death, and the only potential risk factor is a possible respiratory infection related to her dry cough Staff considers the presence of the crib bumper to be incidental and irrelevant in this death.*** Staff notes that the EPIR IDI summary narrative incorrectly reports the victim as a 2 month old girl.

6	20	NOTE: The EPIR summary narratives (IDI, IPII-MECAP or DTHS) do not indicate that this case involves a 2 month-old preemie twin girl sleeping in the same crib as her twin brother. This is reported in the IPII-MECAP report and full IDI, based mainly on telephone interviews with the mom and the responding paramedic (also a State Trooper). The twins were born 3 weeks early and had been placed at opposite ends of a full sized crib. The paramedic/trooper clearly reported that each twin slept on similar homemade cushions (4" thick, adult pillow-sized pieces of semi-rigid foam covered by a pillow case) that created a 5-6" gap with the crib sides. He reported that the mom said "*she found the victim in the crib wedged between the foam cushion and the side rail of the crib. The victim's face was against the mattress of the crib."* Lividity patterns were consistent with the prone victim's head being immobilized.in this gap, in a face down position. The DCRT notes the death resulted from *"asphyxia, due to external facial compression (suffocation) - accident"* with *"face wedged in crib between pillow, mattress and bumper".* The IPII-MECAP reports notes the ME told the state trooper to advise the mom *"of the cause of death from autopsy and to remove cushions so same problem wouldn't arise with brother."* It is unclear why the mom told the CPSC investigator that only the surviving twin boy slept on a homemade cushion. ***Staff considers this death resulted from wedge entrapment-related suffocation of a vulnerable young preemie twin in a prone position. The physical restriction due to use of the large, semi-rigid foam cushion in the crib, rather than multiple occupants or a crib bumper, is considered the primary cause of death. Staff considers death could have resulted under similar circumstances, even if a bumper was not present so considers the crib bumper to be irrelevant as the primary cause of death.*** (NOTE: the IPII record says death occurred on 6/3/93 but it is really 6/3/92 which explains why it is not linked to the DCRT and IDI EPIR records) ***Supplemental autopsy confirmed Asphyxia due to external suffocation (compression of nostrils and mouth when infant became wedged between the bed cushion and crib bumper); OPINION: death "is due to asphyxia related to facial compression when the infant rolled off of a bed cushion and became wedged face-down in the corner of a crib. The manner of death is accident."***
7		Note: the IDI information is from a family friend: She said the 5 month-old male usually slept in a prone position but was lying supine, having somehow got his head wedged between the slats of a 15 year-old crib. The DCRT is not readily available to staff but the EPIR record notes that death was accidental, caused by asphyxia due to neck hyperextension, coupled with the pressure of a bumper pad resting on his neck. The friend reported that the ~15 year-old crib had *"wider than usual slats in the side rails" (wide slat spacing?)* and *"it had a broken part"* (unspecified part). She also said that the baby was found with his ***"head turned at an odd angle with his left side of his head against the side rail," "right side of his face against the mattress,"*** and ***"his body laying perpendicular to the crib rail"***. In the IPII-MECAP the ME notes that the mom ***"found the infant with his head wedged between the bars of the crib". Staff considers this death is due an excessive gap between the crib slats of an older crib missing a part (slat(s)?). Excessive gaps between crib slats are a recognized entrapment/fall hazard that can cause death by hanging strangulation when an child's body but not head slips into the gap, regardless of the presence of a crib bumper. Staff considers that the crib bumper appears irrelevant as the primary cause of death. A supplemental autopsy report confirmed death due to accidental asphyxia consequent to head entrapment between crib slats.***
8	16	Staff notes the death of this 7 month old girl occurred in 1991 (per DTHS record) not 1992 (per INDP record). The baby was reportedly found by her mother with "*her head wedged between the side of the mattress and the bumper pad attached to the crib slats.*" She brought the cold, unresponsive baby to the police department for assistance because she had no phone and the nearest hospital was 12 miles away. CPSC staff requested the full police report but it was never received. The fact that the mother reported the baby's head was **wedged against the side of the mattress** suggests her head had become entrapped in an excessive side gap resulting from either a structurally defective crib and/or an ill-fitting mattress. ***Although the surface contacting the baby's face is not specified, 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. Staff considers that the crib bumper appears irrelevant as the primary cause of death. Supplemental information requested - not***

		received (as of Nov 2012).
9	24	A 2 month-old boy was found lying prone with his head in the crib corner and his face pressing down into an underlying thick quilt. The ME diagnosed the death as meeting the criteria for SIDS. Contrary to the Thach narrative interpretation, the CPSC IDI does not clearly report that the baby's head was wedged in the crib corner by bumpers (no pressure markings seen on head at autopsy, and *close proximity of the bumper to the infant's face was ruled out by the parent 's responses to the CPSC special investigation questionnaire*. Staff disagrees with Thach et al's statement that the baby's *face* was *"covered"* by a comforter; staff interprets *"face covered"* as meaning something lying on top of the face, as opposed lying on top of the back or side of the head, and staff would not describe a face pressing s*traight down into a quilted comforter* (as the mom clearly reports for this case) as the face being covered. Reconstruction photos show the shiny quilt edging (not bumper!) lightly touching the right side/rear of the baby's head, not his face but it unclear if this was representative of the death scene since the IDI noted *"The fringe of the quilt may have covered his head"* presumably based on the mom's input. ***Staff considers the prone position, young developmental age and thick quilt beneath the baby's face heightened the risk of the SIDS for this 2 month-old boy who was born 2 weeks early. Staff does not consider the crib bumper is relevant as the primary cause of death.*** ***No new information in supplemental information provided in 2012***
10	15	Limited information. The only record for this case of the death of a 1 month-old boy is a DTHS report, but the original document is no longer available from archives, having now been destroyed by the Federal Records Center (personal communication from Clearinghouse staff). Staff's initial opinion was based on the EPIR DTHS summary narrative, which indicated that the boy was found unresponsive in crib, and died from *positional asphyxia* due to being *"wedged between pillow and bumper pad"* .***Despite limited details, and lack of information on the position of the infant's face, staff considered pillow-related wedge entrapment to be the primary cause of death because pillows are recognized as entrapment and/or suffocation hazards in a crib, and can cause an infant death even if a bumper is not present. Staff considers the pillow caused this death and the crib bumper appears irrelevant as primary cause.*** ***Staff's initial view is supported/confirmed by supplemental information in an autopsy and coroner's report which confirmed that the baby was found lying face down in his crib. His head had been "resting on a pillow covered with a blanket.....the infant's head was sort of slipped off the pillow and his head was wedged between the pillow and the bumper inside the crib"; "Anatomic findings note 3) Pattern of skin marks which matches the pillow cover is seen over the face"; Additional crib contents, 2 baby blankets and a thick blanket used as a mattress pad and a thick bumper pads surrounded the entire inside of the bed"***
11		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. A 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)

12		Limited details: the IPII-MECAP source report is not readily available and the single sentence IPII case narrative indicates that the 4month-old boy died in his crib, while sleeping in prone position with his face down between the mattress and bumper pad. Staff is not clear of the boy's exact position when found and what his face was touching. ***The ME attributed his death to SIDS. There is no other information available to staff, therefore, without further information, staff must accept the ME's ruling of SIDS.*** ***Supplemental information does not mention a crib bumper, but notes that the baby was born at 27weeks gestation, suffered a perinatal intracerebral bleed and was kept in the IC - PICU for several weeks before being released. Autopsy found significant brain pathology (including an asymmetrical ventricular system, white matter cavity consistent with a perinatal hemorrhage) and possible seizure disorder (p8-9/10).***
13		Initially Limited Information: No source DTHS document available, only the EPIR DTHS narrative, which simply states that the 2 month-old girl's *"head went between pillow and padded crib wall. Face down in soft bedding - Asphyxia: suffocation, face down in soft bedding"* . ***Despite limited details concerning the item in contact with the baby's face, staff considers pillow-related wedge entrapment to be the likely primary cause of death, because pillows are recognized as entrapment and/or suffocation hazards in a crib, and can cause an infant death even if a bumper is not present. Staff considers a pillow likely caused this death and the crib bumper appears irrelevant as the primary cause.*** ***Supplemental findings relevant information that the baby had been "placed prone "on a full size pillow, with her head on its left side." At 10:30, mom found "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 had been sickly since birth (3 weeks early) had a congenital heart defect and a chronic cough.***
14	5	Limited information. The only record for this case of the death of a 14 month-old boy is an IPII-MECAP report, but the original document is missing from archives (personal communication from Clearinghouse staff). Staff's opinion is based on the limited information provided in the EPIR IPII summary narrative which states the *"14 month-old baby boy died sleeping in a crib with his face firmly pressed against a bumper pad. Baby was treated weeks ago for a head and chest cold with extensive breathing treatment"* . Staff assumes that an otherwise healthy 14 month-old boy is developmentally capable of moving his head if his face simply became pressed against a bumper pad. The boy's reported history of a prior respiratory infection that required extensive breathing treatment suggests some respiratory medical issue could be the most likely primary cause of death, perhaps asthma? ***Despite limited information, staff considers it unlikely that the crib bumper is relevant as the primary cause of death.*** ***Supplemental information notes this older boy had abnormal brain symmetry (cerebellum cerebellar peduncle 40% smaller but normal histology) and a history of serious breathing issues. He had recently been diagnosed with reactive airways, and had prior and ongoing infections - his father had refused MD recommended Prelone steroid treatment, and he saw him again just 2 days before death for ongoing congestion. These findings appear to support staff's views. Note: although the father specified no objects were close to his head when found, the death scene description somehow evolved to face pressed against bumper pad in the MEs report of positional asphyxia accidental? The autopsy reads "discovered face down on his stomach with his face pressed against a bumper pad" "pressure marks, nose"(see indistinct ME's photo showing a baby face down on mattress, with top of head simply touching the bumper); both mum and dad say he was lying face down in the crib between the mattress pad and the bumper pad and no objects were near him - he had been very sick)***

15	19	A 2 month-old boy was put to sleep in his crib at 10 pm and was found by his mother at ~5 am prone and unresponsive. He was declared dead at the scene by the ME and coroner and his death was investigated by the local child death review committee. The full autopsy found nothing suspicious and opined his death was accidental likely due to "*probable suffocation when he became entrapped within his crib between the side wall of the crib and the edge of a mattress.*" The CPSC IDI was conducted almost a year later and contains conflicting information, reportedly based on verbal input from an investigator in the Sheriff's department who said the baby's head got caught between a baby blanket and the bumper pad in his crib. There is no supporting documentation for this opinion in the official police report and no mention of crib bumper in the official autopsy, DCRT, or review committee report, prepared within 2 months of the death. Based on the ME's report of ***entrapment between the crib side wall and mattress edge***, staff considers it likely that the baby somehow became wedged entrapped in an excessive side gap resulting from either a structurally defective crib and/or an ill-fitting mattress. ***Although the surface contacting the baby's face is not specified, 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. Staff considers that the crib bumper appears irrelevant as the primary cause of death.***
16	14	This case involves a 10 month-old boy who somehow climbed out or fell out of his crib. His body got caught in a gap between the external crib sides and a nearby dresser, with his chin resting on the edge of the dresser. The death was ruled as "*asphyxia by compression of upper neck while wedged between furniture and crib*" on the DCRT (signed by MD), which notes that no autopsy was done. It was an Coroner's Investigator's opinion that the boy ***probably*** stood on the bumper pad and climbed over the crib railing (as is also opined by Thach et al.,) Staff notes that the victim was reportedly a "larger than average" child and that he was likely much too tall for a mattress set only 15" below the side rail. Projected anthropomorphic data for this child suggests a height exceeding >28.5" and center of gravity of about 15.7" which suggests he could easily have climbed over or fallen over the 15" side rail when standing on the mattress. There is no mention of the crib bumper in the DCRT, police report, or death scene investigator's report. Staff views Author's note/opinion as an ill-considered unobjective biased view not supported by case facts. ***Staff considers this death was caused by a mattress set too high which allowed the large child to fall/climb out of the crib leading to his partial hanging strangulation while caught between furniture and the exterior crib frame; the crib bumper appears irrelevant as the primary cause of death. Supplemental information does note indicate whether the reconstruction photos, using a doll, were taken in the involved crib/at the scene - but importantly, the photos confirm the boy's head and body were facing away from the crib and previous information reported by HS notes the rail was low enough for the large child to easily get out of the crib without turning his body to climb over the rail. Furthermore, the bumper is not mentioned in the autopsy findings on the cause and manner of death.***
17		Not in a crib…..in a toddler bed. Also, at 5 years old, child is outside bumper age range
18		This crib death involves an 11 month-old boy with a history of severe asthma (on prescription medications hydramine and albuterol) who was taken to the ER the day before his death due to a severe asthma. The boy's foster mother placed him supine in his crib late in the evening, and found him lifeless, lying prone, but with no facial obstruction at 2:20 am. A bumper pad with missing ties was reportedly wrapped loosely around his waist but was not implicated in the death which was ruled by ME to be a natural death caused by cardiac arrest due to chronic asthma (autopsy found chronic inflammation of airways and lung pathology). ***Staff considers the crib bumper to be uninvolved in this death based on the ME's finding of death being caused by the child's preexisting chronic asthmatic condition.***

19		Limited information: The mother of a baby girl reported that her daughter was at her babysitter's home and was placed prone, on thick bedding, in a bumper-lined crib that also contained a comforter and toys. The "crib's head board and foot board and side rails were covered with blankets". The baby was found ~2h later, unresponsive, and pronounced dead at the local hospital. According to the mother's hotline call, the autopsy stated the cause of death was SIDS, but she later spoke to the coroner (unclear if an MD or not) who said they couldn't prove if her daughter died from suffocation, but it was possible. The Mom's call indicated concern that her babysitter was still babysitting, but had not known that soft bedding and toys and prone sleeping position were unsafe. She wanted warning labels on labels on comforters indicating the risk of suffocation to babies under 2 years of age. Staff notes that the victim's age is unclear being reported as 6 weeks in IPII age field and 9 months in IPII consumer complaint text. Staff considers that the complaint only mentions the bumper pad incidentally, not as any causative factor in this death. From the limited information given, staff must accept the ME's ruling of SIDS, with involvement of the prone position risk factor that is known to increase risk of SIDS. Supplemental information in an MD's autopsy report clarifies that the baby was a 6wF (47d) and it notes the death was ruled SIDS with the baby found in the prone position The autopsy finding of "adenals: acute hemorrhage in medulla" is not mentioned in ME's final diagnosis and it's significance is unclear, but perhaps might suggest some acute torso trauma? There is no information related to the crib environment or any specific mention of a crib bumper.
20	3	This case involves a 7 month-old boy found not breathing, in his crib, by his babysitter who called 911. She said he was lying on his back with his face turned toward his right side and his face was "up into the corner of the bumper pad". The baby had had a respiratory infection (5 days on an antibiotic) and the police responders noted that they had difficulty attempting artificial respiration because his airways appeared blocked and his jaw appeared locked even though he was still warm (not in rigor). Paramedics transported the baby to the ER where he was pronounced dead. Contrary to the DTHS EPIR narrative, the police report clearly states that an autopsy was conducted in their presence. The police report contains officer's notes on the autopsy indicating that the MD 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. He apparently 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 (staff has no notes on microscopic findings or lab culture tests). It is unclear why the DCRT, signed more than 3 months later, ruled the cause to be "positional asphyxia" as a result of "infant's face in corner of crib". Strangely, it appears to be signed by a non-MD coroner (funeral home employee) and has conflicting information as to whether an autopsy was done saying NO (box 25a), Yes (box 25b). The EPIR DTHS summary narrative incorrectly states AUTOPSY NO; whereas police records clearly indicate an autopsy was done in their presence. Although full autopsy findings are not available, staff considers that an older child, lying supine, is developmentally capable of moving his head if his face is obstructed and that this boy likely died from a medical issue related to complications of a known respiratory infection. Staff finds that the crib bumper appears confounded (unlikely) as the primary cause of death. Supplemental information - supine - strange finding crease on forehead? denuded tracheal epithelium? - consult with forensic pathologist Dr Mary Case - Dr Thach co-author-troubling interpretation
21	13	According to the initial IPII-MECAP report (a 4-page autopsy report), the death of this 4 month-male resulted from *"asphyxia by suffocation, accidental"* associated with *"a history of being found wedged in bed clothing (crib bumper)*". The full IDI contains a full police report with death scene photos and statement given by the father. He reportedly found his son prone in the crib with *"arms up and his face into the soft padding."* Contrary to the autopsy MECAP report, there is no mention of any kind of ***wedging*** in police report or father's report which simply notes "an apparent indentation in the soft padding where the baby's face was." An indent can be seen bumper in the black and white police photos taken at the death scene. These also show a sagging bumper and thick blankets were present in the crib. This case is confounded by the inconsistency between the ME and police reports regarding "wedging", plus the infant's prone position, and the thick blankets in the crib. ***Due to these multiple confounders, it is unclear whether the crib bumper had a primary role in this death.***

22		Limited details: the 2 line NEISS case narrative indicates that the 3 month-old girl was sleeping on 2 pillows (large and small) and was found with dead with her face in the crib bumper. Despite limited details, staff considers presence of the two pillows as the likely primary risk factors that wedged/entrapped the young baby's face against the bumper pad. ***Pillows are recognized as entrapment and/or suffocation hazards in a crib, and can cause an infant death even if a bumper is not present. Staff considers pillow(s) likely caused this death and the crib bumper appears a secondary not primary cause of death. Supplemental information refutes NEISS summary re:3mF's "face in bumper railing". ME inquest notes COD: Positional Asphyxia (wedging), Contributing: Dehydration) Accident, also "baby found wedged between pillows in crib with blanket in mouth and could not be resuscitated" "pulmonary congestion and edema, mild - opines " smothering.....due to being placed in a position wedged by pillows and blankets in such a way that her face and mouth were covered and breathing was restricted". Note- the father initially reported finding the baby prone wedged by the bumper guard but at the hospital told the social worker the baby was between pillows - inconsistent. photos indistinct - not clear if adult or infant pillows***
23		Not in a crib…..side mesh of crib suggests portable crib
24		Limited information: A 3 month-old boy was placed in a crib at 11:00 pm, then reportedly found 8.5 hours later, lying supine and unresponsive, by his father, who removed him from the crib. The only other information available in the 2 page IPII-MECAP report from an ME office investigator is that a pillow, blankets, and bumper were in the crib. The cause of this crib death is unclear from the available information, and there is no information indicating specific involvement of the crib bumper, which appears to have been mentioned simply incidentally in the MECAP report. ***In the absence of any further information, staff considers the presence of a pillow in the crib as the most likely primary risk factor in this death, and discounts specific involvement of the crib bumper. Supplemental information - during questioning at the scene, on the lack of agreement between lividity patterns and his report of finding his son dead lying supine his crib, the father finally admitted that he had been cosleeping with the boy and found his unresponsive in the parental bed - changing staff's assessment to overlay during co-sleeping but supporting it concern with the accuracy of the initial report of supine, unresponsive healthy child,***
25	18	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. This case does not involve a crib bumper used on a crib, and therefore, is considered out of scope of the current staff CPSC staff crib bumper review.*** **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.**

26	23	Limited information: The 5 page IPII-MECAP report notes that a 3 month-old girl was placed on her side in her crib at ~7:45 pm and was heard crying about 90 minutes before being found unresponsive at ~10:45pm. It indicates that she was found lying prone and *"wedged between adult pillows and a crib bumper";* elsewhere it notes that after review, the ME's initial view of SIDS as the pending possible cause was amended to *"asphyxia, wedged between pillow and crib bumper, accident".* Whether one or more pillows was present is not clear and the item(s) in contact with the baby's face were not specified. ***Despite the limited details, staff considers pillow-related wedge entrapment to be the primary cause of this death because pillows are recognized as entrapment and/or suffocation hazards in a crib, regardless of the presence of a crib bumper. Staff considers the pillow caused this death and the crib bumper appears irrelevant as the primary cause.*** NOTE: THIS DEATH OCCURED IN A CRIB AND NOT IN AN ADULT BED AS SPECIFIED IN THE EPIR -IPII SUMMARY NARRATIVE (CODER"S ERROR) ***Supplemental Information in the autopsy report is that the baby was put to bed in the crib with an adult pillow and was found wedged between the pillow and the bumper on her stomach. it is not specified whether the pillow or bumper was in contact with her mouth/nose.***
27	2	This case involves a 7 month-old girl found dead in her crib. Although the autopsy report and the DCRT documents both note the ME's findings as *"asphyxia"* with injury caused by *"face against an overstuffed crib bumper",* the ME report does not convey the full facts evident in the police report. The police report has death scene photos and officers' statements that clearly show the baby was found dead in a broken crib that was missing its mattress and head board. The crib was filled with thick bedding; several large pillows/ thick blankets were used as a makeshift mattress and a pillow was used as a makeshift headboard. The girl was found on her back with her head tipped backwards and downwards below her shoulder level. Her neck was hyperextended into a 10-inch gap between the pillow/blankets used as a mattress and the pillow used as the headboard. Her inverted face was pressed against the pillow used as the headboard. Although an untied manufactured crib bumper was present in the crib, it was not involved in her death. ***Staff considers the primary cause of death to be the broken crib (missing mattress and headboard) coupled with use of multiple pillows in the crib. Staff believes these crib defects directly lead to a positional asphyxia type death involving neck hyperextension plus occlusion of the mouth and nostrils of the baby's inverted head. The unsecured crib bumper appears irrelevant and uninvolved in this death.***
28	12	Limited information: Despite the limited information, the death certificate clearly notes that this 4 month-old boy died as a result of *positional asphyxia* when he was found *"face down in crib, pinned between bumper pad and sibling sister".* The IPII-MECAP report further clarifies that the sister was his twin. ***Staff considers this death resulted from wedge entrapment in a prone position caused by multiple occupants in the crib. The bumper was not touching the victim's face and staff considers death could have resulted under similar circumstances, even if the bumper was not present. Despite limited details, staff considers the crib bumper to be irrelevant as the primary cause in this death.***
29		Limited information: A 10 week-old boy was found reportedly found *"against the edge of the crib, against the bumper pad and face down in the mattress"* according to a 1pg IPII-MECAP report (from ME). ***Staff considers that the limited details give no clear indication of primary involvement of a crib bumper in the death of this very young infant, found face down on a mattress. The cause of death, as ruled by the ME, is unknown to staff, but based on the limited details appears consistent with prone-related SIDS.***
30	11	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 DTHS 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)
31		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). ***Supplemental information 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."***
32	1	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 considers the crib bumper appears irrelevant as primary cause in this death. - Note 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.***
33		Limited details: the 1 page DCRT indicates this 3 month-old girl was put to sleep in a crib containing an adult pillow and was found dead in a prone position. The coroner (unclear if an MD?) ruled the death to be *positional asphyxia, accidental*. ***Despite limited details, and lack of information on the position of the infant's face relative to the bumper, staff considers the presence of the pillow in the crib to be the likely primary cause of death, because pillows are recognized as entrapment and/or suffocation hazards in a crib, and can cause an infant death even if a bumper is not present. Staff considers a pillow likely caused this death and the crib bumper appears irrelevant as the primary cause. Supplemental information provided additional details of incident timing, possible asthma, airway congestion but still do not provide any information regarding a role for the crib bumper, aside from simply being present in the crib (but appears missing in crib photo?). witnesses reliability is suspect, and the coroner noted that the scene had been***

		totally altered, but ruled death to be positional asphyxia, accidental. No clear cause evident to staff, but based on prior experience with cases involving adult pillows in cribs, the pillow-confounded sleep setting appears the most likely cause of death.
34		Limited information: the 1 page DCRT reports a 19 month-old girl was found unresponsive in her crib with "her face wedged between the mattress and bumper". The ME ruled her death asphyxia due to suffocation by obstruction of nose and mouth, and the DCRT specifically notes the victim had sustained "chronic anoxic encephalopathy due to meconium aspiration at birth" i.e., significant serious brain injury since birth. Staff considers a healthy 19 month old child would not simply suffocate against a crib bumper and would move unless somehow wedged/entrapped against the bumper. However, in this case the brain-damaged older child already had a greater risk of death. ***Staff considers the brain damage sustained at birth to be the primary risk factor involved in this child's death. For this reason, staff considers the bumper pad irrelevant as the primary cause of death in this case. Supplemental information confirms this case involves the atypical situation of a highly vulnerable older child with significant medical issues related to perinatal brain damage (microcephaly), who 30 minutes after her feeding tube session, somehow moved from supine to prone position and was unable to move from that position. She was found "lying on her stomach with her face wedged between the crib bumper and the crib mattress. This was reportedly the first time she had rolled over. There was no bedding on the mattress with just the plastic cover present."***
35		On the second night that a healthy 4 month-old girl was placed prone in a thrift store crib, she was found unresponsive the next morning having moved into a crib corner where the mattress had no support (it could be depressed). The parents took the baby to the ER where she was pronounced dead. 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.* No police investigation was done for this case. An addendum to the completed IDI notes the ME ultimately ruled the pending cause of death to *"positional asphyxia."* and this is confirmed by the final death certificate in the EPIR DTHS database which states "ACCIDENT, POSITIONAL ASPHYXIA, FOUND UNRESPONSIVE IN DEFECTIVE CRIB" (Staff note: this DTHS record is not linked to the IDI and IPII record in EPIR.) The crib was collected as a CSPC sample. The frame appears in good shape but the original mattress support was missing when purchased at the thrift store. Therefore, the parents rigged a support using 5-6 lengths of wood, spaced diagonally across the crib frame, but this left the mattress inadequately supported in two corners. There was no evidence of foul play. The autopsy report noted the baby's "face buried in a quilt and bumper pads" but the ME's photo reenactment shows only the quilt beneath the prone baby's face and the bumper pad touching the sides and perhaps back of her head, not her face. ***Staff considers this death was clearly due primarily to use of a defective broken crib, missing its original mattress support. The inadequate makeshift mattress support allowed the mattress to tilt down in one corner, causing the baby's head to be pressed face down on to a quilt. Although the crib bumper might have further restricted the baby from lifting her downward tilted head off the quilt, staff considers this scenario would likely have proved fatal with such a young immature infant, regardless of the presence of the bumper which did not play a primary role.***

36		This case involves a healthy 4 month-old girl found unconscious in her crib by her father. She was pronounced DOA at the ER <30 minutes later: The baby was reportedly found prone ("face down" per dad). Her arm was wedged between the crib and the mattress according to the ME autopsy report and DCRT. There is no mention of what was in contact with baby's face. Limited information says the police secured the scene and removed the crib sheet, blanket, and bumper as evidence. The IDI contains the full gross autopsy report (done the next day), plus subsequent toxicity screen, microscopic pathology, and blood, lung, CSF cultures findings - (no obvious anomalies found). The autopsy and DCRT (which was signed nearly 2 months after death) note the cause of death was considered "ASPHYXIA DUE TO COMPRESSION OF HEAD AGAINST CRIB BUMPER with cause of injury specified as "HEAD COMPRESSED AGAINST CRIB BUMPER WITH ARM WEDGED BETWEEN CRIB AND MATTRESS". DCERT. ***Although the specific object contacting the baby's face is not specified, staff considers that an excessive side gap crib issue is likely involved due to the report of the baby's arm being wedged between the crib and mattress. 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. Staff considers that the crib bumper appears irrelevant as the primary cause of death.***
37		Limited information: the 1 page DCRT (signed by MD) initially had cause of death marked as pending but was amended 5 weeks after the incident to *positional asphyxia*. It reports that a 5 month-old girl died after being "*trapped face down against padding in crib corner"*. It is unclear what caused this 5 month-old to become "trapped" in a prone position. It seems probable that another object(s) was involved, but there is no record of this in the limited case record. There is no specific mention of a bumper pad. ***Based on the ME's ruling of positional asphyxia and the baby being "trapped", staff considers an unsafe object(s) in the crib was likely involved but cannot categorically rule out involvement of the bumper pad itself. Supplemental information in the ME's autopsy opined the cause of death to be positional asphyxia "due be being trapped face down against the padding in the corner of the crib". but no information is provided on what exactly "trapped" the baby in this position. Furthermore, it is not clear why the lung microscopic pathology finding reporting "congestion; aspiration of the regurgitated stomach contents" is not discussed in the ME's opinion?***
38		Limited details: the 1 page IPII-MECAP report indicates a 4 month-old boy was found unresponsive in his crib with his *face up against the bumper pad (*which might suggest a supine position?) ***The ME attributed his death to SIDS. There is no other information available to staff, therefore, without further information, staff initially only had no reason to question the ME's ruling of SIDS, Supplemental information indicates this 4 month old boy, born 6 weeks early, had been placed to sleep, lying prone on top of a pillow. He somehow "had scooted up on the mattress and the police report clarifies it was the right side of his face that was up against the side of the crib pad" where he was found dead, which for a prone child staff is interpreting as meaning that the front of hs face i.e., nose and mouth must have been facing down into bedding/mattress suggesting that the pillow apparently trapped him in this position.***

39		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). Her divorced mum and boyfriend (not girl's father), 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.***
40		Limited information: the 1 page IPII-MECAP (from ME) simply states that a 4 month-old girl was *"found prone with her face toward a round "mat" in a crib. Her head was between the railing & round mat. There was a bumper pad around the inside of the crib"* . ***Staff considers that the limited details give no indication of any involvement of a crib bumper in this death and that the bumper presence is simply mentioned incidentally by the ME. Supplemental information Indistinct reenactment photos with baby next to crib side, not in corner, and no obvious "round mat" further confound this case ruled Positional Asphyxia per ME. Bloody mucus, 2d URI history and positive post mortem lung cultures could suggest a possible medical issue confounder but no indication that baby was trapped in corner against bumper or that bumper was involved other than simply being present next to the L side of the baby's head (not mouth or nose) - CSS/prone/MI.***
41		Not in a crib …..in a toddler bed
42		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 believes the crib bumper appears confounded as primary cause of death.***

43		This case involves a healthy 2 month-old girl who was still asleep at ~8am, when her mom moved her to the middle of her crib. Mom reportedly found her unresponsive <1h later, with her face pressed up against the bumper pad and one arm under the bumper, between the bumper and side rails. She was not breathing when the mom "turned her over to check her" (prone implied?). The mom left to get the dad who began CPR while she called 911. Paramedics resuscitated the baby and transported her to hospital; she was moved to a larger hospital in critical condition. After 2 days, she was declared brain dead and life support was stopped. The autopsy ME opined the cause of death as *Squeal of Suffocation (anoxic ischemic encephalopathy'; acute tubular necrosis; acute myocardial necrosis) with injury due to entrapment; Accident.* Staff notes that in police photos, the bumper was not tied correctly to corner posts; only 4/6 ties appear used and tied incorrectly so as to raise the bumper on the front-facing side of the crib (tie position possibly explained by the fact that the crib can be converted to a toddler bed and has large uneven sized corner posts, making it difficult securely tie short bumper ties). The IDI synopsis does not detail specific items of concern police reported in the cluttered crib, (i.e., an adult pillow (black), baby pillow, comforter and blanket. Other items include a toy bear, baby clothes, diaper, and 2 boxes of diaper wipes. The exact position of the baby's arm, body, head and face in the crib when found, and the position of other crib items relative to the baby, are unclear. Staff believes it probable that pillows (or other bulky items specified in the crib) wedge-entrapped the baby with her face pressed against the bumper. Note: photos show another adult pillow on the floor (unclear if it was involved?). ***Although the baby reportedly had her arm caught behind the bumper, staff does not consider this a plausible explanation for the baby's face being "pressed against" the bumper. Staff considers this baby's death was likely caused by at least one of the multiple large objects in the crib, most likely the adult pillow. Pillows are recognized as entrapment and/or suffocation hazards in a crib, and can cause an infant death even if a bumper is not present. Staff considers the crib bumper appears irrelevant as the primary cause of death.***
44		Limited information: the 1 page DCRT reports a 21 month-old boy suffocated when his face became pressed against a crib bumper pad while sleeping. His death was ruled as *"asphyxia - suffocation, accidental"* on the DCRT signed by "assistant deputy ME (non-MD)". The DCRT, but not the EPIR-IPII summary record, also reports under other significant factors contributing to death included ***"Remote neonatal Intracerebral hemorrhage and infarction of uncertain etiology"*** which is indicative of significant brain pathology. ***Staff considers a healthy 21 month old child would not simply suffocate against a crib bumper and would move unless somehow wedged/entrapped against the bumper. Staff considers the brain damage sustained at a younger age to be the primary risk factor involved in this death. For this reason, staff considers the bumper pad irrelevant as the primary cause of death in this case. Supplemental information RESTRICTED: ME investigation confirms 22mM had severe cerebral palsy birth defect, complex medical history, required a feeding tube and had "little muscle control, cannot stand or turn over, has no fine motor skills." Parents said he "sleeps on a foam pillow that has "sides" on it to support him through the night (sleep positioner?). They reported he was put in the crib ~9:30 pm, then found cold and unresponsive at 7:20 am. He was no longer on the pillow but per father, was at "the end of the crib, his face against the bumper along the side of the crib". Using a teddy bear, the father demonstrated the boy's as found position to the ME investigator (on the scene ~1 hr later). An indistinct photo (p39/43) shows the bear lying on its left side with its back towards the bumper-covered short crib end, and its head turned inwards towards the crib center/tilted upwards into the bumper on the long crib side. The ME stated that the boy had unfixed posterior body lividity and right facial lividity, and noted that that was not appropriate for "baby found on left side" - the ME suggested plagiocephaly might give an impression the rhe boy had been lying on his right. HS staff does not understand how this explanation reconciles the inconsistent reported as found position "on left" with the gravity dependent lividity patterns which suggest the boy died lying on his back with his head turned to the right? HS staff concludes that the exact circumstances of this well cared for older child's death are unclear, particularly the object in contact with his face is unknown, but clearly the boy was severely physically***

		compromised and possible entrapment by a pillow/sleep positioning device against a bumper cannot be ruled out.
45		Limited information: the 2 line NEISS case narrative states that the 2 ~~month~~ **YEAR** old girl was found *"face down in crib between pillow & bumper, cold, stiff & not breathing, sm amount of blood found in crib: death cause unknown"* It is not clear what was in contact with the face of this prone child. ***Despite limited details, staff considers presence of a pillow as the likely primary risk factor in this death. Pillows are recognized as entrapment and/or suffocation hazards in a crib, and can cause an infant death even if a bumper is not present. Staff considers pillow most likely caused this death and the crib bumper appears a secondary not primary cause of death. Supplemental information in the Coroner's verdict reports the 2yF died a natural death caused by seizure activity over several months. The autopsy attributes death to "cardiorespiratory arrest due to seizure activity". It does not mention victim being found face down in crib between pillows and crib bumper?!***
46		This case involves a 2 month-old girl found lifeless by her dad, 11 hours after last being seen alive. She reportedly was placed supine in her crib with her head elevated by pillows. She was later found lying prone in the cluttered crib, with her head turned 180 degrees from the original placed position (south to north end of crib); her head was "partially wedged" "face-down" between a pillow and the bumper pad. Two adult pillows, a sofa cushion (square, throw type), toys, and a jewelry box (why?) were also reported in the crib (seen in police photos). A pink blanket and "crib pad" are also reported; staff believes the latter item might mean the matching quilt (to bumper) seen beneath pillows/sofa cushion in photos. The victim had a 3 day history of antibiotic use for a stuffy nose. The ME's autopsy report and DCRT ruled the death as "POSITIONAL ASPHYXIA" and lists "CHRONIC INTERSTITIAL PNEUMONITIS" as a contributing factor. The final DCRT was signed 2 months after death and included "DECEDENT PLACED IN UNSAFE CRIB" noted as the cause of injury. ***Staff considers the presence of a pillows and sofa cushion as the likely primary risk factors in this death. Pillows are recognized as entrapment and/or suffocation hazards in a crib, and can cause an infant death even if a bumper is not present. Staff considers pillow most likely caused this death and the crib bumper appears irrelevant as the primary cause of death.***
47		Limited information: According to the 1 page DTHS record, a 3 month-old girl died after being "wedged between bumper guard and pillow" Her death was ruled as accidental due to *positional asphyxia* according to the DCRT. it is unclear if the coroner who signed the DCRT was medically qualified. ***Despite limited details, and lack of information on the position of the infant's face, staff considers pillow-related wedge entrapment to be the likely primary cause of death, because pillows are recognized as entrapment and/or suffocation hazards in a crib, and can cause an infant death even if a bumper is not present. Staff considers a pillow likely caused this death and the crib bumper appears irrelevant as the primary cause. Supplemental information reported the baby routinely slept on a pillow. Final Pathologic DX 1) Positional Asphyxia, A) Clinical history of decedent face down in mattress/pillow; decedent found with face, nose and mouth in mattress and pillow. B) Decedent allegedly sleeping on pillow; decedent apparently rolled off pillow. Although there is some ambiguity in reports as to whether her head was face down into the pillow or turned to her left, the MD's final pathological diagnosis specifies face, nose and mouth in mattress and pillow and the primary cause of death still appears to be pillow wedging***

48		On 08/31/08, at ~00:30 am, a healthy, 2 month old girl was placed prone in her crib on a foam mattress, on top of a thick floral comforter. She was alive in that position, head turned to right, when checked by her mother at ~2:30 am, (on return from visiting the baby's father in hospital with an undiagnosed illness (later diagnosed as acute encephalitis!). At 8:45 am, she found the baby face down, (corresponding brownish orange stain found on comforter), cold and unresponsive. Neighbors (nurses) tried CPR until paramedics arrived, but she was pronounced dead at hospital. Autopsy found no obvious signs of trauma; a 4 mm probe patent tunnel was found between atrial walls (septum primum and secundum), but the foramen ovale was completely covered, so it is unclear if there was any intra-atrial hole-in the heart functional defect; brain histology revealed intense vascular congestion, but no encephalitis. The coroner ruled the cause of death " acute cerebral anoxia" and the manner "could not be determined". A crib bumper is only mentioned incidentally in source documents as part of crib contents, i.e., "*a pink floral crib bumper bordered the edge of the crib. All sides were tied securely to the corners of the crib."* ***Staff considers that the cause of death in this case is confounded by several plausible risk factors: prone sleep position, face on top of soft compressible bedding (comforter+foam mattress); serious illness of family member (contagious?); and possible congenital atrial defect and the crib bumper is not implicated.***
49		This case involves a healthy 10 week-old boy who was placed in his crib (~1:15pm) in a supine position, as supported by a large C-shaped nursing pillow. The dad said he went to wake the baby just after 2pm to go shopping (<1h nap?). The baby was not breathing so he called 911 and took him outside while doing CPR. When police arrived (2:11pm) the baby was warm, but pale and unresponsive, with mucus (possibly vomit) leaking from his mouth. The dad was hitting the boy's back to clear a presumed obstruction. Police helped with CPR until paramedics arrived. Police reports say the dad found the baby on his side having somehow *"flipped over, crawled up over the nursing pillow and his face was against the padded bumper and mattress"* with his *"mouth up against the bumper almost wedged between the mattress and the bumper"*. Police took undisturbed bedroom scene photos while paramedics worked on the baby. These show a very cluttered crib: C-shaped pillow, quilts, blankets, toy, bottle, book and inexplicably a wall clock); they also show an adult pillow on the floor which appears stained (any involvement is unclear?). The ME's autopsy report opines *"Probable asphyxia due to obstruction of the nose and mouth*" notes "*found unresponsive lying with his face wedged against the bumper of his crib and the mattress*". There is no mention of the nursing pillow in autopsy report. The DCRT repeats these autopsy findings and also notes ***"sleeping on XXXXX pillow" (brand name omitted by staff)*** as another contributing condition in this accidental death. The case was closed and no formal police investigation done. The exact position of baby's body/head/face when found is not clear. Staff notes that the IDI synopsis reports victim "found lying with his face wedged against the bumper pad and the mattress, lying on his side" but does not mention the baby's head was wedged in position against crib sides by the large C-shaped XXXXX nursing pillow in the crib. It also omits the "probable" from ME's autopsy and DCRT finding of "probable asphyxia due to obstruction of the nose and mouth" ***Staff considers this baby's death was likely caused by misuse of the large C-shaped nursing pillow in the crib. Pillows are recognized as entrapment and/or suffocation hazards in a crib, and can cause an infant death even if a bumper is not present. Staff considers the crib bumper is irrelevant as the primary cause of death.***

50		**A** healthy 7.5 month-old boy was found unresponsive in crib, lying prone, with his head trapped at the headboard end. Police reports differ slightly as to the baby's position as found, i.e., 1) prone with *"head propped between the mattress and the frame"; and 2*) *"face down, his head stuck between the head of the crib and the mattress with the infant's throat against the mattress".* The autopsy reported no evidence of trauma and opined deaths was due to *accidental positional asphyxia* and noted ***"head wedged between the mattress and the headboard of the crib" "nose was into the mattress".*** The mom said she placed the baby supine in the crib at ~10am. He was later found by the dad at ~12:45pm. The parents reported having no phone and so asked a neighbor to call 911. However, when the police arrived, the dad (described as "very calm") was outside talking on a cell phone and the neighbor was inside doing CPR; the mom was at the baby's feet, crying, smoking, and talking on another cell phone ***(2 cell phones?)***. The baby's 2 year-old sister shared the room and, according to the Mom, *"likes to pull the bumper pads away from the crib"*. The bumpers were untied in 3 corners (headboard corners and one footboard corner). Note: bumper involvement was first suggested by a detective to the CPSC investigator. ***The cause of death is not fully clear, but 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. An excessive gap between the mattress and crib frame is a recognized entrapment hazard that can cause death by positional asphyxia/suffocation, regardless of the presence of a crib bumper. Staff considers that the crib bumper appears irrelevant as the primary cause of death.*** Curiously, in death scene photos, a toy broom is seen wedged between the crib side rail and the mattress. It's potential role in the death is unclear. Possibly, it was used to wedge a too small mattress in place or perhaps the 2 year-old sister untied bumper and used broom to "play" with the baby?
51		Not in a crib …..in a bassinet
52		Limited Information: DTHS 2 month old girl died from cardiorespiratory failure due to severe brain injury and asphyxiation after being wedged between a mattress and a crib. The IDI notes that different information is presented elsewhere.; one line in a copy of a Georgia Bureau of Investigation Report reads *"Reportedly, on 5/6/09, the decedent was found wedged between her baby bed and the baby bumper of the bed."* The IDI also informs, that when the injury occurred, the girl was airlifted from a local ER to a larger hospital, and, after 16 days, life support was eventually discontinued at the parent's wishes No autopsy was done and there was no official investigation report or scene photographs taken by any agency. The CPSC DRS essentially contains no useful information other than the response to Q26 which specifies *"Scene of the incident was never examined by coroner or law enforcement official."* ***Inconclusive - Staff considers the circumstances of this child's death cannot be established from such limited information.***
53		A 7 month -old girl was reportedly placed supine in her crib by her father, sometime after 11 am. He said he checked her hourly from ~1pm, but then fell asleep on couch and woke up at about 5:30pm when the mom called from work. The baby was quiet at that time so he assumed she was still asleep and did not check her again until his girlfriend came home (~7 to 7:30pm). He then got a "bad feeling' and reportedly found the baby blue and lifeless, face down with a quilt (also described elsewhere by the father as a blanket) wrapped around her neck at least one time. The police report notes the 911 call (by Mom) was received shortly before 8 pm. It seems strange that dad did not check the baby at 5:30 pm (>5.5 h in crib) and waited another 2.5 h before checking her. During scene reconstruction with the ME investigator (who noted the parents to be unemotional), the father first indicated finding the baby supine, but with prompting recalled his original report to police that she was prone when found, and that he had to roll her over twice to free her from the blankets. The police report detailed four blankets in the crib; an afghan type blanket; a lightweight baby blanket, an embroidered blanket (quilt?) and a rather large and heavy tan/brown micro fiber blanket. The initial autopsy findings suggested asphyxia with a history of winding in blankets. This final ME report finding signed >2m after death, discussed the fact that asphyxia is a diagnosis of exclusion and noted *"a history of winding in blankets and undeniable prone position favors asphyxia"* in opining the cause of death to be *asphyxia*-manner *accidental.* ***Staff notes that there were no autopsy findings to support strangulation by constriction of neck vessels or airways. Furthermore, there is***

		no indication that a crib bumper was involved in this death.
54		**PART RESTRICTED!** DTHS:2 month old girl suffocated, ruled SIDS; found face down in crib. IDI: notes baby was last seen alive ~11pm when placed prone in her crib by her mother. Later found prone, blue and unresponsive when mom checked at 11:30 am (>12h!). Responding police noted mom was hysterical, but father strangely devoid of emotion. ER MDs had concerns about marks on the baby; CT scan apparently showed evidence of a basilar fracture and subdural hematoma, suggesting possible abuse. Police concerns were fed by the parents' case history (bipolar disorder, medications; father's prior violent behavior/anger management concerns). However, at autopsy, the forensic pathologist reported no evidence of physical trauma. **THE ME's CONFIDENTIAL RESTRICTED AUTOPSY REPORT** differs greatly from the EPIR DTHS record. It opines an accidental death due to *"position asphyxia," "found in a crib facing the mattress bumper"* and handwritten notes indicate found in face down position with lividity on the right side of face and body. The death scene reconstruction report/photos done with mom by Child Protective Services & Police on incident day indicate the baby had turned 180 degrees from her initial placement. One policeman reports the baby was *found face down between the mattress and crib bumper*, and later says *wedged face down between the mattress and crib padding,* whereas, the SUID form reports the baby was found "*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 reported lividity patterns on the right side of the baby's face and body are most consistent with a position facing down and away from the bumper, towards the middle of the crib. Photos show several blankets in and over the side rail of the crib; one corner of the bumper appears tied higher than the middle side rail bumper tie. ***Staff considers this strange case is confounded by inconsistent information, even from official sources and so is Inconclusive in terms of the cause of death or the bumper's role.***
55		This case involves the death of a 3 month-old girl found unresponsive in her crib by her 10 year-old brother at ~10:45am. She was not yet a 4 month-old girl as stated in the EPIR IDI and IPII database summary records, and in fact, was born 6 weeks prematurely (~2 months old by gestational age). She had had a 2 day history of diarrhea and was on a prescription medicine (Axid) for a reflux issue. Reportedly, she was last fed about at ~11:30 pm, then put in crib around 1 am and left there for more than ***10 h!*** (The dad told police she cooed when he kissed her cheek before leaving for work at 8am, but based on her reported location it is not clear if this was possible for him to do. (SI: did he lean right over the side rail across to the baby on far side of crib?). The mom said that she looked in on the sleeping baby at ~9:17 am but made no attempt to feed her at that time (staff notes that it seems strange to leave any young baby, particularly a preemie, unfed for almost 10 hours?). Therer are ambiguous reports of baby's crib location (basement or 2nd floor) and her "as found position" supine or with face turned to one side per Mum and 10y son who found baby. (Compare police report and reenactment photos taken at the time of incident with photos done for the subsequent CPSC IDI on-scene reenactment done 21 days later. Only the report that the baby's forehead was pressed into side rail bumper, and that her nose and mouth were only lightly touching bumper are consistent. The new crib mattress was reported to be too small for the used crib. After a 10 month investigation, the ME finally ruled this a SIDS death; due to natural cause. It seems very strange that the ME's detailed autopsy notes that "*The written police report was not made available to this death investigation.*" ***There is no other information available to staff that leads to alternative conclusions, therefore, without further information, staff must accept the ME's ruling of SIDS***

56		This case involves the death of a healthy 2 month-old boy. He was placed prone in crib at ~8pm after being fed. About 2.5h later, the dad found him prone, unresponsive with his head against the crib bumper, but did not know if his nose and mouth were against the bumper because and he was not wearing glasses and had not turned on the light to prevent waking the baby's 19m sibling who was also sleeping in the room. The crib sheet near bumper location where the baby was found had a wet patch with small red stain (noted to be bloody emesis in the ME's final report. This and the facial lividity patterns, suggests the baby vomited while face down against the sheet/mattress. An investigator from the ME's office report the baby's fists were clenched. There were no obvious suspicious signs of trauma or unusual parent behavior/reaction. The ME's autopsy report opined that the death as "suffocation- accidental" with findings of hemorrhagic atelectasis, petechiae of thymus and visceral pleura of lungs, pulmonary edema/congestion and facial lividity; and history of being found unresponsive prone in crib against/near a soft fabric bumper. It is not clear to staff how the ME diagnosed this death as accidental suffocation as opposed to prone-related SIDS/SUID. ***From the limited available details on the prone infants face relative to the bumper, staff cannot reliably assess the role of the bumper as the primary cause of death.***
57		Not in a crib….. In a playpen
58		**RESTRICTED IDI** *(notice on IDI page 1)* This IDI was triggered by a hotline complaint from the victim's grandmother. A healthy 6.5 month-old boy was reportedly found unresponsive in his crib around 2:15-2:30 pm after being put down for a nap at 12:30 or 1:15 pm by his mom, who lived in family pool house apartment. The are multiple inconsistencies in various reports concerning the death of this boy that on the final death certificate was eventually ruled an accident due to "*suffocation in a non-standard sleeping environment; decedent found in crib with face between bumper pad and mattress" .* It is reported that on discovering the unresponsive boy, the mom phoned the dad (on his way home from school), then rushed the baby to the main house where her own mother (victim's grandmother) tried CPR while she called 911 - (the 911 call records note a male caller with a hysterical female crying in the background which suggests either the father was already at home or a delay in calling 911 until he arrived home). The baby was flown to a hospital and was resuscitated but was brain dead; life support was withdrawn the next day. Note: the hospital ophthalmologist reported finding uneven bilateral retinal hemorrhages and indicated they were rare without abuse (there was a concern of possible shaken baby syndrome expressed by the ophthalmologist and also noted in the ME's records) It is not clear why the ME ruled the hemorrhages were due to (DIC) consequent to disseminated intravascular coagulation due to raised intercranial pressure from cerebral hypoxia. At autopsy, the ME noted bruising on the mid back (not to be confused with the Mongolian sport also noted on the back). Note : the crib was very cluttered (pillows, fleece blanket, 2 beach towels, ~8 soft toys) per police report photos; different crib contents were noted by the parents in the subsequent CPSC reenactment of the death scene. ***Given the inconsistent ambiguous report detail, staff cannot make any firm assessment of the crib bumper's role in this inconsistent ambiguous report, but suspects pillows and other clutter in the crib may have been involved.***

59		This death involves the overnight death of a 7 week-old boy who had a significant medical history of breathing issues (described by the parents as "infant asthma" and sleep apnea). About ~2 weeks before his death, he had a spinal tap and was hospitalized for 2 days for fever and vomiting (reported as virus treated by antibiotics???). He died overnight after being placed on his left side in an inclined infant sleep positioner, intended for use in a crib. He had rolled out of the positioner and was wedged face down between the bumper-covered crib sides and the outer raised edge of the positioner. The ME's autopsy report notes his death was ruled an accident and reported as *"Probably asphyxia, a) found prone with face wedged between bumper pad and mattress , b) use of sleep positioner."* The father reported finding the boy *"face down in the corner of the crib"* and with *"his nose between the bottom of the bumper pad and the mattress".* The reported case details are ambiguous as to whether the baby's face was pressed against a comforter that was between him and the mattress, or the crib bumper as reported by the ME. Reenactment photos also show a blanket was on placed on top of the positioner, beneath the infant. The baby's reported history of breathing issues, which influenced the parents to use the sleep positioner, are possibly related to the autopsy toxicity screen report findings of significantly elevated dysfunctional hemoglobin (Hb) species: COHb (5%), MetHb (10%), and Sulf Hb (12%). These Hb aberrations of an unclear basis (endogenous metabolic error/disease/external poison?) are not discussed by the ME in the autopsy report. ***Staff considers the primary cause of this baby's death was suffocation consequent to entrapment by the sleep positioner. Use of infant sleep positioner products in a crib is now recognized as presenting an entrapment hazard that can cause positional asphyxia/suffocation death regardless of the presence of a bumper. Staff considers the use of the positioner caused this death and the crib bumper involvement is irrelevant as the primary cause.***
60		**RESTRICTED INFORMATION!- DTHS COMMENT PURGED OF MFR INFO:** DTHS: ME ruled a 6 month old girl died of probable positional asphyxia when she became wedged between a inclined infant sleep seat and a bumper while sleeping in a crib. IDI: The healthy 6 month old girl's babysitter had placed her supine, in an inclined infant sleep seat. The victim's parents used this device inside her crib, without the harness being fastened, on a routine basis. The baby was last seen alive when her parents returned home around around midnight. Her father found her ~ 6:50 am the next day, still on her back but turned 90 degrees in the seat, with her unsupported head tilted backwards (hyperextended) off one side of the device so "t*hat the right side of her face was nuzzled against the crib bumper."* This is consistent with prominent drying of right cornea/sclera and prominent congestion of brain tissue found at autopsy. ***Staff considers the primary cause of this death to be misuse of the inclined infant sleep seat in the crib, which allowed the baby to get into a hazardous position - unsupported head /hyperextended neck - leading to brain vascular congestion/suffocation. In this case, the bumper played a secondary role, but with a combined hyperextended neck/downward tilted head position, death can occur in the absence of the bumper.***
61		Limited information the 1 page IPII-MECAP report indicates that the 1 month-old boy was put to sleep in his crib on top of an adult pillow. He apparently died when he became wedged between the pillow and the bumper covered crib frame (rolled off of the pillow?). There is no specific mention of the item in contact with the baby's face. ***Despite limited details, staff considers pillow-related wedge entrapment to be the likely primary cause of this death, because pillows are recognized as entrapment and/or suffocation hazards in a crib, and can cause an infant death even if a bumper is not present. Staff considers a pillow likely caused this death and the crib bumper appears irrelevant as the primary cause. Supplemental information in ME case summary and autopsy confirm pillow-related wedge entrapment and anterior facial lividity indicates prone death position - described as accidental death due to sustained positional asphyxia (rest illegible). The pillow is described as an adult pillow; the presence of a cloth covered wedge (possible sleep positioner?) and a large amount of clothing, further complicates and confounds the sleep setting.***

62		A healthy 3 month-old boy was placed him prone in crib by his father after having his morning bottle. The mom was already asleep in the same room after returning from her night job. The father biked to store and was away an hour. On return, he found the boy unresponsive, face down in a pillow, with his head described as being "against" and "next to" the crib bumper. Staff notes that it not clear whether the child's face was in contact with the bumper. Dad's shouting woke the mom, and 911 was called (12:14pm) while CPR was attempted. Police and paramedics arrived ~12:18-12:21 pm and transported the boy to ER. He arrived at 12:35 pm and was pronounced dead at 13:02 pm. Police took immediate death scene photos showing a cluttered crib containing a large green pillow with a wet stain where the baby's head was located. The prone baby's death is confounded by presence other crib items: 2 comforters, 3 receiving blankets, a light yellow blanket, blue towel, 2 stuffed toys and a baby bottle were also reported in the crib. There were no suspicious findings. The police report indicates that their case was closed after the ME ultimately attributed the death to "positional asphyxia, accident" A subsequent IPII-MECAP report to CPSC simply notes a positional asphyxia crib death with bedding, pillows and bumper pads present. ***Staff considers presence of a pillow as the likely primary risk factor in this death of this prone 3 month-old child because he was reported to be face down into the pillow so likely suffocated. Pillows are recognized as suffocation hazards in a crib, and can cause an infant death even if a bumper is not present. Staff considers a pillow as the probable primary cause of this death and the crib bumper appears irrelevant. Supplemental information recreation" photo it simply shows a prone doll face down on a mattress in a bare crib without bedding or bumpers. (i.e., safe sleep setting with unsafe prone position!). Completely different to IDI incident crib scene photos. Unclear what relevant information this adds to support any role for the crib bumper.***
63		DTHS: 2 month old girl, due to positional asphyxia, accident, in a prone position with face against bumper. IDI: At ~ (9:30pm, the victim's and her twin sister had been placed in prone position in the same crib by their mother, both in prone position. A mattress sheet, cotton blanket and crib bumper were the only items reported in the crib per IDI narrative NOTE- the Sheriff's report mentions a bath towel found in the crib, but its position and form relative to the decedent when found (rolled up, folded or unfolded) is not mentioned. The mother reportedly found the baby at ~7:45 am, face down, cold and unresponsive, with one arm between the bumper padding and mattress. The CPSC investigator notes that in a telephone interview, the Coroner corrected statements in written coroner and sheriff's office reports which said that the victim's face was against the bumper; he clarified that the positional asphyxia resulted from the baby's face being against the crib mattress, rather than the crib bumper. There is no mention of the position of the surviving twin in relation to the victim when first found. ***This death involves multiple confounders (twin, and towel in bed, conflicting officials' reports), thus, no reliable conclusions can be drawn to implicate the bumper as the primary cause of death, which staff considers unlikely.***
64		DTHS: 1 month old girl, ME ruled death caused by suffocation due to an unsafe sleep environment; she became wedged between a crib bumper pad, and pillow holding a bouncy chair. IDI: A 5 week old girl died under extremely unusual circumstances when inexperienced, misguided parents tried to make nighttime breastfeeding more convenient. They placed their baby's crib next to their bed and "rigged" it so that the side rail was removed and the crib mattress was raised near the height of their mattress. They placed a pillow on the crib mattress, then placed one end of an infant bouncy seat on top of the pillow, in an attempt to maintain a reclined angle, more like a bed than a seat. The placed their baby in the seat on top of a blanket, so could not use the harness. After a 1 am feed, the father woke at ~6:30 am to find the baby had fallen out of the seat and had become wedged on her right side between the pillow, bouncy seat and bumper covered crib frame. ***It is clear that this death was caused by multiple failures in the primary crib sleep setting (misuse of bouncy seat, pillow used as propping device, crib used with side rail removed and mattress raised too high.) Staff considers the presence of the bumper was of little or no concern.***

65		**RESTRICTED IDI (ACTIVE COMPLIANCE CASE):** This death involves a 4 month-old girl in an infant sleep seat product that was inappropriately placed in a crib (the manufacturer's warns that the seat should always be used on the floor). The parents started using the seat when the baby was ~12 weeks-old (re: projectile vomiting concerns). They routinely used it in the crib along with three 8x8 inch decorative pillows in the crib, which they explained *"were always kept in the crib just in case the victim started to kick against the footboard and was able to push the seat towards the headboard."* The CPSC investigator reports that the dad fed the baby at ~1am, then found her unresponsive at ~2.55 am *"halfway out of the infant seat with her head hanging off and tilted back with her neck hyper-extended and her face in the bumper pad of the crib. The victim was still loosely strapped into the infant seat."* The IDI also indicates that officials who later inspected the crib found *"a cupping in the area where the victim's head was facing"*. The dad called 911 while the mom attempted CPR, then ran the girl to the firehouse down the road. The baby was pronounced dead at 3:37 am in the ER. The autopsy ME opined ***"she died of position/ compression asphyxia, sustained when she was entrapped between a nap nanny and bumper pads in a crib. Accident".*** **NOTE**: the IPII-MECAP report that triggered the IDI notes the ME investigator specifically asked exactly how the baby was lying in the seat ; a detective advised that she was belted in, "*but the head was hanging off and tilted back with the neck portion hyper-extended and its face in the bumper pad of the crib."* Neither the IDI or the police reports clarify whether the girl's head was hanging over the side or the back of the infant seat, or exactly where the observed cupping was located. Furthermore, staff notes that in the IDI pdf file, two separate police reports of 7 and 14 pages respectively appear to be mixed together to form a single 14 page report with non-consecutive pages; as such, specific detail on whether the baby's head and neck were hyper-extended backwards (into pillows?) or sidewards (into bumpers) and any potential involvement of the bumper and/or the pillows, is not clear. ***Regardless, staff considers misuse of the sleep seat in the crib resulting in entrapment of the baby's hyperextended head and neck, is clearly the primary cause of this death.***
66		***RESTRICTED IDI!*** *IPII: Child DRT member reports 2 deaths on nursing pillows 8/30/10 and 10/09/10. NOTE RESTRICTED IDI: is for 8/30/10 but the EPIR IDI date code is wrongly entered as 8/20/10:*The 4 month old boy (nearly 5m) was placed supine in his crib propped up on a C-shaped nursing pillow at ~1am. The next day, at ~8:15 am, his mother found him cold, blue and unresponsive. He had moved to a prone position and had appeared to crawl part way over the nursing pillow but his downward tilted head had become wedged in the gap between the pillow and the bumper covered crib sides. In the reenactment photos using a doll, it is not clear whether the face (nose and mouth) was pressed against the nursing pillow or bumper. ***Staff considers this baby's death was caused by misuse of the large C-shaped nursing pillow in the crib. Pillows are recognized as entrapment and/or suffocation hazards in a crib, and can cause an infant death even if a bumper is not present. Staff considers the crib bumper is irrelevant as the primary cause of death.***
67		**RESTRICTED IDI!** IPII: Forensic/ME? investigator reports the death of a 2 month old boy in his crib, face down on a pillow - a 1" red spot (blood) was found on the pillow. The mother reported the boy had had congestion problems since birth and so she routinely placed him to sleep on his right side, on the pillow, against the bumper pad (presumably this means his back against bumper, though it is not specified). IDI: has the same IPII report plus police report and photographs of the crib and contents, clearly showing a standard sized adult pillow, two large stuffed toys (elephant, bear), and a traditional cloth bumper that appears to be appropriately tied in place. The IDI notes no scene recreation of the baby's found position was done. It also has an autopsy report that notes fixed lividity on the right side of the boy's face and torso, and moderately congested, edematous lungs with diffuse, scattered, fine petechial hemorrhages in the pleural surfaces. This evidence is consistent with accidental death, caused by asphyxia due to suffocation face down on a pillow. However, based on cardio-histopathological findings, the ME ruled this case to be a natural death caused by lymphohistiocytic myocarditis (small foci of intramyocardial lymphohistiocytic inflammation associated with myocyte necrosis seen in multiple random sections of right and left ventricles.) ***Staff considers either a medical issue or a recognized adult pillow hazard is the primary cause of this death and there is no evidence implicating the bumper as being involved. NOTE IPII narrative that victim found***

		supine is a coder error.
68		**RESTRICTED IDI!** IPII: ME reports the death of a 3 month old boy, placed and found prone cold and unresponsive in his crib, The boy's parents have a history with child protective services re child neglect, drugs (another infant tested positive for cannabinoids and benzodiazapines), bumps and black eyes, etc. IDI The father reports feeding the baby at 3pm, then placing him prone in his crib which contained items including a pillow, blankets, stuffed toys, bumper and cigarette lighter! On arriving at home around 6pm, the mother found the baby in the crib, prone, cold and unresponsive. Rather than call an ambulance, they drove him to the ER, where staff noted lividity and rigor mortis (likely dead longer than 3 hours!). An autopsy found no obvious physical trauma or sign of illness, but detected diphenhydramine (benadryl) in blood taken from the thoracic aorta (2.4mg/L in a 6.15 kg child). The IPII report notes that the MD asked police to ask if the child had been given benadryl, and if so why, and how much, but staff found no documented police follow up to this question. Based on information available at the time, the autopsy concluded the boy died as a result of "undetermined causes" and commented that the thoracic aorta source of the blood specimen complicated interpretation of the drug level. *(NOTE: according to micromedex, children, particularly infants, tend to be more sensitive that adults to the toxic effects of diphenhydramine; the lowest lethal dose reported for an infant is 62.5 mg (11.5 mg/kg) and severe toxicity has been reported at 10-15 mg/kg).* ***Staff considers the bumper is mentioned only incidentally in this case which could possibly involve overdosing of an infant with benadryl.***
69		IPII- A mother reported that her 4 month old son died of SUID while sleeping in an specialized infant product (SIP) an inclined infant sleep seat IDI: The mother disagreed with the ME's ruling on the cause of death of her son and contacted CPSC. The mother bought the SIP because her infant (3rd child) suffered from gastric reflux and her pediatrician had advised elevating his head. She admits knowingly ignoring the labels warning against using the SIP in a crib. She also deliberately used the SIP without fastening its harness, choosing instead to place a blanket on its surface to protect it against spit up. .On the incident day, she put the baby in the SIP around midnight, then heard him cry around 5 am and went to prepare hs bottle, but he quietened, so she returned to bed. She did not enter his room until about 8 am, then found him cold, unresponsive in the SIP. He was lying on his back, completely sideways, with his shoulders still in the SIP, but his neck hyperextended over one side, and his unsupported head tipped backwards, such that it appeared the top was touching the mattress. It is not clear if his face was contacting the bumper which was noted to be properly secured to the crib spindles. The baby was transported to hospital by paramedics but could not be revived and was pronounced dead at 9:30 am. After a full autopsy, the ME ruled this a natural death due to SIDS. The mother believed hed son had suffocated and contacted the ME's office who reportedly told her "there is no physical damage to the lungs" and "no capillaries burst" .and without physical evidence of positional asphyxia, the cause of death would be SIDS. ***Staff considers the primary cause of this death to be misuse of the sleep seat in the crib, which allowed the baby to get into a hazardous position - unsupported head /hyperextended neck - leading to brain vascular congestion/suffocation. In a combined hyperextended neck/downward tilted head position, death can occur in the absence of the bumper.***

70		**NOTE RESTRICTED IDI** IPII- 2 hours after being put unbelted in a specialized infant product (SIP), an inclined infant sleep seat, used inside a crib, a 7 month old boy was found dead trapped in a face down position between the SIP and the bumper covered crib side. IDI: The victim had complications, as a preemie, including gastric reflux.. The SIP had been used in a bassinet until 2 weeks before the death, when the mother moved it to a full sized crib. The boy was healthy at the time of death and had started to roll over. His mom breast fed him 2 hours before she then found him dead in the crib. Various versions of his "as found" position indicated he was "lying face down in the crib" and the mother notes she is not certain if his head and feet are in the same orientation as used in the SIP or if rotated 180 degrees. There in no indication of the baby's head being caught between the SIP and crib bumper/sides and suspended above the mattress surface as depicted in a CPSC scene recreation done 2 months after the death (unclear if that recreated scenario is likely?). The ME ruled this case a SUID (sudden unexplained infant death) and found the manner of death could not be determined. In comments, the ME noted that circumstances suggested possible asphyxia, but the evidence was not conclusive. ***Staff considers the primary cause of this death to be misuse of the sleep positioning device in the crib, which allowed the baby to get into a hazardous position when he rolled off the device and fell face down into the confined entrapment zone created between the device and the crib perimeter.***
71		IPII- ME's preliminary report on the death of a 5 week old boy due to suffocation by bedding, apparently due to wedging between an adult pillow and crib padding.. The father fed the baby at 1 am then placed him in his crib on top of an adult pillow, in a prone position, with his head turned to the right. At 8 am, he found the baby cold and stiff, responding paramedics and police noted lividity and rigor and declared the boy dead. ***Although the information is still quite limited, staff considers the most likely primary cause of this death to be the presence of the adult pillow in the crib beneath the baby, because pillows are recognized suffocation and entrapment hazards.***

BEFORE THE
U.S. CONSUMER PRODUCT SAFETY COMMISSION

PETITION REQUESTING A PERFORMANCE STANDARD 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

May 9, 2012

INTRODUCTION

The Juvenile Products Manufacturers Association (JPMA www.jpma.org) is a national trade organization representing 95% of the prenatal to preschool industry. JPMA continues to work with government officials, consumer groups, and industry leaders on programs to educate consumers on the safe selection and use of juvenile products. *Naptime to Nighttime* and Baby Safety Month are only a few of the programs JPMA sponsors to keep today's safety conscious parents informed.

PETITION TO ESTABLISH A PERFORMANCE STANDARD FOR CRIB BUMPERS

JPMA is petitioning the CPSC to adopt a rule to define and distinguish between hazardous "soft" pillow-like crib bumpers and traditional crib bumpers that can be distinguished from them.

The public will benefit from a clarifying standard. CPSC messaging has focused on restricting "soft" bedding from cribs for use with children under one (1) year of age. Despite information to the contrary related to the safety of traditional crib bumpers some groups altogether advocate for the elimination of such products from the marketplace. Ironically consumers and caregivers, with a long successful use of such products want such products and if unable to purchase safe products would more likely than not create makeshift products. Data from CPSC's own newly instituted www.saferprodusts.gov web site indicates that the predominant complaints relating to crib use involves entrapment, breaks, abrasions and contusions in crib slat openings (which are mandated as tightly limited pursuant to 16 CFR 1219 and ASTM 1169-10)[1]

JPMA is concerned that the elimination of crib bumpers from the marketplace will lead to unintended consequences and may encourage parents to use towels, adult blankets, pillows or other makeshift structures or materials as a protective barrier from the tight

---

[1] Code of Federal Regulations Full-Size Baby Cribs and Non-Full Size Baby Cribs: Safety Standards, 2010 16 CFR 1219, sec. A.2 & G.4/ ASTM Standard Consumer Safety Specification for Full-Size Baby Cribs, F 1169-10, sec 5.8

dimensions and hard wooden surface of the crib slats. Data has demonstrated that caregivers have used unsafe alternatives in the sleeping environment to create a soft sleeping surface for babies or placed babies in altogether unsafe overly "soft" sleep environments. This behavior could occur with makeshift bedding used in the baby's crib as well. This is highly risky behavior to be discouraged.

According to the CPSC data, limb entrapment is the number one cause of injury associated with cribs, accounting for over 12% of incidents reported, and adult (not juvenile) bedding products accounted for almost 78% of reported hazardous incidents involving "soft" bedding.[2] Various safe sleep advocacy groups, including the JPMA, continue to promote the need for information and education on safe sleep practices (see for example our cited "*Naptime to Nighttime*" program as well as our Web site www.cribsafety.org). Data demonstrates that the message is not reaching the child rearing population or perhaps is being ignored. As a result, we are concerned that any recommendations that results in the de facto elimination of safe and useful products specifically designed for infant use will result in alternative makeshift hazardous product or hazardous use of adult bedding in infant sleep environments. Experience in cities such as Milwaukee, Baltimore and Chicago suggests that this is a significant problem that needs to be addressed.

Part of this effort should include clear communications about safe sleep practices and clear distinguishing requirements that better delineate hazardous soft bedding from juvenile bedding that does not present a substantial hazard and provides utility and protection when used in the care of infants.

In an ongoing effort to create the safest products, crib bumper pad manufacturers have taken the lead in discussions to further enhance the existing ASTM voluntary standard for infant bedding. Currently balloted items include enhancements to the warning statements to ensure consumers are properly using and affixing bumper products in cribs and that they are affixed so as to allow secure positioning in the crib. The warnings also emphasize the proper fit and use of ties. This along with a new test method for tie strength will result in a stronger standard.

In addition, several manufacturers have supported enhanced retailer crib bumper pad requirements for the past several years including use of a firm filling material as well as a thickness standard for the bumper pad. An ASTM ballot recently passed to create a test method to measure the maximum thickness of 2" pre and post wash to ensure continuity of the test method. Several manufactures who sell to the largest juvenile product retailers are already meeting this requirement in the marketplace. A rule that provides a method to distinguish between appropriate and inappropriate products will greatly benefit the public and permit continued production, sale and use by consumers who desire to use safe, secure, traditional crib bumpers.

---

[2] Howell, J, Edwards, P (2010) *Staff's Draft Proposed Rules for Cribs. Full-Size and Non-Full-Size*. U.S. Consumer Product Safety Commission

In 2011, JPMA commissioned a third party review of previous studies of crib bumper pads by Exponent Failure Analysis, a leading engineering and scientific consulting firm providing solutions to complex technical issues. Based on the findings, claims of increased risk to infants from traditional crib bumper use were unfounded. The data and studies reviewed lead Exponent to note methodological problems that were apparent in the criteria used and that such data did not establish such hazards. A summary of this study is attached for Commission's Reference.[3] The available data and published scientific studies disclosed no primary proximate causation between use of traditional crib bumper pads and an increased risk of infant fatality. Finally, according to the Consumer Product Safety Commission (CPSC) the greatest risk is to an infant sleeping in a prone position or in a crowded sleep environment that includes pillows, cushions and adult bedding. The CPSC has indicated that in their review so far they have found no direct primary causal connection between crib bumpers and infant fatality.[4]

When used according to manufacturer's instructions, properly designed crib bumper pads can help prevent limb entrapment and head injuries. Product innovation will continue to result in a wide variety of traditional and alternative bumpers and crib rail liners on retail shelves. Parents should have a choice in determining the protection level they want to provide in their baby's cribs. JPMA strongly encourages the Commission to consider the desirability of policies that support consumer choice.

JPMA is supportive of safe sleep education and agrees with many of the updated recommendations that were outlined in the policy statement *SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment* such as *back to sleep*, use of a firm sleep surface, room-sharing without bed-sharing, removing soft objects such as adult pillows, quilts, and comforters from cribs and other infant sleep environments.

The U.S. Consumer Products Safety Commission has, to date, found that there is **no evidence** of a primary casual connection between traditional crib bumpers and suffocation when the product is used as reasonably intended. JPMA supports an international ASTM safety standard that would require all crib bumpers sold or leased to meet certain dimensional, labeling and performance criteria. ASTM Standards currently include more than 12,000 safety standards set by ASTM, in use in 135 countries around the world.

---

[3] Sala, J, Prange, M (2011) *Crib Bumpers and the Infant Sleep Environment: An Evaluation of the Scientific Evidence* Exponent Failure Analysis

[4] Wanna-Nakamura, S (2010) White Paper – *Unsafe Sleep Settings Hazards Associated with the Infant Sleep Environment and Unsafe Practices Used by Caregivers: A CPSC Staff Perspective.* U.S. Consumer Product Safety Commission; CPSC Chairman's Comments to JPMA meeting participants Washington D.C. 2011-12

ASTM STANDARD PROPOSED PERFORMANCE REQUIREMNTS PROVIDE A REASONABLE BASIS FOR A MANDATORY CRIB BUMPER PERFORMANCE STANDARD

In an ongoing effort to create the safest products, crib bumper pad manufacturers have taken the lead in discussions to further enhance the existing ASTM voluntary standard for infant bedding, including crib bumper pads. The following recommended changes to the existing bedding standard are either currently out to ballot with ASTM or have been previously approved by the subcommittee through the ASTM balloting process and are recommended as the basis for any federal requirements as follows. Additionally an ASTM Task Group is currently working on developing uniform instructional materials for incorporation into the Infant Bedding standard.

Bumper Tie Test Method

This test was developed to reduce the incidents of ties breaking away from the bumper pad.

The test method is as follows:
Bumper Tie Strength – Following the testing specified in the following section, a bumper pad tie shall not fully detach from the bumper pad. Partial detachment or tearing is allowed.

> *Bumper Tie Attachment Strength*: Apply a tensile force of 20 lbs. on the bumper pad tie(s) in a perpendicular direction away from the attachment point of the ties to the bumper pad. The force shall be applied evenly within a period of 5 seconds, and maintained for an additional 10 seconds.
> Bumper pad ties that share a common attachment shall be tested together, as if one tie.

Note: There is no single clamp or attachment means specified for the bumper pad tie attachment strength test. Any suitable means may be used to apply the force specified in section 6.x. The loading device shall be a self-indicating force gauge or other appropriate means having an accuracy of +/- 0.5 lbs. (+/- 2N)

Bumper Pad Warnings

Suffocation Warning

- The warning to reduce the risk of suffocation is to be placed first as the risk of suffocation is greater than the other issues stated in this section due to the bumper ties being shortened and falls due to climbing up on bumpers is not commonly an issue.
- Changing to “keep top of bumper up and in position” and “allow bumper to sag down or in” in place of “use this bumper if it sags” better describes the action necessary to avoid the suffocation risk. The word “sag” will be kept as it is a good descriptive term. “Down or in” is there to cover both the top sagging down and the bumper sliding into the sleep surface. DO NOT use bumper if sagging cannot be corrected.

Strangulation Warning

- "Entanglement" is being deleted as suffocation is the injury risk.
- The "DO NOT use this bumper…" statement is to be combined with the strangulation hazard statement as strangulation is the issue here as well and it reinforces the "securely attached" statement.

Fall Warning

- The addition of "To prevent injury from falls from climbing out" identifies the source of the risk and why the action communicated in the warning is required.

⚠ 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.

- To prevent entanglement or strangulation, position ties outside of crib and be sure they are secure. DO NOT use this bumper if all ties cannot be securely attached to the crib.

- To prevent injury from falls from climbing out, remove bumper when child can sit up unaided or can pull to a standing position.

Bumper Thickness Standard

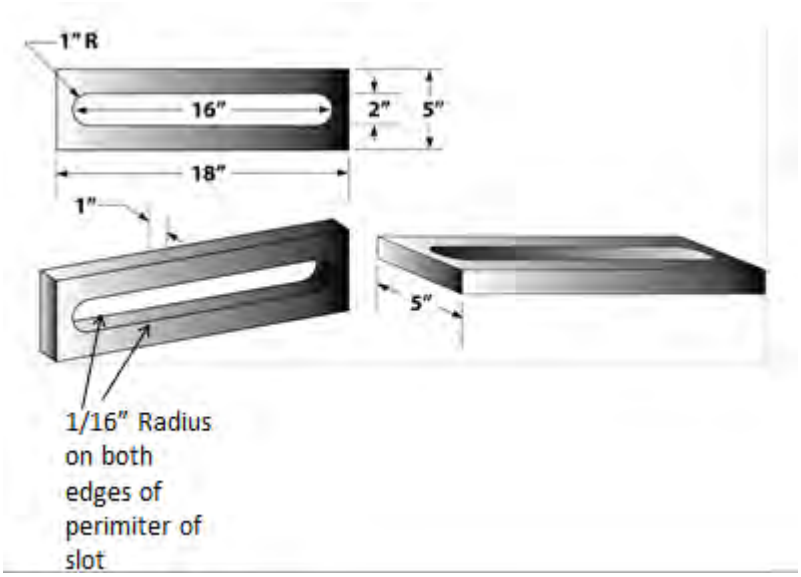
In order to define and eliminate "pillow-like" crib bumpers from the marketplace, the standard will include a test method to measure the thickness of the product. Many mass retailers have required their vendors to meet thickness requirements for the last two years so the vast majority of manufacturers are already meeting this requirement; however, a uniform method for testing to this requirement does not exist. ASTM is standardizing this method and will require that crib bumper pads meet a 2" pre- and post-wash requirement which will simulate a real world experience with this product.

3.1.7 *fabric*, *n*—any woven, knit, flexible material that is intended to be sewn together as an assembly. (Note: this fabric definition was modified from the Play Yard Standard F406)

6. X *Maximum Bumper Thickness* For crib bumpers manufactured of fabric and filled with a natural or man-made fibrous material, each bumper section shall slide through the Bumper Thickness Test Fixture over its entire length when tested in accordance with section 6.X. The bumper shall be tested in its pre-washed state and also after three wash/dry cycles performed according to the manufacturer's care instructions.

7. X *Bumper Thickness Test* – Align the Bumper Thickness Test Fixture so that the surface of the fixture with the opening is horizontal. Insert a bumper end into the opening so that the bumper end protrudes just beyond the lower surface of the test fixture and attach a 5lb static weight to the midpoint of the protruding bumper end. Keeping the bumper positioned vertically, allow the weight to slowly draw the bumper through the opening. The entire length of the bumper must pass completely through the test fixture slot within 30 seconds of commencement of the test to achieve a passing result.

Note: If bumper ties or other localized means provided to secure the bumper to the crib interfere with the bumper sliding through the Bumper Thickness Test Fixture, ease the ties or fasteners through the fixture and then continue the test.



Note: Test fixture shall be fabricated from aluminum and have a smooth finish

FIG. X Bumper Thickness Test Fixture

X1. RATIONALE

X1.1 The intent of this requirement is to limit the maximum thickness of crib bumpers. The CPSC has stated that pillows in the infant's sleeping environment pose a potential suffocation hazard, and therefore bumpers that are "pillow –like" should also be regarded as potentially hazardous. Also, ASTM standards for maximum thickness exist for other padded items infants interact with such as play yard pads. The 2 inch opening of the Test Fixture limits the overall thickness of bumpers to a thickness that has not been known to present a hazard and allows for excessive fabric, fabric seams and bumper ties. The 5lb 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.

CONCLUSION

JPMA respectfully requests that the Commission commence rulemaking to establish a reasonable performance standard for crib bumpers that distinguish non hazardous traditional crib bumpers from hazardous pillow-like *"soft"* bedding.

Sincerely,

Michael Dwyer, CAE
Executive Director

Juvenile Products Manufacturers Association, Inc.
15000 Commerce Parkway, Suite C • Mt. Laurel, NJ 08054 • 856.638.0420 • 856.439.0525
E-mail: jpma@ahint.com • Website: www.jpma.org

Cited & Other References

Wanna-Nakamura, S. Letter to Frederick Locker. 2 Apr. 2004.

Medford, R. L. Letter to Bridget Reuter. 22 June 1999

Code of Federal Regulations Full-Size Baby Cribs and Non-Full Size Baby Cribs: Safety Standards, 2010 16 CFR 1219, sec. A.2 & G.4/ ASTM Standard Consumer Safety Specification for Full-Size Baby Cribs, F 1169-10, sec 5.8

Howell, J, Edwards, P (2010) *Staff's Draft Proposed Rules for Cribs. Full-Size and Non-Full-Size*. U.S. Consumer Product Safety Commission

Sala, J, Prange, M (2011) *Crib Bumpers and the Infant Sleep Environment: An Evaluation of the Scientific Evidence* Exponent Failure Analysis

Wanna-Nakamura, S (2010) White Paper – *Unsafe Sleep Settings Hazards Associated with the Infant Sleep Environment and Unsafe Practices Used by Caregivers: A CPSC Staff Perspective.* U.S. Consumer Product Safety Commission.

Naptime to Nighttime, (2011). [Brochure] JPMA

JUN 25 1999

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

June 22, 1999

Ms. Bridget Reuter
Assistant Director of Public Relations
JPMA
236 Route 38 West, Suite 100
Moorestown, New Jersey 08057

Dear Ms. Reuter:

I am responding to your request for clarification regarding our safety alert on soft bedding. In the alert, CPSC, the American Academy of Pediatrics and the National Institute for Child Health and Human Development provided recommendations on safety bedding practices when placing infants to sleep.

In your letter, you asked for clarification of CPSC's position on the use of crib sheets, mattress pads, crib top sheets, wedges and positioning devices intended to keep the baby on its back, and light weight blankets, including receiving blankets. These are clarified in the bullet points below.

- Caregivers should use crib sheets that are designed to fit the crib mattress. A bottom-fitted crib sheet should fit securely at each corner so that it does not become loose, even after several washings. If using a top sheet, caregivers should place their baby with feet at the foot of the crib and tuck the sheet around the crib mattress, reaching only as far as the baby's chest.

- If caregivers use a light-weight or receiving blanket, the baby should be placed with feet to foot of crib with the blanket tucked in tightly around the crib mattress, reaching only as far as the baby's chest.

- If a mattress pad is used, it should be thin and designed to fit the crib mattress securely at each corner so it does not become loose.

- Various devices have been developed either to maintain sleep position or to reduce the risk of rebreathing. Staff does not believe that available information supports either the safety or efficacy of these products.

CPSC's position on the use of bumper pads may also need clarification. Because pillows in the infant's sleeping environment pose a potential suffocation hazard for infants, bumper pads that are "pillow-like" should also be regarded as potentially hazardous and should not be used. CPSC staff observed a number of different bumper pads that fit the "pillow-like" definition. In addition, if bumper pads are used they should:

- be removed when the baby can pull up to the standing position so that the baby will not use them to climb out of the crib;
- fit around the entire crib and tie or snap into place, and;
- have straps or ties at least in each corner, in the middle of each long side, and on both the top and the bottom edges. Any excess length should be trimmed off after tying to prevent an infant from becoming entangled in the ties.

In a CPSC study of deaths diagnosed as SIDS, we found that about 30% of the infants who died were found with their noses and mouths completely covered by soft bedding. Based on 3,000 SIDS deaths, staff estimated that as many as 900 deaths were associated with suffocation from soft bedding. Additionally, a number of research studies have found certain types of soft bedding to be a risk factor for SIDS.

I hope this clarifies the issues raised in your letter.

Sincerely,

Ronald L. Medford

Ronald L. Medford
Assistant Executive Director
Hazard Identification and Reduction

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Mr. Frederick Locker
Locker, Greenberg & Brainin, P.C.
420 Fifth Avenue
New York, New York 10018

Dear Mr. Locker:

I have been asked to respond to your letter to Jacqueline Elder dated November 12, 2003 on the subject of suffocation and strangulation of infants with traditional infant bedding.*. You asked if we could review our data and advise you "if there are any suffocation or strangulation incidents directly related to the use of traditional crib bumper pads, infant blankets and stuffed toys in infant cribs (exclusive of SIDS diagnosis in cribs where such products may have been present)."

Following your inquiry, the Directorate for Epidemiology's Division of Hazard Analysis staff conducted a search of three databases maintained by CPSC: Injury and Potential Injury Incidents (IPII); In-Depth Investigations (INDP), and Death Certificates (DTHS)[1]. The searches retrieved a total of 94 infant death cases covering the period from 11/1/1995 to 12/31/2003. The deaths were attributed to suffocation/positional asphyxia and in one case strangulation. In most of the cases, the coroner/medical examiner/police reports listed bedding as a contributing factor in the infant's death.

CPSC's Health Sciences staff conducted a careful review of each of the above records and concluded that in 21 cases the association of bedding with the deaths appeared to be incidental and that other mitigating factors or products were more likely to have contributed to the deaths. In 38 cases, the available information was minimal and Health Sciences staff considered that no reliable conclusion could be drawn. In one case the medical examiner stated that the cause of death was due to hanging by a blanket, however the police detective stated that the victim lacked strangulation markings around the neck and no one had indicated that the blanket was found tightly wrapped around the victim's neck. In 34 of the cases the evidence of "death due to

*The views expressed in this letter are those of the CPSC staff, have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

[1] Codes and word searches used:
Bedding and bumper pads: 1537 bassinets and cradles, 1543 cribs, 1529 portable cribs, 1542 baby mattresses or pads, 1545 cribs not specified. Stuffed animals: 3004 toys not elsewhere classified, plus word searches using "stuff", "suffocation" and "asphyxia."

suffocation on bedding" was stronger. These incidents involved cribs and other sleeping surfaces. In 30 of these cases the sleep environment was cluttered with adult sized blankets, quilts, and pillows. In 3 cases the infants were found face down in "soft bedding" and in one incident the infant was found face down in "infant bedding."

While there are four cases in which infants were found face down on "soft bedding or "infant bedding" there is no additional data detailing what that bedding was. In the one report where the medical examiner concluded that the death was due to strangulation from a blanket, there are conflicting reports from the police. Although bumper pads and stuffed toys were mentioned as being in the crib in some of the other deaths, there was insufficient detail to conclude that these were the causative agents in the infants' deaths.

Sincerely,

Suad Wanna-Nakamura, Ph.D.
Physiologist
US CPSC/600-01
4340 East-West Highway
Bethesda MD 20814-4408

Tel. 301-504 7252
Fax 301-504 0079
e-mail snakamura@cpsc.gov

Naptime to Nighttime

Traditional infant products, when used properly, provide an infant with a safe environment in which to sleep. The Juvenile Products Manufacturers Association (JPMA) reminds you to follow these tips for safe infant sleep practices.

Infant Bedding Safety

- To reduce the risk of SIDS, pediatricians recommend healthy infants be placed on their backs to sleep, unless otherwise advised by your physician.
- ALWAYS use a crib sheet that fits securely on mattress and wraps around the mattress corners.
- Only a tight fitted sheet, mattress pad and/or waterproof pad should be used under the baby.
- When using bumper pads avoid those that are pillow-like. Bumper pads must fit properly in your crib and tie or snap securely into place. Bumper ties MUST NOT exceed nine inches. Make sure the bumper pad can be secured along the sides of the crib.
- Use bumper pads only until the child can pull up to a standing position. Then remove them so baby cannot use the pads to climb out of the crib.
- Many bumpers are now sold in four pieces. For each bumper segment, if all ties on that segment cannot be securely attached to the crib DO NOT USE the bumper segment.
- NEVER place infants to sleep on pillows, sofa cushions, adult beds, waterbeds, beanbags, or any other surface not specifically designed for infant sleep.
- Remove pillows, sheepskins, pillow-like stuffed toys and products not intended as infant bedding from the crib when infants are sleeping. NEVER place additional padding under an infant.
- Do not overdress your baby. Consider using a sleeper, wearable blanket or other sleep clothing as an alternative to any covering.
- For newborns, consider swaddling.
- Check periodically for loose threads or stitching which could cause gagging or choking.

JPMA

Crib Safety

- The safest place for a baby to sleep is in a fully functional, properly assembled, JPMA Certified crib. Before you use a crib, check to make sure the crib has not been recalled.
- You should never purchase or use second hand cribs handed down from friends or family members as they may not meet the most current safety standards.
- Drop side cribs are no longer available for purchase; however if you are using a previously purchased drop-side crib, parents should ensure the drop side or any other moving part operates smoothly. Remember to ALWAYS secure the moveable side when baby is in the crib.
- Make sure there are no missing, loose or broken parts or improperly installed screws, brackets or other hardware on the crib or the mattress support. Check the stability and hardware on the crib often. Do not substitute hardware. Only use hardware obtained directly from the manufacturer.
- Always use a properly fitting mattress as infants can suffocate in gaps between a poorly fitting mattress and the crib sides or ends.
- Never leave items not intended for the crib hanging on the corner posts or sides of the crib. Babies can pull those items into the crib or become entangled in them.
- When your child is able to pull to a standing position, set the mattress to the lowest position and remove bumper pads, large toys and other objects that could serve as steps for climbing out. It's time to move your child to a toddler bed when he or she begins to climb out or reaches a height of 35 in.
- Never place the crib near windows where cords from blinds or drapes may strangle a child.
- Mobiles should be removed from the crib when baby can push up on hands and knees or pull up to a standing position.
- If using a baby monitor with cords, make sure all cords are out of arm's reach of your child. Never place any item in or on the crib that has cords, strings, etc. as babies can become entangled and strangle in these items.
- Do not put a baby monitor in the crib, bassinet, or toddler bed.

These important safety messages are brought to you by the Juvenile Products Manufacturers Association (JPMA). For additional guidelines on the safe selection and use of sleep related and other juvenile products, visit www.cribsafety.org or www.jpma.org.

Exponent®

Crib Bumpers and the Infant Sleeping Environment: An Evaluation of the Scientific Evidence

Project No. 1100051.000

September 16, 2011

Prepared for:

Juvenile Products Manufacturers Association (JPMA)
15000 Commerce Parkway, Suite C
Mt. Laurel, NJ 08054

Prepared by:

Joseph B. Sala, Ph.D. and Michael T. Prange, Ph.D., P.E.

Exponent Failure Analysis Associates
3401 Market Street, Suite 300
Philadelphia, PA 19104

Executive Summary

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

However, in an earlier article, Deaths and Injuries Attributed to Crib Bumper Pads (Thach et al., 2007), the authors raised concerns as to the safety and appropriateness of crib bumper pads as part of an infant sleep environment. The authors conclude, "this case series provides evidence that the risks from crib bumper pads or padded bassinettes (death) outweigh the possible benefits provided by such padding (minor bruises and contusions)… We conclude that bumpers should not be placed in cribs or bassinets."

Thach et al. (2007) has often been cited by others as scientific evidence that crib bumpers pose a serious risk of fatality to sleeping infants. For example, a team of researchers (Yeh, et al., 2011) publishing on injuries associated with cribs offered no independent analysis of infant fatalities associated with crib bumpers, nor did they present a specific analysis related to the potential for crib bumpers to mitigate injuries. Yet, citing Thach et al. (2007), they recommended that "the use of crib bumper pads is strongly discouraged because the possibility for serious injury, including suffocation and strangulation, greatly outweighs any minor injury they may prevent."

The conclusions of Thach et al. (2007) about the suffocation hazards posed by crib bumper pads remain in contrast to the scientific findings of others. Re-analyses of the Thach et al. (2007) data is ongoing, and preliminary examination of currently available portions of their data set has raised concerns about the validity of their findings and conclusions. For example, methodological problems are apparent in the criteria used to select the incidents included for analysis and in the analytical treatment of other potential contributors. Furthermore, an attempt to recreate the "injury analysis" presented by Thach et al. (2007) highlighted similar methodological and analytical concerns. A more thorough analysis of the injuries that occur to infant children within the crib demonstrates that crib bumpers could serve to mitigate the injury potential (e.g., lacerations, fractures) across a variety of the common accident modes (e.g., contact with railings, extremities caught between railings).

Background Information

Scientific literature, research, and data related to hazards and unsafe practices associated with infant sleep environments have investigated the possible relationship between crib bumpers and infant fatalities. However, the majority of these accounts do not provide evidence that crib bumpers present a significant hazard or risk. For example, neither recent nor historic reviews of national injury and fatality data performed by the Consumer Product Safety Commission (CPSC) have identified crib bumpers as a unique or identifiable source of serious injury or death to sleeping infants (Scheers et al., 2003; Chowdury, 2010, 2009a, 2009b; Wanna-Nakamura, 2010). For example, Wanna-Nakamura (2010) reviewed four databases maintained by CPSC (Injury and Potential Injury Incidents – IPII, Death Certificates – DTHS, In-Depth Investigations – INDP, and National Electronic Injury Surveillance System – NEISS) covering the period from January 1, 1990 to May 6, 2010 for incidents that reference the possible involvement of a bumper pad. In more than 10 years of data, 28 records referencing "bumper" and "pad" were identified and subjected to a further detailed review. This analysis stated that in the majority of the reports of the instances, there was "minimal" information. However in the majority of cases where there was some information upon which a review could be performed, it was evident that "the most significant risk factor appeared to be the fact that infants were in the prone position." Additionally this review highlighted that other factors, such as the presence of soft bedding including cushions and pillows, could have contributed to the deaths. Finally, the paper noted that one fatality was associated with an atypical usage of the crib bumper around a toddler bed and did not occur in a crib.

More recently, a systematic review of publicly available databases as well as published and unpublished reports related to infant mortality during sleep and the sleep environment (Schwartz, et al., submitted) found no association between bumper pads and SIDS/infant deaths. The available evidence led the authors to conclude that the presence of bumper pads does not increase the risk of infant mortality. For example, the researchers searched literature databases for controlled epidemiological studies that could inform this issue, and identified a potential 144 articles, of which twelve met inclusion criteria for detailed review. The authors noted that all of the available controlled epidemiological research failed to mention or report any relationship between crib bumpers and infant mortality. Furthermore, the authors cited a UK research program that specifically considered bumper pads in its investigation of sudden unexpected deaths in infancy and noted that the original study found no relationship between crib bumpers and infant mortality, stating that "there was a higher use of bumper pads among the (living) control infants."

Despite the above, one study (Thach et al., 2007) purports that the use of crib bumpers is dangerous and advises against their use. Thach et al. (2007) reviewed fatality data for the years 1985 through 2005 for infants under the age of two that reference bumper pads (utilizing the same CPSC databases as those considered by Wanna-Nakamura) and noted "27 cases of infant death involving bumper pads or similarly padded bassinets (4 of the 27 cases)." Based on the information available within these records, the authors classified these incidents into three accident scenarios, reporting that 11 cases were caused by an infant's face being pressed against a bumper pad, 13 cases were due to an infant being wedged between a crib bumper and another object, and three cases had occurred subsequent to a tie from the bumper pad becoming wrapped around an infant's neck. Additionally, the article describes a review of crib-related injury data (based on the NEISS database) for infants six months of age and younger for the years 2000 – 2004, reporting 25 injury records. However, the authors discount seven of the incidents stating "[t]he seven reported cases of limb fractures or closed head injury were likely not caused by

accidents." In summary, the authors report to have identified "a number of fatal accidental infant deaths directly attributable to crib bumper pads," concluding "[t]his case series provides evidence that the risks from crib bumper pads or padded bassinettes (death) outweigh the possible benefits provided by such padding (minor bruises and contusions)" and "bumpers should not be placed in cribs or bassinets." The opinions reached by Thach et al. (2007) stand in contrast to the data and analyses offered elsewhere in the scientific literature.

Reanalysis of Thach et al. (2007) Data

In order to assess the apparent discrepancies observed within the scientific literature, we attempted to re-analyze the data referenced within the 2007 Thach et al. paper. However, the original data on which Thach et al. (2007) based their review was not available; Dr. Thach reported that he could not locate his original data set. We performed a search of the same data sources using the same search terms cited in the article and attempted to identify the same records. To this end, we were able to find 22 of the 24 fatality records reported by Thach et al. (2007) to be related to infants having their face into or being wedged between a bumper and another object. At the time of this reanalysis, we did not have access to all the complete incident records maintained by the CPSC on all the records in question, but rather utilized the available information, including data within the electronic databases, CPSC incident records when available, and the information provided within the original Thach et al. (2007) article. Additionally, we duplicated the search for crib-related injuries within the NEISS database described, but, as discussed below, were unable to match the records or replicate the findings reported.

Our reanalysis has highlighted a number of methodological concerns related to original Thach et al. (2007) work. With respect to the fatality incidents reported, our reanalysis questions the inclusion criteria and the interpretation given in concluding that these individual incidents were "directly attributable to crib bumpers." None of the 24 incidents referenced by Thach et al. (2007) has sufficient evidence to support such a conclusion. Indeed, based on the data available at the time of this reanalysis, 22 of the 24 records (92%) are either unrelated to the issues raised by Thach et al. (2007) or contain at least one other factor that could account for the fatality. As described in Table 1 below, eleven of the records (46% of the data relied upon) were associated with an unrelated product or accident mode; seven incidents did not involve cribs or modern crib bumper pads. For example, one case involved a child that fell out of a crib and died subsequent to becoming wedged between the outside of a crib and a dresser, one case involved a child that is believed to have rolled out of "day bed" and interacted with a bumper pad hung around the open ends of this bed, and two cases referenced "plastic" bumper pads (which are no longer manufactured or sold).

Re-Analysis of 24 Records Cited in Thach				
Unrelated Product/Accident Mode		**11**		**46%**
Not Crib/Crib Bumper		*7*		
Unrelated Accident Mode		*4*		
Confounding Factors		**11**		**46%**
Multiple Confounds		*6*		
	Other Items in Crib		*5*	
	Sick/Compromised Child		*2*	
	Crib/Mattress Problems		*2*	
	Prone Sleeping		*3*	
	Bumper Not Secured		*2*	
Single Confound		*5*		
	Other Items in Crib		*3*	
	Sick/Compromised Child		*2*	
No Detailed Information Available		**2**		**8%**
Total		**24**		**100%**

Table 1: Summary of fatality cases identified by Thach et al. 2007

Another eleven records have significant confounding factors. Confounding factors are conditions present in these cases that are unrelated to the crib bumper but could affect the outcome (death of the child). Over half of these 11 incidents have more than one confounding factor present. Therefore these confounding factors make conclusions regarding the causal role of the crib bumper unreliable. For example, the images below (Figure 1) taken from the in-depth investigation files where the presence of a crib bumper was mentioned, show a variety of other conditions in the environment that could affect the fatal outcome. Similar to the images below (Figure 1), eight of the eleven cases specifically reference objects being present in the crib that are known risks to the infant sleeping environment (e.g., blankets, pillows) while others reference highly atypical sleeping environments (e.g., crib with most its hardware missing and the substitution of a folded and wrapped blanket for a mattress). Four of the eleven incidents reference that the children involved had compromised respiratory health. Of the five records where only one confounding factor has been identified, four are cases in which the complete CPSC incident record

has not been made available for review and the only record available for the remaining case was a one-page death certificate. In general, the more details provided for the cases identified by Thach et al., the more tenuous any causal relationship between the crib bumper pad and the infant fatality appears.

The amount of information in the records for the remaining two incidents simply does not offer sufficient detail to support conclusive statements as to whether the crib bumper contributed to the incident. It should be noted that, based on the information available within the electronic database, a systematic review of sleep position could not be performed, but as observed by Wanna-Nakamura (2010) on a similar and partially overlapping set of data and from analysis of the available records received from the CPSC, a substantial number of the fatalities reviewed occurred to infants in a prone sleeping position.

Review of electronic database entries and the complete CPSC records available for the incidents referenced in the Thach et al. study provides additional details not included in the descriptions of the incidents provided in the published study. These additional details lead to questions regarding how the authors concluded a bumper pad was causal to the infant's death. For example, in one instance while an infant's face was described as being towards the bumper pad, information in the CPSC records described that the child was facing an area where an opening in the bumper pad existed, that the face was not covered by the bumper pad; the death was ruled SIDS. Other examples of details referenced in records but not provided in the narratives in Thach et al. include a child with a history of sleep apnea, a child's head being covered by a blanket, and a child being placed in an adult bed between two pillows and a bumper pad. Given the additional details available, it is unclear if or how this information was considered in the analysis by Thach et al. and why it was not included in the descriptions of the incidents. While we have yet to receive and review all the available information for the incidents underlying the original work of Thach et al., for those cases where we have been provided additional information, that information has lead to further questions regarding the inclusion criteria and conclusions presented.

Figure 1: Four images depicting the presence of objects in and condition of sleep environments associated with infant fatalities. Note: the pictures in the top row are taken from records #3 and #13 from Thach et al. 2007.

With respect to the Thach et al. (2007) review of non-fatal injuries associated with cribs, we were unable to replicate the set of records or the findings presented in their paper. While the article states that "[t]here were 25 non-fatal crib injuries in the database," our attempt to duplicate the same search returned 272 records. It is unknown what method the authors used to select the subset of 25 records presented within the article. Regardless, of these 25 reported records, the authors' analysis dismisses the injuries that they deem "serious," by suggesting that the injuries were actually intentional; "such cases would immediately raise a pediatrician's suspicion of intentional injury." The authors' suspicion of parental intent and reticence to accept the available narrative data related to injuries is in contradiction to their acceptance and reliance on the same form of data reviewed for fatalities. The data considered and the analysis provided by Thach et al. (2007) cannot address questions as to the range of crib-related injuries experienced by children and whether the presence of a crib bumper may be a means of injury prevention.

Potential Injury Mitigation by Bumper Pads

We performed a new analysis of crib-related injury data in the NEISS database to address questions raised by Thach et al. (2007) as to whether bumper pads may be expected to mitigate injuries occurring to children within the cribs and if so, what types of injuries might they potentially mitigate. We utilized the most current five years of emergency room reported injury data available (2005 – 2009). Similar to the Thach et al. (2007) inclusion criteria for the review of fatality data, injury data for children under the age of two years old were included in the analysis. Injury records associated with crib products (excluding play yards, bassinets, and rails) were read and coded as to whether the available information allowed one to determine whether the injury occurred inside or outside the crib. For all records where it could be determined that the injury occurred inside the crib, two independent coders determined the child-crib interaction by which the accident occurred (the "accident mode"). Notably, among the "accident modes" were instances in which an injury was subsequent to a child hitting the interior of the crib, a child falling and contacting the interior of the crib, or a child's limb being between the crib railings.

A total of 1790 records resulting in 46,724 estimated injuries related to crib products were found over this five year period. The majority (66%) of injuries occurred outside the crib, while 17% occurred while the child was inside (Figure 2 A). The accident mode analysis of the inside-the-crib injuries revealed that the most common accident modes were the child falling or hitting the inside of the crib surface (31%) and getting caught between the crib rails (12%, Figure 2 B). By far the most common body part injured in the fall/hit accident mode was the head (87%, Figure 3). The majority (74%) of those head injuries could likely be classified as superficial (e.g., contusions and abrasions), however, even these injuries were of sufficient severity that the child was taken and examined at an emergency room. Almost one fifth (18%) of the "hit" and "fall" head injuries were categorized as "internal" including diagnoses of closed head injury. Crib bumpers have the potential to prevent or mitigate (lessen) the injuries that occur by contacting the crib inner surfaces. The padded surface of the bumper can distribute the contact load and reduce the head accelerations during the impact therefore reducing the risk of both superficial and more serious head injuries. The potential for injury prevention or mitigation will depend on a number of factors including the location of the impact relative to the bumper, the severity of the impact, the age of the child, and the bumper size and padding characteristics.

Not surprisingly, the extremities (arms and legs) were the most common (92%) body parts injured in accidents where an infant was caught between the crib rails (Figure 4). A substantial number of fracture/dislocation injuries occurred to the arms (58%) and legs (34%) in this accident mode. A crib bumper could potentially prevent these injuries by acting as a barrier and not allowing the extremity to pass between the crib rails. The prevention of limb entrapment will depend on several factors including the location of the limb relative to the bumper, age and capabilities of the child, and the method and quality of the bumper installation.

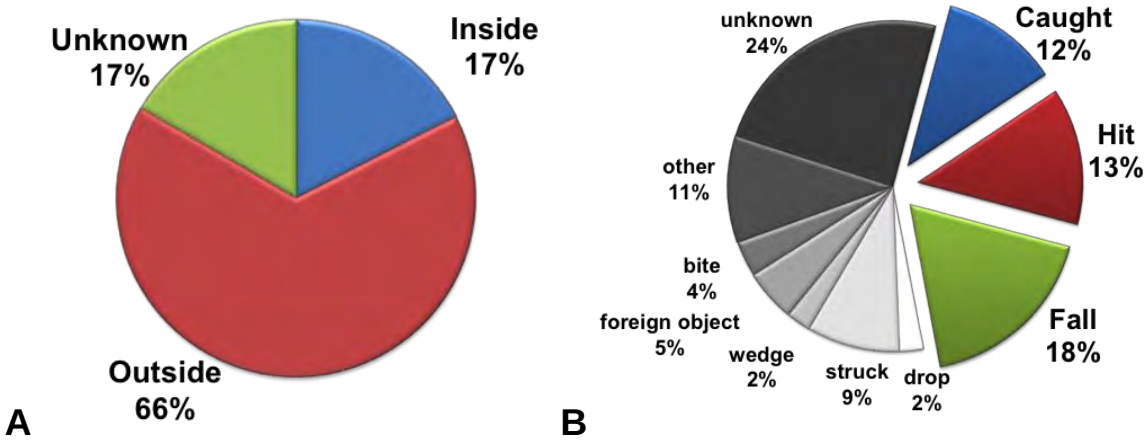


Figure 2: Distribution of crib-related injury based on (A) the location where the injury occurred, (B) mode of the accident where the injury occurred inside the crib

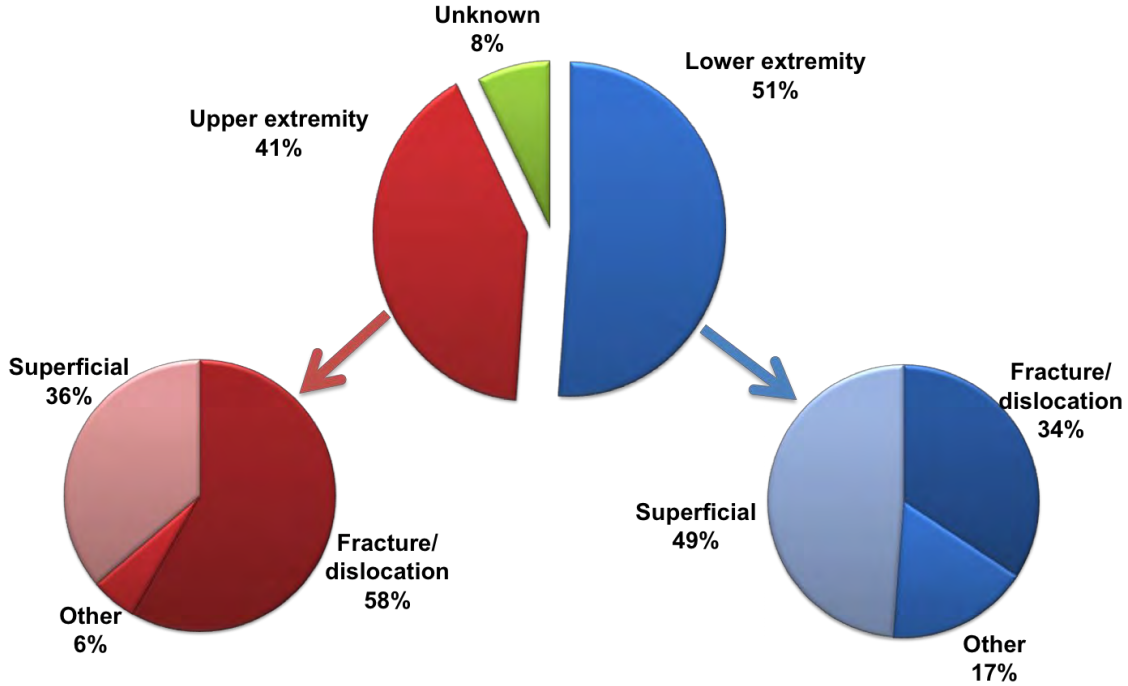


Figure 3: Distribution of the body region injuries and the types of head injuries in the "hit" and "fall" accident modes.

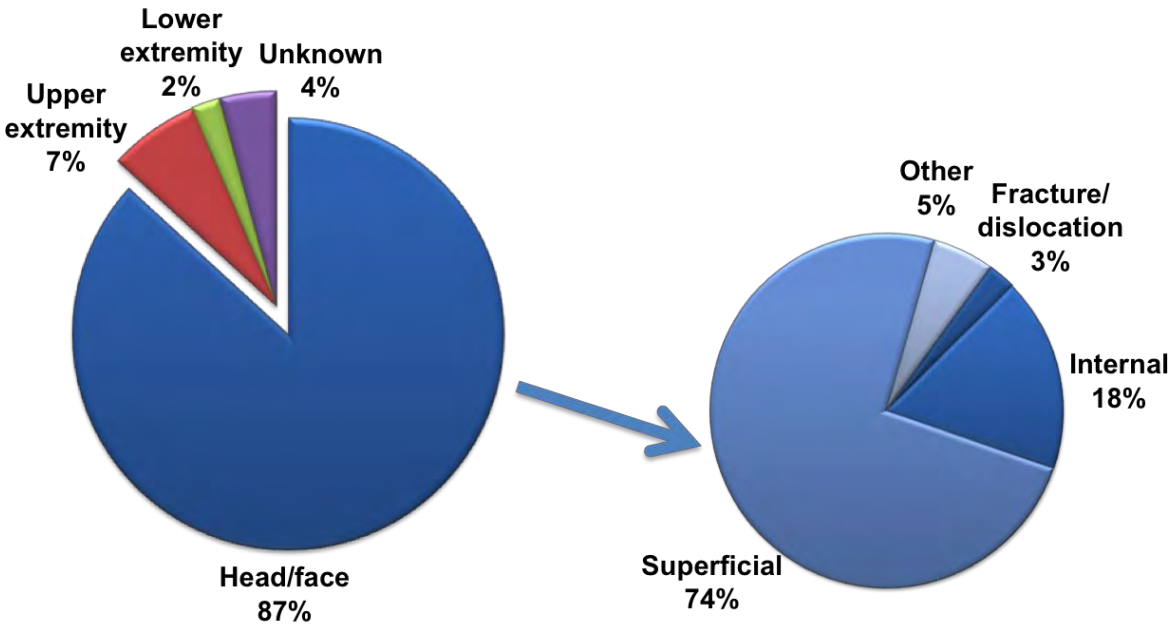


Figure 4: Distribution of the body region injuries and the type of extremity injuries in the "caught" accident mode.

Conclusions

Investigations into sleep environments of infants consistently fail to identify crib bumpers as a unique or separate source of serious injury or death to sleeping infants. Studies focusing efforts on evaluating sleep-related hazards generally, and crib bumpers explicitly, similarly do not find crib bumpers to be a significant risk. One article, by Thach et al. (2007), presents contrasting findings, concluding that crib bumper pads pose significant suffocation hazards. However, methodological problems related to both the selection of incidents for inclusion and the analytical treatment of these data raise concerns as to the validity of the ultimate conclusions. Indeed, our reanalysis of the same fatality data leads to conclusions consistent with the majority of research on this matter. Furthermore, our attempt to recreate the "injury analysis" presented by Thach et al. (2007) again found methodological and analytical concerns. A more thorough analysis of the injuries that occur to infant children within the crib demonstrates that crib bumpers could serve to mitigate injury (e.g., lacerations, fractures) across a variety of the common accident modes (e.g., contact with railings, extremities caught between railings).

References

Chowdhury, R. (2010) *Nursery product-related injuries and deaths among children under age five*. U.S. Consumer Product Safety Commission. November, 2010.

Chowdhury, R. (2009a) *Nursery product-related injuries and deaths among children under age five*. U.S. Consumer Product Safety Commission. February, 2009.

Chowdhury, R. (2009b) *Nursery product-related injuries and deaths among children under age five*. U.S. Consumer Product Safety Commission. November, 2009.

Scheers, NJ, Rutherford, GW, and Kemp, JS (2003) *Where Should Infants Sleep? A comparison of Risk for Suffocation of Infants Sleeping in Cribs, Adult Beds, and Other Sleeping Locations.* Pediatrics. 112:883-889.

Thach BT, Rutherford, GW, Harris, K (2007) *Deaths and Injuries Attributed to Crib Bumper Pads.* The Journal of Pediatrics. 151: 271-274.

Wanna-Nakamura, S (2010) *White Paper – Unsafe Sleep Settings Hazards Associated with the Infant Sleep Environment and Unsafe Practices Used by Caregivers: A CPSC Staff Perspective*. U.S. Consumer Product Safety Commission.

Yeh, ES, Rochette, LM, McKenzie, LB, Smith, GA (2011*) Injuries Associated with Cribs, Playpens, and Bassinets Among Young Children in the US, 1990 – 2008*. Pediatrics. 127: 479-486.

Professional Background

Joseph B. Sala is a Senior Managing Scientist at Exponent and a member of the Human Factors Practice. He routinely addresses how the capabilities and limitations of people interact with the products, equipment, and systems in their environment, and how this interaction affects safety. Dr. Sala frequently uses large-scale databases (e.g., National Electronic Injury Surveillance System, National Fire Incident Reporting System) to analyze the frequency and patterns of accidents, identify patterns of unsafe behaviors, and measure risk.

Dr. Sala has performed a number of investigations into how the particular developmental abilities of children affect safe usage of products. He has performed research on child behavior and capabilities an applied this to product development. He has reviewed accident data, complaint records, product designs, and cognitive and physical developmental attributes of children in order to perform hazard assessments on a variety of products.

Dr. Sala received a Bachelor's Degree in psychology from and performed Honors research in psychology at Rutgers University. He holds a Ph.D. in experimental psychology from Johns Hopkins University and conducted post-doctoral research at Stanford University, with a focus in cognitive neuroscience. He has published papers and presented at conferences related to human factors issues, including visual information processing, brain functioning, and risk communication. He is a member of the Human Factors and Ergonomics Society, the Association for Psychological Science, Society for Neuroscience, and the Society for Risk Analysis.

Michael T. Prange is a Managing Engineer in Exponent's Biomechanics practice. He addresses issues involving human injury biomechanics and occupant kinematics to assess the severity and mechanism of injury incurred during traumatic events. He has expertise in human injury biomechanics, specializing in head and neck injury tolerance and pediatric biomechanics. His work includes analysis of injuries occurring in transportation accidents; incidents involving consumer products; and accidental and inflicted injury scenarios.

Pediatric injury biomechanics is a focus of his consulting practice and research. He has over a decade of experience addressing questions involving the unique aspects of pediatric biomechanics and injuries. He has investigated the injury mechanisms and kinematics of children during automotive transportation (vehicle seatbelts, child safety restraints, airbags), accidental falls, and child abuse. His research experience includes studies of pediatric traumatic brain injury, structural and failure properties of the pediatric neck and spine, child restraint systems, biomechanics of shaken baby syndrome and household falls, biological material testing of the mechanical properties of tissue, helmet protection, and computational models of injury prediction. He also has unique experience in the determination of pediatric head and neck structural properties and injury tolerances using pediatric cadaveric specimens.

He obtained his Ph.D. and M.S.E degrees in bioengineering from the University of Pennsylvania. He also holds a B.S. with honors in biological engineering from North Carolina State University. He is a member and past organizer for the Society of Automotive Engineers. He is a licensed Professional Engineering in the state of Pennsylvania.