



## **White Paper - Unsafe Sleep Settings**

### **Hazards Associated with the Infant Sleep Environment and Unsafe Practices Used by Caregivers: A CPSC Staff Perspective.**



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

## **I. Use of Non-Traditional Bedding in the Infant Sleep Environment**

According to recent U.S. Consumer Product Safety Commission (CPSC) staff annual reports entitled *Nursery Product-Related Injuries and Deaths Among Children Under the Age of Five* (2008-2009), extra bedding, such as pillows and comforters, accounted for the majority of infant deaths in cribs and other sleep product settings (Chowdhury, 2008 and 2009).

In cribs, the majority of deaths were attributed to positional asphyxia and suffocation due to a crowded sleep area in which adult size pillows and multiple types of bedding were used. The remaining suffocation deaths were due to: 1) compromised integrity of the crib, including the use of old cribs with missing or broken components, and introduction of new hazards as a result of attempted home repairs, and 2) the presence of hazardous conditions around the crib, including but not limited to strangulation hazards with window cords and electric wires, baby monitor cords, humidifier cords, and pacifier ribbons (Chowdhury, 2008 and 2009).

The vast majority of infant deaths in play yards were also attributed to positional asphyxia and suffocation due to a crowded sleep area. The use of extra mattresses, adult size pillows and/or quilts placed under the infant, in combination with prone (on the stomach) sleeping position, accounted for these deaths. Most of the remaining deaths were strangulations due to the presence of hazardous conditions (like those mentioned above, for cribs) around the play yard. In bassinets and cradles, the presence of extra bedding and “non-traditional” infant bedding such as adult size pillows placed in these products accounted for the majority of the infant deaths (Chowdhury, 2008 and 2009).

Health Sciences staff analysis of the death data associated with bedding for cribs, bassinets and play yards showed that most of the deaths involved infants who were placed to sleep in the prone position.

### **Pillows and Extra Bedding**

The rate of Sudden Infant Death Syndrome (SIDS) deaths in the United States has decreased dramatically since 1992 (Mitchell, 2007). This decrease has been largely attributed to the effectiveness of the American Academy of Pediatrics (AAP) “Back to Sleep” campaign. Despite the proven effectiveness of the campaign’s recommendation to place infants to sleep on their backs in order to reduce the incidence of SIDS, there remain a significant number of caregivers who continue to place infants to sleep in the prone position. In addition, CPSC continues to receive anecdotal reports of suffocation deaths in its various CPSC databases: Injury and Potential Injury Incidents (IPII)<sup>1</sup>, Death Certificates (DTHS)<sup>2</sup>, and In-Depth Investigations (INDP)<sup>3</sup>. The information contained in all of these databases is anecdotal.

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<sup>1</sup> The IPII file contains data on consumer product-related incidents extracted from consumer complaints, as reported to 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.

<sup>2</sup> The DTHS file includes information from death certificates purchased by CPSC from all 50 states and the District of Columbia.

CPSC staff has reports of 531 infant deaths associated with pillows or cushions from January 1992 through May 2008; an average of about 35 deaths per year of infants under one year of age (Wanna-Nakamura, 2008). In the vast majority of the deaths, the infants were placed to sleep in the prone position. Half the incidents involved infants placed to sleep on top of a pillow or cushion. It is possible that caregivers placed these products under the baby to make the surface softer and more comfortable for the baby. The other half of the incidents were deaths due to suffocation and positional asphyxia in a crowded sleeping setting where pillows, other bedding material, and clutter were found. It appears that caregivers, who place their infants to sleep in a prone position that exacerbates the infant's risk of suffocation, are also using pillows and other unsafe sleep arrangements. The majority of the infants who died were under four months of age. Among pillow-related deaths where the location was reported, about a quarter occurred in infant cribs, bassinets, cradles, and play yards. The rest occurred outside the infant sleep area, such as on adult beds or sofas, or on the floor.

## **II. Use of Traditional Infant Bedding in Infant Sleep Environment**

### **Bumper pads**

CPSC staff conducted a search of four databases maintained by CPSC: IPII, DTHS, INDP, and NEISS<sup>4</sup> covering the period from January 1, 1990 to May 6, 2010. The search covered the following product codes: 1542 (baby mattresses or pads), 1543 (cribs), 1545 (cribs not specified), and 1529 (portable cribs). The search also included “bumper” AND “pad” in the narrative text.

The search retrieved a total of 52 infant deaths where bumper pads were mentioned in the narrative. A preliminary review excluded 24 deaths that were diagnosed by the medical examiner as SIDS, or entrapments due to structural failure of the crib. The remaining 28 deaths were attributed to suffocation/positional asphyxia and strangulation, and these involved victims ranging in age from 1- 21 months. In most of the cases, the coroner/medical examiner/police reports listed bedding, such as pillows, cushions, and/or quilts, as contributing factors in the infants' deaths.

CPSC staff conducted a careful review of each of the 28 records and found that the available information was minimal in 18 of the 28 incidents. In the majority of the cases where there was some information available: 1) the most significant risk factor appeared to be the fact that infants were in the prone position, and 2) other mitigating factors, particularly the presence of pillows and cushions, could have contributed to the deaths.

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<sup>3</sup> The INDP file contains data from follow-up investigations reported (“conducted” instead of “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.

<sup>4</sup> 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 U.S. 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.

Examples of scenario descriptions which include other confounding or contributing factors are:

- *“lying prone in a crib with a full size pillow and bumper pad”*
- *“there was a pillow blankets and bumper around the inside of the crib”*
- *“found wedged between pillow and bumper pad”*
- *“head caught between blanket and bumper pad”*
- *“deceased against bumper pad with his face down in mattress”*
- *“found wedged between bumper pad and mattress”*
- *“wedged between adult pillow and bumper pad”*
- *“wedged between bumper pad and pillow”*
- *“pinned between sibling and bumper pad”*
- *“sleeping on cushions bumper pads and crib mattress”*
- *“waterbed mattress crib mattress as well as stuffed toys and loose blankets”*
- *“wedged between a pillow and a bumper pad”*
- *“placed on top of a sofa cushion numerous other items and pillow were in the crib”*
- *“face down in pliable mattress forehead against bumper pad”*
- *“found on the back in crib there was a pillow blankets and bumper pads”*
- *“face down between blanket and bumper pad”*
- *“flipped off nursing pillow and found between blanket and bumper pad”*
- *“Accident (head compressed against crib bumper with arm wedged between the crib and mattress) per Medical Examiner”*
- *“There were several other items in the crib that may have contributed to the incident” (these included an adult pillow, small baby pillow, baby blanket, stuffed toy, multiple baby clothes and an apparent used diaper”)*
- *“Bilateral retinal hemorrhage, suspected hypoxic-ischemic encephalopathy due to positional and/or mechanical asphyxia and possible shaken baby syndrome” per medical examiner*

In ten incidents, no other contributing factor, other than prone sleep position, was mentioned. The limited scenarios were reported as:

- *“face obstructed by bumper pad”*
- *“found on the back face against bumper pad”*
- *“face pressed against bumper pad”*
- *“suffocated in corner against bumper pad”*
- *“face against plastic bumper”*
- *“on his stomach with his arms up and his face into the soft padding surrounding the inside of the crib”*

In one incident, which atypically involved an older victim (21 months), the child was found in a convertible crib set in the toddler bed configuration. The bumper pads were being used inappropriately in this toddler bed. The parent stated

- *“the toddler rails were up and the bumper pad tied tight so he will not fall, he went ahead and fell out”*

In this incident, the child’s body passed through the opening between the side of the toddler bed and the rail and his neck was caught in the bumper pad.

### **III. Specialized Infant Sleep Products**

Since the identification of prone (stomach) sleeping as a high risk factor for SIDS and the launch of the "Back to Sleep" campaign, there has been a proliferation of new infant sleep and sleep-related products on the market.

One category of products is sleep positioning products used to keep infants on their backs during sleep. These products are composed of a base mat and a pair of lateral support blocks (bolsters) intended to restrain the infant during sleep. There are no current studies that show the effectiveness of such products in reducing the risk of SIDS. The products appear to be intended to restrain the infant in the position in which he/she is placed. This category of product appears to serve no useful purpose.

The second group of products is wedges or products with an incline, some of which are equipped with a harness restraint and some which may have a set of lateral bolsters. These products are marketed (or labeled) to as helping reduce acid reflux and colic in infants.

CPSC staff is aware of nine deaths associated with inclined positioning devices (six deaths) and flat mat positioning products (three deaths). The deaths occurred between the period of January 1, 1997 and August 20, 2009. One fatality was associated with what seemed to be a positioning wedge equipped with a restraint and intended for an infant with acid reflux. In this incident, the infant slid off the restraint and was found dead lying along the crib railing. The cause of death as stated by the medical examiner was “positional asphyxia with history of bi-pulmonary dysplasia.” The eight remaining deaths were associated with sleep positioning products. It appears that in four of these deaths the infants were placed on their sides, two were placed on their stomachs, within the product, and in two the position was not reported.”

Two of the nine deaths occurred outside the product. The infants were found wedged in the space between the product and a component of the crib and/or other bedding product. In one incident it was reported that the infant slipped off the restraint and was found lying face down along the crib railing and in the second incident the infant was found face down on a pillow wedged between the product and the side of the bassinets.

CPSC staff has significant concerns about both types of infant positioning devices, inclined wedges and positioning devices equipped with a flat mat. While it would seem unlikely that a parent or a caregiver who is aware of the intent of the product would place an infant on it in the prone position, foreseeable misuse (placing infants on their stomachs) contrary to instructions this scenario continues to occur. In addition placement of infants (on the side) in these products can be fatal yet some instructions indicate it is acceptable to do so if side sleeping is “recommended” presumably by a physician or health care provider.

Although the intended function of these products is to keep an infant in a supine (on the back) position, and the products are likely purchased for this reason, CPSC data shows that some parents and caregivers have placed infants to sleep on their stomachs in these products with fatal outcomes. Staff is also concerned with the use of infant positioning devices to maintain an infant on its side. This is an unstable position as infants placed on their sides are more likely to flip into a prone position rather than onto their backs because their backs are pressed against the bolster side of the sleep positioning product. Finally, infants placed in the proper position (on their backs) who are developmentally capable of scooting upward or downward or who are capable of flipping off the product are at risk of becoming entrapped between the product and the component of the sleep product they are in (cribs, play yards,... or bassinets.)

#### **References:**

1. Chowdhury, R. 2009. *Nursery product-related injuries and deaths among children under age five*. <http://www.cpsc.gov/LIBRARY/nursery08.pdf> and
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3. Wanna-Nakamura, S. 2009. *Exemption from Classification as Banned Hazardous Substance; Exemption for Boston Billow Nursing Pillow and Substantially Similar Nursing Pillows, Final Rule*. Federal Register, December 19, 2008, Vol. 73, No. 245 , p. 77494 and at <http://www.cpsc.gov/businfo/frnotices/fr09/bostonbillows.pdf>
4. Mitchell EA, Hutchison L, Stewart AW (July 2007). "The continuing decline in SIDS mortality". *Arch Dis Child*. 92 (7): 625–6.