

FOR PUBLICATION IN THE MARYLAND REGISTER:

Department of Health & Mental Hygiene Request for Comment on Proposal to Prohibit Sale of Baby Bumper Pads

The Department of Health and Mental Hygiene (“the Department”), pursuant to § 22-501 *et seq.* of the Health-General Article of the Maryland Code, requests comment by November 4, 2011, on a proposal to prohibit the sale of bumper pads in Maryland for use in infant cribs. On April 8, 2011, the Department requested initial public comment on the use of bumper pads in infant cribs. The Secretary of Health and Mental Hygiene then convened a panel of health professionals to review the comments submitted and other available evidence. As more fully discussed below, three out of four members of the panel recommended that the Secretary impose a ban on the sale of bumper pads for use in infant cribs, and the fourth stated such a proposal, if considered, should be first put forward for public input. A proposal consistent with the panel’s recommendation is set forth below. After review of all additional comments, the Secretary will determine whether to propose regulations, pursuant to § 10-101 of the State Government Article, prohibiting the sale of bumper pads for use in infant cribs beginning January 1, 2013.

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1. Background

In Maryland each year, approximately 50 infants die from Sudden Infant Death Syndrome, Sudden Unexplained Death of Infancy, or accidental suffocation and strangulation, all of which may be associated with unsafe sleep arrangements.¹ These

¹ Data provided by the Vital Statistics Administration, Maryland Department of Health and Mental Hygiene.

deaths are considered potentially preventable. Reducing sleep-associated deaths is an important component of efforts to reduce infant mortality.²

Bumper pads are pieces of cushioned lining designed to be attached to the inner portions of the sides of an infant's crib from birth until the infant begins to pull to stand (approximately six to nine months of age).

In recent years, some pediatric experts and health agencies have expressed concern that the use of bumper pads for infants is an unsafe sleep practice.³ This concern has been based in part on evidence, discussed below, that bumper pads have been a causal factor in fatal asphyxiation in infants in Maryland and elsewhere in the United States and Canada. Manufacturers of crib bumper pads maintain the products are safe and beneficial.⁴

Because bumper pads are not subject to premarket approval, there has been no review by a public health or regulatory agency finding that the products' benefits exceed their risks.

The ties on crib bumpers are subject to an ASTM voluntary standard for all infant bedding materials. Because the "neck circumference of a 5th percentile 0-3 month old infant is 7.2 in.," ASTM has issued a general standard stating that "flexible ribbons, strings, or ties...shall not exceed 7 in." ASTM has allowed an exception to this general standard for ties on crib bumper pads, stating that crib bumper pads may have ties as long as 9 in., because shorter lengths "may not allow the parent or care provider to be able to sufficiently secure the bumper guard or headboard bumper guard, or both to the crib rail."⁵

Other voluntary standards are under development, but not in effect. Standards under consideration include the warnings: "To prevent suffocation, keep top of bumper up and in position. DO NOT allow bumper to sag down or in toward the sleeping surface"; "To prevent strangulation, position ties to outside of crib and be sure they are secure. DO NOT use this bumper if all ties cannot be securely attached to the crib;" and "To prevent injury from falls from climbing out, remove bumper when child can sit up unaided or can pull to a standing position."⁶

² Maryland Department of Health and Mental Hygiene. Plan for Reducing Infant Mortality in Maryland. March 2011. Online at www.statestat.maryland.gov/gdu/14infantmortalitydeliveryplan.pdf (Accessed Aug. 29, 2011).

³ See, e.g. Thach, BT et al. Deaths and Injuries Attributed to Infant Crib Bumper Pads. *J Pediatr* 2007, 151(3): 271-274. Moon RY. "And Things that Go bump in the Night": Nothing to Fear? *J Pediatr* 2007; 151(3):237-238. 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 Aug. 29, 2011).

⁴ L. Pfeiffer, Juvenile Products Manufacturers Association, letter to Dr. Joshua M. Sharfstein, Maryland Department of Health and Mental Hygiene. 28 July 2011.

⁵ ASTM. Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories F1917-08. 1 August 2008.

⁶ Current items pending ballot for revision to the ASTM Bedding Standard. Provided by Juvenile Products Manufacturers Association to Maryland Department of Health and Mental Hygiene (Aug. 2011).

The federal Consumer Product Safety Commission is reviewing the safety of crib bumper pads.⁷ In April 2011, the Maryland Department of Health and Mental Hygiene initiated a review of these products.

2. Process

There have been three stages to Maryland's review of crib bumper pads.

Public Comment. On April 8, 2011, the Maryland Department of Health and Mental Hygiene (the Department), pursuant to § 22-501 *et seq.* of the Health-General Article of the Maryland Code, requested comments concerning the use of bumper pads in infant cribs. The announcement was published in the Maryland Register on April 22, 2011. (Appendix 1) The comment period closed on May 9, 2011.

The Department received 9 comments, including responses from family members of an infant; medical professionals in the field of pediatrics; a neonatal nurse practitioner; the local chapter of the national pediatric professional organization; a national organization representing manufacturers of infant and child products; a researcher with expertise in the field of sudden infant death; and injury professional. (Summary in Appendix 2)

First Advisory Panel. The Secretary appointed a panel to advise the Department on what action, if any, is warranted regarding the use of bumper pads in infant cribs. Panel members included Dr. Peter Beilenson, Howard County Health Officer; Dr. Tina Cheng, Professor of Pediatrics and Public Health, Johns Hopkins School of Medicine; Dr. Joseph Wiley, Chairman of Pediatrics, Children's Hospital at Sinai; and Dr. Gaurov Dayal, Chief Medical Officer, Adventist HealthCare. None of the panel members reported conflicts of interest.

Notice of the public meeting and the panel resources, including all comments received, were published on the Department's website. The panel met on May 20, 2011 for approximately 90 minutes. The panel was asked to review the evidence and comment on a set of questions. (Appendix 3)

Second Advisory Panel. Following the first advisory panel meeting, the Juvenile Products Manufacturers Association requested an opportunity to provide data and analysis. This request was granted. The panel met a second time on July 13, 2011 for approximately 90 minutes, with several speakers supported by the Association providing a 30-minute presentation and answering questions. The Association speakers included: Frederick Locker, General Counsel; Lauren Pfeiffer, Assistant Executive Director; Joseph B. Sala, Ph.D. Senior Managing Scientist, Human Factors Exponent; Michael T. Prange, Ph.D., P.E., Managing Engineer, Biomechanics Exponent; and Robert Enten, Gordon Feinblatt, LLC. Joining the advisory panel for discussions at this meeting was the Assistant Chief Medical Examiner Dr. Patricia Aronica-Pollack.

⁷ Gabler E. Hidden Hazard of Crib Bumpers. Chicago Tribune. 12 December 2010.

3. Analysis

Maryland's analysis of crib bumper pads has focused on the potential risks and potential benefits of these products and on whether any risks associated with the use of crib bumper pads could be mitigated adequately by proper labeling or by the issuance of a warning by the Department.

There were no published studies or other data available to directly compare risks versus benefits of crib bumpers. The Department considered the evidence on risks and benefits separately.

Risks. The primary risk under consideration is the risk of asphyxiation and death. The potential mechanisms for this risk include direct contact of the bumper with the face of the infant, obstructing air flow, and strangulation from the straps or ties to the bumper. It is the view of Dr. David Fowler, Chief Medical Examiner of Maryland, that these mechanisms pose a risk of injury or death to a young infant. In a letter dated May 16, 2011, attached as Appendix 4, Dr. Fowler wrote:

An infant does not need to have their nose and mouth covered to asphyxiate. Simply being close to an object such as a stuffed toy or a bumper may slow the air movement and lead to a slow refresh rate of essential oxygen. Humans need a minimum of 16% of oxygen in the air that they breathe to survive. Air usually has 21% oxygen and this provides a relatively small margin of safety. If the air is restricted from movement, there is a real risk the infant can reduce the oxygen content to below 16% since the air movement caused by their breathing is negligible.⁸

Evidence of this harm comes from autopsy reports. In Maryland, the Office of the Chief Medical Examiner has identified one infant fatality in which the bumper contributed and nine in which a bumper was present and the death likely was caused by asphyxia. Three main additional data sources were reviewed:

- A 2007 study by Bradley T. Thach and colleagues, published in the *Journal of Pediatrics*, reviewing 20 years of data from the Consumer Product Safety Commission and finding 27 deaths attributed by medical examiners or coroners to bumper pads.⁹

⁸ Fowler D, Office of the Chief Medical Examiner. Letter to Dr. Joshua M. Sharfstein, Maryland Department of Health and Mental Hygiene. 16 May 2011.

⁹ Thach, BT et al. Deaths and Injuries Attributed to Infant Crib Bumper Pads. *J Pediatr* 2007, 151(3): 271-274.

- A 2004 review by Health Canada finding 23 reports of injuries related to crib bumpers, including one strangulation death, one suffocation death, and three near-suffocation occurrences.¹⁰
- A July 2010 white paper from the Consumer Product Safety Commission. The Commission reviewed its databases and found 28 deaths involving bumper pads. The Commission noted, “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.” The Commission identified 10 incidents, involving bumper pads, in which “no other contributing factor, other than prone sleep position, was mentioned.” These included: “face obstructed by bumper pad,” “found on the back face against bumper pad,” “face pressed against bumper pad,” “suffocated in the corner against bumper pad,” “face against plastic bumper,” and “on his stomach with arms up and his face into the soft padding surrounding the inside of the crib.”¹¹

After reviewing the available evidence, the advisory panel found that infant bumper pads posed a rare, real risk to infants. Dr. Beilenson summarized: “We have a consensus that there is a risk of death to infants from using crib bumpers, and further research should be done on substantial or how much, but there is a risk of death.”¹²

The Juvenile Product Manufacturers Association responded with a study reviewing the cases in the paper by Dr. Thach and colleagues. The analysis found that eight of the deaths were unrelated to traditional bumper pads, four had too little information to review, and 12 had “confounding factors,” meaning that there were other potential dangers in the cribs, such as blankets or pillows. In two cases, the analysis cited “sick/compromised child” as a confounding factor.¹³

At the second advisory panel meeting, the experts discussed whether this analysis exonerated the potential causative role of bumper pads. They noted that the cause of an infant death in a crib can be multifactorial. Dr. Pollack stated:

There are many contributors. One of them is the crib bumper. You’re going to have a child who goes prone and goes up against the crib bumper. Children can roll and they can roll up against the crib bumper and they become prone.

¹⁰ 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 Aug. 29, 2011).

¹¹ Consumer Product Safety Commission. White Paper - Unsafe Sleep Settings Hazards Associated with the Infant Sleep Environment and Unsafe Practices Used by Caregivers: A CPSC Staff Perspective. July 2010.

¹² Transcript of Crib Bumpers Advisory Meeting, 20 May 2011, p. 69.

¹³ Juvenile Products Manufacturers Association. Crib Bumpers and the Infant Sleeping Environment: An Evaluation of the Scientific Evidence. June 2011. Online at <http://www.dhnh.state.md.us/news/crib/pdf/JPMA-Summary>. (Accessed Aug. 29, 2011).

Sometimes they're placed on their bellies and sometimes they can roll and not get back over. So you're going to have now a prone child. So when you now say, well, these are all prone, we have to throw those out because they're prone. I don't know how you can do that. These are multifactorial cases and I don't know how you can now say, well, you can't just blame a crib bumper because you also have a prone child and throw out cases.¹⁴

At the second meeting, Dr. Dayal and Dr. Wiley reiterated their judgment of a rare but concerning risk of death from crib bumpers. Neither Dr. Cheng nor Dr. Beilenson expressed a change in their views of the evidence.

A secondary risk discussed at the second advisory panel meeting is the risk of an infant climbing up on top of the bumper and falling from the crib. There was no data on this potential risk presented.

Benefits. The primary benefit under consideration was the potential for reduction of trauma to babies from the hard sides of a crib. The Juvenile Product Manufacturers Association presented data to the committee that there have been approximately 46,000 reports of crib-related injuries, of which 17% occurred inside the crib.¹⁴

At the second advisory panel meeting, the Association's speakers acknowledged that these data contained significant limitations. For example, the data did not distinguish between children in cribs with bumper pads and children who were not.

The advisory panel also questioned the viability of a mechanism of significant head injury for an infant in a crib without a bumper pad, given that babies are unlikely to generate significant force for a head injury while lying down. Dr. Sala, speaking for the Juvenile Products Manufacturers Association, agreed that a significant head injury was highly unlikely.¹⁵

The absence of confirmed cases or data points on benefits was noted by both the advisory panel and the Association's speakers. As an attorney for the Juvenile Product Manufacturers Association Robert Enten said: "There are no studies of what happens to an infant when he's put in a crib that doesn't have a bumper pad."¹⁶

The expert panel concluded in its first meeting and reaffirmed at the second that there was no evidence for meaningful benefits of bumper pads to infants. Dr. Beilenson stated: "I see no way, no health benefit from any of the research that I've read."¹⁷ In Dr. Dayal's view, "the benefits are questionable at best."¹⁸ Dr. Cheng stated, "There isn't strong

¹⁴ Transcript of Crib Bumpers Advisory Meeting 13 July 2011, p. 72.

¹⁵ Transcript, 13 July 2011, p. 59.

¹⁶ Transcript, 13 July 2011, p. 48.

¹⁷ Transcript, 20 May 2011, p. 33.

¹⁸ Transcript, 20 May 2011, p. 26.

evidence to support finding that the use of crib bumpers provides any benefits to infants.”¹⁹ And Dr. Wiley noted that even if there might be some benefits, it is unlikely they could outweigh the risks. He stated:

... when you read all of this literature, all of the comments, nowhere does it ever suggest that an unprotected crib, in other words, a crib without bumpers, ever results in an injury severe enough to cause death.²⁰

4. Additional Policy Considerations

Context. The advisory panel raised the importance of considering the issue of crib bumpers in the context of overall safe sleep efforts. In their view, the message of “do not use bumpers” should be embedded in an overall safe sleep message, in which families are advised that babies sleep best “alone, on their back and in a crib.”

Unintended Consequences. The Juvenile Products Manufacturers Association suggested that a ban on crib bumpers could encourage unsafe sleep practices and put babies at risk, by leading to more co-sleeping or more hazardous sleep environments. In a letter to the Department dated July 28, the Association wrote, “... we are concerned that any regulations that eliminate safe useful products specifically designed for infant use will result in alternative makeshift hazardous product use. This in turn will result in severe harm to our most vulnerable citizens.”²⁰

This concern was discussed at length by the advisory panel. Three members recommended addressing this risk by providing education to parents and a phased in approach to regulatory action. At the second meeting, Dr. Dayal stated:

Unintended consequences can go both ways. You could also – I could just as well argue the fact that we’re putting bumpers in leads you to believe ... putting things into [cribs] is a safe thing to do. And by not having bumpers, you can reinforce the message that nothing should be placed [in the crib].²¹

Labeling. The advisory panel considered and decided against the idea of adding warning labels to bumper pads advising of a potential risk of death. Panel members stated that this could send a “mixed message” to parents about why the product was still on the shelves. In addition, the panel members did not find that labeling would mitigate the risk. Dr. Wiley stated, “... even if it’s done right, I’m not convinced by what I have read that that mitigates the risk. So I don’t think a label personally changes that risk.”²² The In its comments, the Center for Injury Research and Policy at the Johns Hopkins School of

¹⁹ Transcript, 20 May 2011, p. 28.

²⁰ L. Pfeiffer, Juvenile Products Manufacturers Association, letter to Dr. Joshua M. Sharfstein, Maryland Department of Health and Mental Hygiene. 28 July 2011.

²¹ Transcript, 13 July 2011, p. 83.

²² Transcript, 20 May 2011, p. 43-44.

Public Health also expressed the view that labeling was not a solution to the risk in crib bumper pads.²³

5. Assessment

The Department appreciates the input and participation of many interested members of the public and industry in its inquiry into crib bumper pads.

After reviewing the comments, documents, and the transcripts of the advisory panel meetings, the Department recognizes that there is a paucity of data about the benefits and risks associated with the use of bumper pads in infant cribs. A small potential risk in a setting such as this is very challenging to study, especially given the wide variety of confounding factors.

Our task is to assess the available data and decide whether a policy change is justified. Based on the data available, the Department finds that the risk of death from crib bumper pads, while small, is real. As expressed by Maryland's Chief Medical Examiner, there is a viable mechanism of concern. In addition, there are multiple credible reports of crib deaths where bumper pads were documented to be in use and the autopsy findings were consistent with asphyxiation.

The Department finds that this risk is not offset by any compelling mechanism or evidence for significant benefit to infants of bumper pads. This too was the conclusion of all four experts who reviewed available data, heard the industry's presentation, and advised the Department.

As a result, the Department discourages the use of crib bumper pads for infants in Maryland. This assessment and recommendation is supported by all four members of the Department's expert advisory panel, by the Maryland Chapter of the American Academy of Pediatrics, and by the Center for Injury Research and Policy at the Johns Hopkins School of Public Health.^{24 25}

The Department also concurs with the panel on the three policy considerations: 1) crib bumpers should be considered as part of the overall safe sleep campaign; 2) an appropriate and extended education campaign can counter potential unintended consequences of a ban, and 3) labeling is not a solution for products for which the risks exceed the benefits when used as intended.

²³ Gielen A, Johns Hopkins Center for Injury Research and Policy, Comment on Crib Bumpers, 9 May 2011.

²⁴ Levy E, Maryland Chapter of American Academy of Pediatrics, Comment on Crib Bumpers, 9 May 2011.

²⁵ Gielen A, Johns Hopkins Center for Injury Research and Policy, Comment on Crib Bumpers, 9 May 2011.

Turning to the question of regulatory action, the Juvenile Products Manufacturers Association expressed its strong opposition to a ban on the sale of crib bumper pads. In its letter of July 28, the Association compared the idea of banning the sale of crib bumper pads to banning the sale of high chairs, strollers, and car seats.²⁶

The Department rejects this analogy. High chairs, strollers, and car seats allow for feeding and transit – benefits that far outweigh rare risks. As a result, the question for these products is how to make them as safe as possible. A crib itself is analogous to a high chair, stroller, or car seat, but a bumper attached to a crib is not.

One member of the advisory panel – Dr. Tina Cheng, stated that she discourages use of bumper pads in her clinic, but did not support a regulatory ban at this time. She stated, “getting to regulation is, you know, is a larger step and I think that you have to have substantial evidence and that you also have to really understand those unanticipated consequences, and I, I’m struggling with that.”²⁷ Dr. Cheng recommended an educational campaign to advise against the use of bumper pads in infant cribs and an epidemiological study to gain additional data. She stated that if a ban were to be considered, it should first be set out for public comment and its acceptance by the public should be an important factor in deciding whether to go forward.

The other three advisory committee members supported a ban. In explaining his position, Dr. Dayal stated:

I also do think that regardless of the educational message, there is an implicit endorsement when a product is available in a market, because as people, well, if it’s that dangerous, how could you be selling this, is I think, a valid concern from the public.²⁸

In explaining his support of regulatory action during the first advisory panel meeting, Dr. Wiley stated:

I believe with what we’re faced with here, in terms of the information that we’ve read and what we know, I do agree that that risk is substantial enough, not substantially proven, but substantial enough in that there are proven deaths and medical examiners have written death documents, saying that the crib bumper was responsible, and that’s a death. That’s not an injury, that’s a death. And that’s enough.²⁹

²⁶ L. Pfeiffer, Juvenile Products Manufacturers Association, letter to Dr. Joshua M. Sharfstein, Maryland Department of Health and Mental Hygiene. 28 July 2011.

²⁷ Transcript, 20 May 2011, p. 64.

²⁸ Transcript, 20 May 2011, p. 77.

²⁹ Transcript, 20 May 2011, p. 67-8.

At the second meeting, he concluded: "I still can't find the benefit substantial enough to outweigh the risk."³⁰

The Department's legal burden for action to prohibit the sale of crib bumper pads would be to find that bumper pads are a "toy or other substance intended for use by children that presents an electrical, mechanical, or thermal hazard," that bumper pads are "a danger to the public health and safety," and that "[p]roper labeling cannot protect the public health and safety adequately." See Md. Code Ann., § 22-502(a). In light of the available evidence on the risk of infant death and the absence of a countervailing benefit, the Department's preliminary conclusion is that this standard is met with respect to younger infants.

The Department could have opted to put forward a formal regulatory proposal at this time. However, consistent with the input of Dr. Cheng and the other panel members, the Department is putting forward its analysis and an informal draft proposal for public comment prior to initiating rulemaking. A decision on whether to move forward to a formal regulatory proposal will be based on a review of the comments received.

6. Proposal

The Department is proposing the following five-part approach for public comment:

Part 1: Definition. The Department proposes to define a "baby bumper pad" as a pad intended to be used around the sides of a crib until the age that the infant pulls to stand. The definition excludes bumper pads or side rail pads for older infants or for children who have special needs, engage in self-injurious behavior, or have epilepsy. (This distinction addresses the concern expressed by the Maryland chapter of the American Academy of Pediatrics in its response to the Department's initial request for comment). (Appendix II)

Part 2: Action. The Department proposes to prohibit the sale of "baby bumper pads" in the State of Maryland beginning on January 1, 2013. This timeline will allow for considerable public education in the context of a "safe sleep" message, as recommended by the Advisory Panel.

Part 3: The Department proposes to give the Secretary authority to suspend this regulation for relevant products by an order should the Consumer Product Safety Commission affirmatively find, in its review, that the benefits of certain baby bumper pads exceed the risks.

Part 4: The Department proposes to give the Secretary authority to suspend this regulation for relevant products by an order should new evidence come to light that, in the context of other available data, leads to the conclusion that the benefits of certain baby bumper pads exceed the risks.

³⁰ Transcript, 13 July 2011, p. 91.

Part 5: The Department proposes to give the Secretary authority to suspend this regulation by an order and adopt voluntary industry standards as required for sale if (1) such standards are adopted by a credible industry body and (2) there is evidence that following the standards significantly mitigates the risk to infants.

7. Request for Public Comments

The Department requests comment on each part of its proposal and on the analysis set forth above supporting the proposal. In addition, the Department requests comment on (a) any voluntary standards that may have been adopted since the Department's prior request for comment, (b) whether certain, specific designs of crib bumpers do not pose the risks described in this document and should be excepted from the standard; (c) whether there is some less burdensome action that would adequately mitigate the risk of infant death associated with the use of crib bumper pads, (d) the economic impact of the Department's proposal, and (e) the Department's legal authority to implement this proposal.

Comments should be submitted by 5pm on November 4, 2011.

Comments may be submitted by mail to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 W. Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499, TTY: 800-735-2258, or by email to regs@dhmh.state.md.us, or by fax to 410-767-6483.

Date of Request: October 7, 2011.

Appendix I: Initial Request for Public Comment in the Maryland Register

FOR PUBLICATION IN THE MARYLAND REGISTER:

Secretary of Health & Mental Hygiene Request for Comment on Use of Bumper Pads in Infant Cribs

Bumper pads are pieces of cushioned lining designed to be attached to the sides of an infant's crib for the purpose of preventing the infant from bumping into the crib. The American Academy of Pediatrics and academic experts in infant mortality have expressed concern that bumper pads may be responsible for more than 20 infant deaths in the United States.^{1,2} The Canadian regulatory agency Health Canada has found bumper pads to be involved in 23 infant incidents in Canada, including two deaths and one near-suffocation, and advises against their use.³ In the United States, the Consumer Product Safety Commission has recently announced plans to consider this issue.

There appears to be limited data on the use of bumper pads in Maryland. In 2007, according to the State's Chief Medical Examiner, an infant was found dead in a crib with her head pressed up against crib bumper pads. The Chief Medical Examiner determined the cause of death to be asphyxia.

The Department of Health and Mental Hygiene, pursuant to § 22-501 *et seq.* of the Health-General Article of the Maryland Code, seeks comment from members of the public, interested parties, health professionals, and persons knowledgeable about product safety, concerning the use of bumper pads in infant cribs. The Department seeks public comment to assist the Secretary of Health and Mental Hygiene both in determining whether to provide input to the Consumer Product Safety Commission and in determining whether there is cause for action on crib bumper pads under Maryland law. Section 22-502 of the Health-General Article defines a "hazardous material," in part, as "a toy or other substance intended for use by children that presents an electrical, mechanical, or thermal hazard," and authorizes the Secretary to promulgate regulations to address such hazards and protect children, including by prohibiting the sale of the hazardous material.

The Secretary requests comment by May 9, 2011 specifically addressing (a) whether crib bumper pads pose a substantial risk to infants; (b) whether there are benefits to crib bumper pads that should be considered; (c) whether any dangers associated with the use of bumper pads in infant

¹ Thach BT, Rutherford GW Jr, Harris K. Deaths and injuries attributed to infant crib bumper pads. *J Pediatr.* 2007 Sep;151(3):271-4.

² Gabler E. Crib deaths and bumper pads. *Los Angeles Times.* 4 April 2011.

³ Health Canada. Policy Statement for Bumper Pads. 17 August 2005. Online at: <http://www.hc-sc.gc.ca/cps-spc/legislation/pol/bumper-bordure-eng.php>.

cribs could be reduced or eliminated by proper labeling; (d) whether the Department should provide input to the Consumer Product Safety Commission in its review of the safety of these products, and if so, what that comment should be; (e) whether the Department should issue a warning to consumers, and if so, the content of the warning; and (f) whether bumper pads should be considered a “hazardous material,” and if so, whether the Secretary should adopt regulations addressing the sale, marketing, or labeling of bumper pads.

In addressing the above issues, the Department encourages commenters to identify any studies of the risks or benefits of using bumper pads in infant cribs.

The Secretary has appointed an advisory panel to review comments and to recommend what action, if any, should be taken. The anticipated members of the panel will be Dr. Peter Beilenson, Health Officer, Howard County Health Department; Dr. Tina L. Cheng, Division Chief, General Pediatrics and Adolescent Medicine, Department of Pediatrics, Johns Hopkins School of Medicine; Dr. Gaurov Dayal, Vice President and Chief Medical Officer for Adventist Healthcare; Jeanne Markowski, a nurse practitioner at Franklin Square Hospital; and Dr. Joseph M. Wiley, Chief of Pediatrics, Sinai Hospital. Dr. Marsha Smith of the Family Health Administration of the Department of Health and Mental Hygiene will oversee the panel process.

Comments should be submitted by 5 pm on May 9, 2011.

Comments may be submitted by mail to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 W. Preston St., Room 512, Baltimore, MD 21201, or call 410-767-6499, TTY:800-735-2258, or by email to regs@dnhmh.state.md.us, or by fax to 410-767-6483.

Date of Request: April 8, 2011.

Correction: April 12, 2011

Appendix II: Summary of Comments Received

In response to the Maryland Department of Health and Mental Hygiene's request for public comment regarding the use of bumper pads in infant cribs, nine comments were received. These include responses from Pediatric researchers in the area of Sudden Infant Death Syndrome (SIDS) and sleep-related infant deaths, medical professionals in the field of Pediatric Emergency Medicine, neonatal nurses, the Maryland chapter of the American Academy of Pediatrics (AAP), the Juvenile Products Manufacturers Association (JPMA), personnel with expertise in Injury Prevention and family members of a deceased infant.

In the commentary submitted by the family members of a deceased infant, both family members attribute the deaths of their infants to the use of bumper pads. Given their experiences, both families express strong support for banning the sale of crib bumper pads in order to prevent further infant deaths.

Comments submitted by researchers in the field of SIDS, pediatric medical and nursing professionals reviewed of the available literature and existing policies on bumper pads. All opposed the use of crib bumpers. Two comments supported labeling about the dangers as a potential strategy for risk mitigation.

The response provided by the Johns Hopkins Center for Injury Research and Policy also includes recommendations against the use of bumper pads. These recommendations are based on the absence of known benefits, lack of evidence demonstrating serious injury if not used and documented cases of death related to use. Similarly, the Maryland Chapter of the AAP also advises against use of bumper pads in infants under 6-months of age. However, it is further stated that for older infants and toddlers, children with self-injurious behavior or with epilepsy, bumper pads may offer some protection. Hence, the decision to use them under these circumstances should be guided by analyzing the risks vs. benefits on a case-by-case basis.

In their response, JPMA reports the results of a commissioned independent analysis of recent studies evaluating bumper pad use and infant safety. The findings from the review indicate that there is no causal relationship between crib bumper pads and infant death. Based on these findings, the Association concludes that: "traditional crib

bumper pads do not pose a substantial risk to infants,”¹ and therefore offers the following recommendations to the Department: 1) refrain from warning consumers specifically about crib bumpers; 2) refrain from designating bumper pads as a “hazardous material” under existing Maryland statutory authority; 3) encourage compliance with current ASTM bedding standards; and 4) support continued parental education on safe sleeping environments including proper use of crib bumper pads.

¹ Dwyer M, Juvenile Products Manufacturers Association, Comment on Crib Bumpers, 9 May 2011.

Appendix III: List of Questions for First Advisory Panel

1. Please discuss as a group the published research presented to the panel.

Question A: Does the evidence support a finding that the use of crib bumpers provides benefits to infants? Please explain your reasoning.

Question B: Does the evidence support a finding that the use of crib bumper pads poses a substantial risk to infants? Please explain your reasoning.

2. If there is concern for risks to infants, please discuss as a group whether labeling is a possible solution.

Question C: Could improved labeling mitigate the dangers associated with the use of bumper pads in infant cribs? Please explain your reasoning and if yes, please suggest the type of labeling you would recommend.

3. The Consumer Product Safety Commission is in the process of considering the safety of bumper pads.

Question D: Should the Department provide input to the CPSC on bumper pads, and if so, what should that input be?

4. One option for the Department is to issue a warning to consumers.

Question E: Is a warning to consumers about the use of all or certain bumper pads justified, and if so, what do you recommend regarding the content of the warning?

5. The Department can regulate “hazardous materials,” defined in part as “a toy or other substance intended for use by children that presents an electrical, mechanical, or thermal hazard.”

Question F: Should the Department pursue regulations that define crib bumpers as “hazardous materials:?”

Question G: If so, should those regulations address the labeling of bumper pads? Please provide specific recommendations if applicable or refer to your answer in Question C if appropriate.

Question H: If so, should those regulations address the marketing of bumper pads? Please provide specific recommendations if applicable.

Question I: If so, should those recommendations address the sale of bumper pads? Please provide specific recommendations if applicable.

Appendix IV: Letter to the Secretary from the Maryland Chief Medical Examiner



STATE OF MARYLAND OFFICE OF THE CHIEF MEDICAL EXAMINER

FORENSIC MEDICINE CENTER

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OXIRIS BARBOT, M.D.

Dr. Joshua Sharfstein
201 West Preston Street
Baltimore
MD 21201

May 16, 2011

Dear Dr Sharfstein

A review of the records at the Office of the Chief Medical Examiner of deaths of infants (child under 1 year of age) identified one child that died an asphyxial death due to the use of bumpers in the crib. In addition there were an additional 9 deaths in cribs where bumpers were documented to be in use. These 9 deaths were determined to be in the SIDS category. SIDS is defined as the death of an infant where no cause of death has been identified after a full investigation including a full post mortem examination, special tests, examination of the place of death, and review of any medical records. There are multiple articles in the medical literature suggesting that there is an asphyxial component to SIDS. Asphyxia often leaves no identifying marks on the infant so there is no medical evidence that can be identified to differentiate SIDS from asphyxia.

In the investigation of child deaths the scene of death is rarely undisturbed. Once an unresponsive infant is found, family and or caretakers usually immediately attempt to resuscitate and summon help. This natural important lifesaving reaction later precludes accurate determination of the position of the infant at the time they were discovered unresponsive. This critical piece of information prevents the Medical Examiner from determining if asphyxia played a part in the death and the death is then classified as SIDS.

Of importance, the infant is born with a respiratory center in the brain that is not fully developed. The tiny lungs only move approximately ½ an ounce of air at each breath and over 30 breaths a minute. In comparison an adult at rest, moves about a pint of air with each breath and much more slowly. These larger volumes disturb the surrounding air enhancing the ability to refresh the air around the nose and mouth.

An infant does not need to have their nose and mouth covered to asphyxiate. Simply being close to an object such as a stuffed toy or a bumper may slow the air movement and lead to a slow refresh rate of essential oxygen. Humans need a minimum of 16% of oxygen in the air that they breathe to survive. Air usually has 21% oxygen and this provides a relatively small margin of safety. If the air is restricted from movement there is a real risk the infant can reduce the oxygen content to below 16% since the air movement caused by their breathing is negligible. Recent articles in the medical literature indicate that a fan in the room reduces the risk of SIDS. This insures that the air is constantly moving and mixing to keep local pockets of air having decreased oxygen content.

Any item in the crib that restricts free air flow increases the risk of asphyxia, and this includes bumpers, stuffed toys, rolled up blankets etc. For these reasons, current recommendations are that infants (under one year) sleep on their back, alone, in a crib with a firm mattress covered by a sheet, with no soft objects such as pillows, quilts, comforters, loose blankets, stuffed toys, or crib bumper pads.

Sincerely



David R Fowler. MB.ChB. M.Med. Path (forens). FACP. FAAFS.
Chief Medical Examiner
State of Maryland