

DEPARTMENT OF HEALTH & MENTAL HYGIENE

Background and Assessment for Proposal to Prohibit Sale of Baby Bumper Pads

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.

On October 7, the Department put forward in the Maryland Register a proposal for public comment consistent with the panel's recommendations. After review of all additional comments, the Department is proposing regulations, pursuant to State Government Article, §10-101, that would prohibit the sale of bumper pads for use in infant cribs beginning June 21, 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 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

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

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.

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

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 a bumper tie test method and 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 ASTM is also considering a "bumper thickness standard" that would require that "crib bumper pads meet a two inch pre-and post-wash requirement which will simulate a real world experience with this product."⁷

The federal Consumer Product Safety Commission is reviewing the safety of crib bumper pads.⁸

Title 22, Subtitle 5 of the Health-General Article of the Annotated Code of Maryland authorizes the Secretary of Health and Mental Hygiene to regulate hazardous materials. Section 22-502(a) of the Health-General Article authorizes the Secretary to adopt rules and regulations that declare as a hazardous material substances that the Secretary finds are intended for use by children that present an electrical, mechanical, or thermal hazard. The word mechanical, as used in the statute, means "relating to physical forces or motion" or "physical" and is not limited to hazards caused by machines or mechanical devices.⁹ Section 22-502(a) also authorizes the Secretary to adopt rules and regulations to declare any hazardous material to be a banned hazardous material and require its removal from commerce if the Secretary finds that the material is a danger to the public health and safety and that proper labeling cannot protect the public health and safety adequately.

In April 2011, the Maryland Department of Health and Mental Hygiene initiated a review of crib bumper pads.

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).

⁷ L. Pfeiffer. Comment on Crib Bumper Proposal. 4 November 2011.

⁸ Gabler E. Hidden Hazard of Crib Bumpers. Chicago Tribune. 12 December 2010.

⁹ See, e.g., definition of "mechanical" in the Oxford College Dictionary.

2. Process

The Department's review of crib bumper pads has proceeded in four stages:

1. Public Comment. On April 8, 2011, pursuant to Health-General Article, §22-501 et seq., Annotated Code of Maryland, the Department requested comments concerning the use of bumper pads in infant cribs. The announcement was published in 38:9 Md.R. 570 (April 22, 2011). 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 1)

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.

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.

4. Additional Public Comment on Initial Proposal. On October 7, 2011, the Department published in the Maryland Register a request for public comment on a proposal to prohibit the sale of baby bumpers pads in Maryland. The Department particularly requested comments on (a) any voluntary standards applicable to crib bumpers that might have been adopted since the Department's prior request for comment, (b) whether there might be some less burdensome action that would adequately mitigate the risk of infant death associated with the use of crib bumper pads, (c) the economic impact of the Department's proposal, and (d) the Department's legal authority to implement the proposal.

More than 30 public comments were received. A summary of these comments are listed in Section 5. Additional Public Comments of this document.

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 of sufficient air flow by the face being very close to the bumper pad, 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 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.¹⁰

Evidence of this harm comes from autopsy reports. In Maryland, the Office of the Chief Medical Examiner has identified one infant fatality to which a bumper appears to have 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.¹¹
- 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.¹²

¹⁰Fowler D, Office of the Chief Medical Examiner. Letter to Dr. Joshua M. Sharfstein, Maryland Department of Health and Mental Hygiene. 16 May 2011.

¹¹Thach, BT et al. Deaths and Injuries Attributed to Infant Crib Bumper Pads. *J Pediatr* 2007, 151(3): 271-274.

¹²Health 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).

- 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.”¹³

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.”¹⁴

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.¹⁵

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 [face down] and goes up against the crib bumper. Children can roll and they can roll up against the crib bumper and they become prone. 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.¹⁶

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.

¹³Consumer 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.

¹⁴Transcript of Crib Bumpers Advisory Meeting, 20 May 2011, p. 69.

¹⁵Juvenile Products Manufacturers Association. Crib Bumpers and the Infant Sleeping Environment: An Evaluation of the Scientific Evidence. June 2011.

¹⁶Transcript of Crib Bumpers Advisory Meeting 13 July 2011, p. 72.

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.¹⁷

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.¹⁸

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."¹⁹

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."²⁰ In Dr. Dayal's view, "the benefits are questionable at best."²¹ Dr. Cheng stated, "There isn't strong evidence to support finding that the use of crib bumpers provides any benefits to infants."²² 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.²³

4. Additional Policy Considerations

¹⁷Juvenile Products Manufacturers Association. *Crib Bumpers and the Infant Sleeping Environment: An Evaluation of the Scientific Evidence*. June 2011. Online at <http://www.dhmd.state.md.us/news/crib/pdf/JPMA-Summary>. (Accessed Aug. 29, 2011).

¹⁸Transcript, 13 July 2011, p. 59.

¹⁹Transcript, 13 July 2011, p. 48.

²⁰Transcript, 20 May 2011, p. 33.

²¹Transcript, 20 May 2011, p. 26.

²²Transcript, 20 May 2011, p. 28.

²³Transcript, 20 May 2011, p. 28.

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.”²⁴

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].²⁵

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.”²⁶

In its comments, the Center for Injury Research and Policy at the Johns Hopkins School of Public Health also expressed the view that labeling was not a solution to the risk of crib bumper pads.²⁷

²⁴L. Pfeiffer, Juvenile Products Manufacturers Association, letter to Dr. Joshua M. Sharfstein, Maryland Department of Health and Mental Hygiene. 28 July 2011.

²⁵Transcript, 13 July 2011, p. 83.

²⁶Transcript, 20 May 2011, p. 43-44.

²⁷Gielen A, Johns Hopkins Center for Injury Research and Policy. Comment on Crib Bumpers. 9 May 2011.

5. Additional Public Comments

After publication of the proposal in the Maryland Register, Department received eight additional public comments in favor of a ban on crib bumpers. These included:

- Nancy Cowles, Executive Director of Kids in Danger, who wrote that “bumper pads can cause suffocation, or in the case of older babies who can use the bumper pads as footing, falls.”²⁸
- Jenny Levin of the Maryland Public Interest Research Group, who commented that “the sale of crib bumpers places the lives of infants at risk unnecessarily.”²⁹
- Alison Sosebee of Baltimore, Maryland, who wrote “I am college educated with a fantastic support group of mothers, who are even NICU nurses and we still found what to buy confusing! I think it is difficult to determine true safety when things are so regularly available. The idea being ‘how can it be unsafe if I can buy one in every single color at every store.’”³⁰

²⁸ Cowles, N, Kids in Danger. Comment on Crib Bumper Proposal. 3 November 2011.

²⁹ Levin J, Maryland Public Interest Research Group. Comment on Crib Bumper Proposal. 2 November 2011.

³⁰ Sosebee A. Comment on Crib Bumper Proposal. 27 September 2011.

- Dr. Eric Levey, President of the Maryland Chapter of the American Academy of Pediatrics, wrote that the “Maryland Chapter of the American Academy of Pediatrics supports the Department’s proposed ban on the sale of crib bumper pads in Maryland. We agree with the Department’s conclusion that ‘the risks associated with the use of crib bumper pads in infant cribs outweigh potential benefits.’”³¹
- Dr. Levey also noted that soon after the Maryland proposal was released, the American Academy of Pediatrics published a new policy statement on safe sleep. This policy includes a recommendation that “bumper pads should not be used in cribs” because “there is no evidence that bumper pads prevent injuries, and there is a potential risk of suffocation, strangulation, or entrapment.”³²

The Department received three additional comments in support of a ban on conventional or traditional crib bumpers.

- On behalf of Breathable Baby LLC, Steven Steinborn and Elizabeth Fawell supported a ban on “unsafe conventional crib bumpers” and said that the ban should not apply to mesh products that are designed differently, such as the Breathable Baby Breathable Mesh Crib Liner.³³
- Catherine Hall and Georgia Fiebrich of Go Mama Go Designs provided a study on carbon dioxide dispersion using their product, Wonder Bumpers. These are described as “vertical rail guards.” Ms. Hall and Ms. Fiebrich supported a ban on “traditional crib bumper pads.”³⁴
- Seabren Reeves of Bitzy Bumpers, which they described as “significantly safer than the industry standard for a safe sleeping environment.”³⁵

The Department received two additional comments supporting ASTM standards for crib bumpers.

- The Juvenile Products Manufacturers Association “reiterated our past comments on this subject” and encouraged the state to adopt ASTM standards for crib bumper pads sold in the state. The Association also contested whether the Department has the legal authority to ban the sale of crib bumpers by regulation. The Association endorsed a public education campaign designed to promote the appropriate use of crib bumpers.

³¹ Levey E. Comment on Crib Bumper Proposal. 19 October 2011.

³² Task Force on Sudden Infant Death Syndrome. SIDS and Other Sleep Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment. *Pediatrics* 2011; 128:1030-1039.

³³ Steinborn S and Fawell E. Comment on Crib Bumper Proposal. 4 November 2011.

³⁴ Hall C and Fiebrich G. Comment on Crib Bumper Proposal. 1 November 2011.

³⁵ Reeves S. Comment on Crib Bumper Proposal. 4 November 2011.

- The Maryland Retailer Association stated it is “not opposing the implementation of a ban on baby bumper pads or crib bumpers” but asked for clarification on the definition, requested a 6 to 9 month implementation period, requested clarification on store inventories, and requested that the Department’s proposal phase out when the ASTM standard is adopted.³⁶

The Department received 20 additional public comments objecting to a ban on the sale of crib bumper pads. The comments generally rejected state action on the grounds that in the face of a small risk, parents should be educated and given the choice to purchase crib bumper pads. For example:

- Dana M.K. Evans, owner of Daisy Baby & Kids in Bethesda, wrote that bumper pads “keeps limbs from being entrapped in the bars” and prevents babies “from hitting their little heads & lying up against wood slats.” She wrote that the evidence of risk was not significant and that “parents need to make choices when it comes to their children.”³⁷
- Lisa Wright, who wrote that “I know that some experts believe these bumpers cause a hazard, but for my baby it was more hazardous not having a bumper in the crib. I believe it should be a parent’s choice.”³⁸

Several of these comments stated that if Maryland were to pursue a ban on crib bumper pads, it should be narrowly tailored to those bumper pads at the highest risk. For example:

- Bridget Kopetzky of Bowie Maryland, wrote that “we didn’t need a law to keep our children safe...at least consider that not all crib bumpers are unsafe and in need of banning.”³⁹
- Courtney Bond wrote, “I personally do not support this proposal and would use the bumper for the safety of my child. The ban should be on the plush/pillowry bumpers and not those endorsed by the AAP if there is to be any ban.”⁴⁰

6. 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, the transcripts of the advisory panel meetings, and public comments, 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

³⁶Donoho P, Maryland Retailers Association. Comment on Crib Bumper Proposal. 2 November 2011.

³⁷Dana M. K. Evans, Dasy Baby & Kids. Comment on Crib Bumper Proposal. 4 November 2011.

³⁸Wright L. Comment on Crib Bumper Proposal. 27 September 2011.

³⁹Kopetsky B. Comment on Crib Bumper Proposal. 27 September 2011.

⁴⁰Bond C. Comment on Crib Bumper Proposal. 29 September 2011; Note: The American Academy of Pediatrics (AAP) does not support the use of any baby bumper pads for cribs.

such as this is very challenging to study, especially given the wide variety of confounding factors.

Based on the data available, the Department continues to find that the risk of death from crib bumper pads, while small, is real. Since our proposal was published in the October 7 Maryland Register, the American Academy of Pediatrics has issued a recommendation against the use of bumper pads in infant cribs, citing evidence and analysis similar to the Department's.

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. Similarly, a recently published study using national data on crib related injuries and deaths found that some infant deaths were related to infants becoming wedged between the mattress and the bumper pad.⁴¹ Providing further evidence for the concern that limited dispersion of exhaled gases and rebreathing as possible mechanisms for SIDS, the use of a fan in the room near a sleeping infant reduced the incidence of SIDS.⁴²

The Department finds that this risk is not offset by 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. It is also the perspective of the American Academy of Pediatrics.

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.⁴³

The Department also continues to agree with the panel on the three policy considerations: 1) discouraging the use of crib bumper pads 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.

Turning to the question of regulatory action, 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., Health Gen. § 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 conclusion is that the statutory standard is met with respect to younger

⁴¹ 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(3):479-486.

⁴² Coleman-Phox, K, Odouli, R and De-Kun Li. Use of a fan during sleep and the risk of sudden infant death syndrome. *Arch Pediatr Adolesc Med*. Vol 162 (No.10). Oct 2008 963-968.

⁴³ Levy E, Maryland Chapter of American Academy of Pediatrics, Comment on Crib Bumpers, 9 May 2011.; Gielen A, Johns Hopkins Center for Injury Research and Policy, Comment on Crib Bumpers, 9 May 2011.

infants. The Department finds that a crib bumper pad is a “toy or other substance intended for use by children that presents a mechanical . . . hazard,” *id.*, because “in normal use” bumper pads’ intended “design” “presents an unreasonable risk of personal injury. . .” See 16 C.F.R. 1500.3(17).

The Juvenile Products Manufacturers Association has argued that the Department does not have the authority to move forward, contending that 1) crib bumper pads do not qualify as a “toy or other substance” because they are made up of several different types of substances; and 2) crib bumper pads do not present a “mechanical hazard.” The Department disagrees with the Juvenile Products Manufacturers Association interpretation of Md. Code Ann., Health Gen. § 22-502(a). Section 22-502(a) closely mirrors language used in 15 U.S.C. 1261 *et seq.*, the Federal Hazardous Substances Act (FHSA). The FHSA has been held to encompass objects made up of multiple substances, like bicycles, when they are being used by children. *Forester v. Consumer Product Safety Com.*, 559 F.2d 774, 786 (D.C. Cir. 1977). When the Maryland provision was first adopted, it used the term “toy or other article” in place of “toy or other substance” in direct conformity with the federal language. The change in the Maryland statute occurred as part of a broad recodification in 1982, and was specifically characterized as an “adoption without substantive change.” 1982 Md. Laws ch. 240, 2098. Therefore, reliance on a narrow definition of the term “substance” is inconsistent with the legislative intent to adopt the federal provision. Moreover, the Department disagrees with the Juvenile Products Manufacturers Association’s assertion that crib bumper pads do not “present an electrical, mechanical, or thermal hazard.” As explained above, the Department finds that crib bumper pads present a mechanical hazard because they present an unreasonable risk of personal injury when used as designed, with respect to younger infants.

Some consumers and store owners have argued that parents should have the choice to purchase bumper pads for infant cribs in Maryland. To the extent that this argument is made irrespective of the risk of the bumper pads, the Department disagrees. Under the law, state and federal agencies can take appropriate and reasonable steps to protect infants from unsafe products. Indeed, there are many products that are not permitted to be sold because of the unreasonable risk they pose to infants and children. To the extent the argument is based on an assessment that bumper pads do not pose an unreasonable risk, the Department disagrees. Our position, consistent with the conclusion of our expert reviewers and the view of the Maryland chapter of the American Academy of Pediatrics, is that any benefits associated with these products are outweighed by the risks, including the risks of suffocation, strangulation and death, which they pose to infants.

It is important to note, however, that the Department’s regulatory action would apply only to the sale of these products in Maryland, not to their use. While the Department would advise against it, Maryland parents who choose to use crib bumper pads would still be able to do so.

The Department is proposing a ban on the sale of bumper pads for infant cribs in Maryland, effective June 21, 2013. Based on public comment, we are making several modifications in our proposal.

The Juvenile Products Manufacturers Association has asked that the Department adopt ASTM standards for bumper pads instead of banning their sale altogether. The proposed regulations recognize the authority of the Secretary to substitute ASTM standards concerning the design and use of baby bumper pads for an outright prohibition on the sale of crib bumpers, but only after final adoption of any such ASTM standards. It does not make sense for the Department to defer to proposed standards, which may be changed prior to adoption by industry. Under the proposed regulations, the Secretary would make available any final ASTM standards for public comment and then make a determination whether to adopt those standards.

The proposal provides the Secretary with the authority to issue an order suspending the regulations should the Consumer Product Safety Commission reach the conclusion that the benefits of baby bumper pads outweigh the risks.

Several manufacturers of new products have asked the Department to be more specific about what types of products are intended to be banned. In addition, several consumers recommended the Department tailor its ban to those products where there is evidence of harm. The Department does not endorse any product for use as bumpers in infant cribs and supports the ABCs of safe sleep, which include that infants should sleep alone, on their back and in the crib.

However, the Department intends, through this proposed regulation, to prohibit the sale of baby bumper pads that are characterized by a pad or pads of non-mesh material resting directly above the mattress running the circumference of the crib or along the length of any of the interior sides of the crib intended to be used until the age that an infant pulls to stand. These types of bumpers are those that have been associated with the risk of suffocation.

To permit adequate time for Maryland retailers to adjust to the proposed regulations, and to permit the development of an educational campaign, the effective date has been moved to June 21, 2013.