



STATE OF MARYLAND

DHMH

**Maryland Department of Health and Mental Hygiene
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Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

Proposed Regulations on Baby Bumper Pads – COMAR 10.11.07

**Testimony of Dr. Joshua M. Sharfstein
Secretary of Health and Mental Hygiene
Before the Joint Committee on Administrative, Executive, and Legislative Review
October 2, 2012**

Thank you for the opportunity to testify today on the Department's proposed regulations to ban the sale of baby bumper pads in Maryland.

I am pleased to be joined by Maryland's Chief Medical Examiner Dr. David Fowler and Assistant Medical Examiner Dr. Patricia Aronica-Pollak, as well as by Dr. Scott Krugman of the Maryland Chapter of the American Academy of Pediatrics.

In this testimony, I will (1) summarize the process followed by the Department in developing the regulations; (2) discuss the Department's legal authority to propose these regulations; (3) explain the evidence for the Department's proposal; (4) review the alternative approach recently proposed by the Juvenile Products Manufacturers Association; and (5) provide the Department's analysis of this alternative.

Here is our conclusion: Baby bumper pads pose an unreasonable risk to infant life and health without compelling evidence of benefit. Adopting an alternative standard for baby bumper pads as recommended by the Juvenile Products Manufacturers Association would not protect infants in Maryland.

Our conclusion is consistent with that of the Maryland Chapter of the American Academy of Pediatrics, representing more than 1,100 pediatricians and allied health professionals in our state. Representing the chapter, Dr. Scott Krugman of the Franklin Square Medical Center has stated that "the data clearly demonstrates that adoption of [the alternative proposal] in lieu of the proposed ban should be rejected."

Dr. Krugman has noted that the American Academy of Pediatrics, following a detailed technical review, has determined that baby bumper pads are "inherently risky and unnecessary."

Our position is shared by Professor Andrea Gielen, Director of the Johns Hopkins Center for Injury Research and Policy, who has written that "the proposed ban is based on careful consideration of the scientific evidence and is consistent with the best practices for infant sleep safety. The [alternative] do[es] not provide any evidence to the contrary."

Also in support of the regulations is MedChi, which has stated that there is "no justification for the Department to substitute [the alternative proposal] in lieu of a ban where there is no substantial basis upon which a family can justify the use of the bumper pads regardless of their manufacturing standards."

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The Department's proposed regulations leave open the option of adopting an alternative standard, should one emerge that protects the health of infants. However, no adequate alternative exists today.

To protect Maryland infants, the Department supports these regulations as proposed.

The Process Leading to the Department's Proposal

The Department has conducted a wide-ranging, thorough, and public review of the safety of baby bumper pads. This review began about 18 months ago and has included five stages, which are described below.

1. Public Comment. On April 8, 2011, the Department requested comments concerning the use of bumper pads in infant cribs. The announcement was published in the Maryland Register on April 22, 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 an injury professional.

2. First Advisory Panel. I 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-Pollak.

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 bumper 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.

5. *Proposed Regulation.* After reviewing the available data, public comments, and proposals, the Department proposed a regulation to ban the sale of baby bumper pads in the State of Maryland starting June 21, 2013. The proposed regulation permits the Department to accept an alternative approach to baby bumper pads that protects the health of infants. A document summarizing the evidence and basis for the regulation were published in the July 13, 2012, edition of the Maryland Register.

The Legal Authority for the Regulations

The Office of the Attorney General has been involved at all stages of the Department's process on baby bumper pads and has supported the Department's legal authority to proceed at each stage.

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. In the statute, a "hazardous materials" is defined as a "toy or other substance intended for use by children that presents an electrical, mechanical, or thermal hazard."

In all critical respects, the statute is identical to a federal statute, 15 U.S.C. § 1261 et seq., that has authorized the federal Consumer Product Safety Commission to prohibit the sale of, among other things, certain baby walkers, children's bicycles, and infant pillows, after declaring certain of these items to present "mechanical hazards."¹

In the case of baby bumper pads, the risk to children is a "mechanical" risk, a term defined as related to physical forces or motion. Section 22-502(a) 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.

The Office of Attorney General has reviewed the arguments made by the Juvenile Products Manufacturers Association contesting the Department's legal authority to proceed and determined that they do not have merit.²

¹ See, e.g., 16 CFR § 1500.18 (regulations pertaining to these items).

² The Office of the Attorney General has specifically rejected the arguments of the Juvenile Products Manufacturers Association that the Department lacks authority to prohibit the sale of baby bumpers under § 22-502 of the Health-General Article, because, assertedly, crib bumpers are not a "substance" and do not present any "mechanical hazard." This argument misunderstands the statute and omits critical elements of its legislative history.

The Juvenile Products Manufacturers Association has focused on the use in § 22-502 of the word "substance," at a point where otherwise identical federal language uses the word "article." Compare Health-Gen. § 22-502(a)(1)(ii) ("toy or other substance intended for use by children that presents an electrical, mechanical, or thermal hazard") with 15 U.S.C. § 1262(e) ("toy or other article intended for use by children presents an electrical, mechanical, or thermal hazard"). There are three fully dispositive responses to this argument. First, the General Assembly substituted the word "substance" for the word "article" in a 1982 re-codification law, and a revisor's note to the 1982 law states both that this "is new language derived without substantive change" and, specifically, that "'substance' is substituted for 'article' to conform to terminology used elsewhere in this subtitle." See 1982 Md. Laws, ch. 280. Thus, far from intending to depart from the otherwise identical federal standard, the legislature intended to retain the federal standard and further intended that "substance" would be understood as a synonym for "article." Second, even if this revisor's note

The Evidence for the Department's Proposed Regulation

Baby bumper pads rest 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 are intended to be used until the age that an infant can sit up or pull up to stand, which is approximately 6 months.

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

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.³

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

did not specifically say so, the context of both the federal and state statutes makes clear that the words "substance" and "article" are used interchangeably. Finally, even setting aside that "substance" is synonymous with "article" in this context, § 22-502 makes clear that a toy is a "substance" for purposes of the statute ("toy or other substance"); the Association offers no explanation why a toy is a "substance" but a baby bumper is not.

The Juvenile Products Manufacturers Association also argues that the danger of asphyxiation associated with baby bumpers is not a "mechanical hazard." While "mechanical hazard" is not defined in the Maryland statute, applying this term to asphyxiation from a baby bumper is consistent both with dictionary definitions of the term and, perhaps even more fundamentally, with the definition of "mechanical hazard" that the Consumer Products Safety Commission applies -- and has specifically applied to prohibit the sale of certain infant pillows and baby bouncers -- under the closely analogous federal statute. See 16 CFR § 1500.3(b)(17) ("an article may be determined to present a mechanical hazard, if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness . . ."). While "mechanical hazard" could possibly be understood in other contexts to refer only to dangers associated with complex machines, a broader understanding of the word "mechanical" -- i.e., pertaining to physical mechanisms or forces -- is clearly applicable here.

³Fowler D, Office of the Chief Medical Examiner. Letter to Dr. Joshua M. Sharfstein, Maryland Department of Health and Mental Hygiene. 16 May 2011.

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.⁴
- 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.⁵
- 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.”⁶

After reviewing the available evidence, the Department’s 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.”⁷

At the second meeting of the advisory committee, the Juvenile Products Manufacturers Association responded with a consultant’s 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.⁸

The advisory panel was not persuaded by the consultant’s analysis. Panel members stated that products in the crib of sleeping infants should not contribute to infant death – even in the presence of other risk factors. Dr. Aronica-Pollak of the Office of the Chief Medical Examiner noted

⁴Thach, BT et al. Deaths and Injuries Attributed to Infant Crib Bumper Pads. *J Pediatr* 2007, 151(3): 271-274.

⁵Health 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).

⁶Consumer 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.

⁷Transcript of Crib Bumpers Advisory Meeting, 20 May 2011, p. 69.

⁸Juvenile Products Manufacturers Association. Crib Bumpers and the Infant Sleeping Environment: An Evaluation of the Scientific Evidence. June 2011.

that there are often more than one contributing factor to infant deaths, and she pointed out that in some cases, babies have literally suffocated against the bumper pad.

Also at the second meeting, the advisory committee discussed the secondary risk of an infant climbing up on the top of the bumper and falling from the crib. Such falls are the most common reasons for serious crib-related trauma to infants. The panel expressed concern about the potential problem with baby bumper pads left in place beyond the intended age of use, which is now about 6 months. However, there was no data in the record on the frequency of this problem.

Benefits. The primary benefit under consideration was the potential for reduction of injuries to babies from the hard sides of a crib. The Juvenile Products 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.⁹

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 injuries of children in cribs with bumper pads and children in cribs without bumper pads.

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.¹⁰ The absence of confirmed cases or data points on benefits was noted by both the advisory panel and the Association's speakers.

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. One of the panelists, Dr. Joseph Wiley of Sinai Hospital, 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.¹¹

Through public comment, the Department heard from a number of families affected by tragedies involving baby bumper pads and from caregivers who have experience taking care of children with bumper pad-related injuries. Based on this evidence, input, and analysis, the Department found that the small but real and unreasonable risk of a serious injury significantly outweighs the unproven and lesser benefits of baby bumper pad use.

During the 18 months that the Department has studied the safety of baby bumper pads, the Task Force on Sudden Infant Death Syndrome of the American Academy of Pediatrics completed a thorough review of infant sleep practices. This review covered available scientific literature, review

⁹Juvenile Products Manufacturers Association. *Crib Bumpers and the Infant Sleeping Environment: An Evaluation of the Scientific Evidence*. June 2011. Online at <http://www.dhmh.state.md.us/news/crib/pdf/JPMA-Summary>. (Accessed Aug. 29, 2011).

¹⁰Advisory Committee Transcript, 13 July 2011, p. 59.

¹¹Advisory Committee Transcript, 20 May 2011, p. 28.

by pediatric experts across the country, and a white paper from the Consumer Product Safety Commission.

The review of the American Academy of Pediatrics mirrored the conclusions of the Department. The Academy found that “infant deaths have occurred because of bumper pads” and that there was a “lack of evidence to support” that the products “prevent injury in young children.” The Academy recommended against their use.¹²

Recently, the National Institute of Child Health and Human Development of the National Institutes of Health released recommendations for safe infant sleep. These recommendations unequivocally state, “Do not use pillows, blankets, sheepskins, or crib bumpers anywhere in your baby’s sleep area.”¹³

The Proposed Alternative

In August, ASTM International released a performance specification for infant bedding and related accessories. The specification was developed by the Subcommittee on Infant Bedding of ASTM Committee F15 on Consumer Products. The Juvenile Products Manufacturers Association, in comments on the proposed regulation, has requested that Maryland adopt this standard instead of a ban.

The specification contains a Bumper Tie Strength Test Method, a Bumper Thickness Standard (requiring that bumpers should pass through a test fixture with a two inch slot to assure that they are not “pillow-like” in thickness) and a warning. The warning states:

Warning: To reduce the risk of suffocation, keep top of bumper up and in position. DO NOT allow bumper to sag down or in toward the sleeping surface. DO NOT use bumper if sagging cannot be corrected. To prevent entanglement or strangulation, position ties to outside of crib and be sure they are secure. Remove bumper when child can sit up unaided or can pull to a standing position.¹⁴

In advocating the use of this performance specification instead of a ban, the Juvenile Products Manufacturers Association stated that they reflected a consensus of interested parties. The Association stated: “The standard setting process involves representatives from industry, consumer advocates, experts, and governmental authorities who are all involved in developing consensus standards based upon scientific hazard analysis.”¹⁵

¹² 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:e1341.

¹³ U.S. Department of Health and Human Services, Eunice Kennedy Shriver National Institute of Child Health and Human Development. What Does a Safe Sleep Environment Look Like? Reduce the Risk of Sudden Infant Death Syndrome (SIDS) and Other Sleep-Related Causes of Infant Death. September 2012.

¹⁴ Of note, babies generally can sit unaided at six months of age.

¹⁵ Letter from Michael Dwyer, Executive Director of the Juvenile Products Manufacturers Association. 13 August 2012. The Association reiterated its contention about a “consensus” in its letter of 28 September 2012, stating that the ASTM International performance specification represented “uniform national consensus requirements.”

Analysis of the Proposed Alternative

To better understand the ASTM International performance specification and the Juvenile Products Manufacturers Association proposal, the Department on September 10 requested public comment. The Department posted the performance specification and asked the following questions:

1. What was the evidentiary basis for the adoption of F1917-12 by ASTM International?
2. What evidence supports the use of F1917-12 as a safety standard for baby bumper pads?
3. What evidence supports that baby bumper pads that meet the performance specification of F1917-12 may nonetheless pose a risk to infants?
4. The Department of Health and Mental Hygiene has proposed a ban on the sale of baby bumper pads in the State of Maryland (see <http://dhmh.maryland.gov/SitePages/crib-bumper.aspx>). Should the Department instead permit the sale of baby bumper pads that meet the performance specification of F1917-12?

We received 17 comments from the public. Based on a review of these comments, the Department has made four findings.

First, the ASTM International performance specification does not, in fact, represent a consensus of interested parties.

The American Academy of Pediatrics (AAP), a participant in the ASTM process, did not support the standard. In an April 5, 2012, letter, citing its extensive review of the medical literature the Academy wrote:

The AAP cannot cast a vote in favor of measures to improve the safety of a product that we deem inherently risky and unnecessary.¹⁶

We also received public comments from Kids in Danger (KID) and the Consumer Federation of America (CFA), which participated in the ASTM process. These organizations stated:

Both KID and CFA participated in the ASTM sub-committee that developed the standard. The standard does not adequately address the suffocation hazard of crib bumper pads. We voted against the proposal in the ASTM process.¹⁷

Second, there are no data to support the use of the proposed alternative.

A short “rationale” section of the ASTM standard asserts that the 2-inch thickness standard reflects a thickness “that has not been known to present a hazard and allows for excessive fabric, fabric seams, and bumper ties.” Other than the same report by the Juvenile Products Manufacturers Association consultants that was reviewed at our advisory committee meeting in the summer of 2011, however, no evidence was submitted in support of the ASTM performance specification during the comment period.

¹⁶ Letter from Robert Block, President of the American Academy of Pediatrics to Keith Schneider, ASTM International. 5 April 2012.

¹⁷ Comments from Kids in Danger and Consumer Federation of America. 28 September 2012.

Third, ASTM International does not appear to expect its performance specification to serve as a safety regulation.

The text of the performance specification states: *“This standard does not purport to address the safety concerns, if any associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.”*

Fourth, Maryland expert scientists and doctors reject the proposed alternative standard and support the adoption of the Department’s proposal.

Professor Andrea Gielen, Director of the Johns Hopkins Center for Injury Research and Policy, commented that “the proposed ban is based on careful consideration of the scientific evidence and consistent with the best practices for infant sleep safety. The ASTM performance specifications for infant bedding and related accessories do not provide any evidence to the contrary.”¹⁸

Dr. Scott Krugman, chief of pediatrics at Franklin Square Medical Center and President of the Maryland Chapter of the American Academy of Pediatrics, commented that “the data clearly demonstrates that adoption of the ASTM Standards in lieu of the proposed ban should be rejected.”¹⁹

Gene Ransom, Chief Executive Officer of MedChi, commented there is “no justification for the Department to substitute the ASTM Standards in lieu of a ban where there is no substantial basis upon which a family can justify the use of the bumper pads regardless of their manufacturing standards.”²⁰

The proposed regulation permits the Department to adopt alternative standards in lieu of a ban with adequate evidence. Should new standards be developed, we would seriously consider them. However, the present ASTM performance specification does not meet this test.

¹⁸ Comments from Andrea Gielen, Professor and Director, Johns Hopkins Center for Injury Research and Policy. 24 September 2012.

¹⁹ Comments from Scott Krugman, President of the Maryland Chapter of the American Academy of Pediatrics. 28 September 2012.

²⁰ Comments from Gene Ransom, III, Chief Executive Officer of MedChi. 28 September 2012.

Conclusion

In comments to the Department, the Juvenile Products Manufacturers Association has compared baby bumper pads with high chairs, strollers, and car seats. The Department rejects this analogy. Unlike these other products, baby bumper pads do not provide important benefits to infants and their families. Rather, these products pose an unreasonable safety risk and should not be for sale as currently designed in our state.

After 18 months of data review, analysis, and public input, we concur with the American Academy of Pediatrics that baby bumper pads as currently designed are “inherently risky and unnecessary.”

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 of Title 22, Subtitle 5 of the Health-General Article of the Annotated Code of Maryland is met with respect to baby bumper pads. The Department finds a crib bumper pad is a “toy or other substance intended for use by children that presents a mechanical . . . hazard.”

We support the regulation as proposed. Thank you for the opportunity to testify today.