



United States
CONSUMER PRODUCT SAFETY COMMISSION
4330 East-West Highway
Bethesda, Maryland, 20814

MEMORANDUM

DATE: November 27, 2006

TO : HS

Through: Todd A. Stevenson, Secretary, OS *TAS*

FROM : Martha A. Kosh, OS *mak*

SUBJECT: Infant Cushion/Pillows; Advance Notice of Proposed Rulemaking

ATTACHED ARE COMMENTS ON THE CF 07-1

<u>COMMENT</u>	<u>DATE</u>	<u>SIGNED BY</u>	<u>AFFILIATION</u>
CF 07-1-1	11/02/06	Bonnie Cable RN, IBCLC	Mt Carmel Health Outpatient Lactation 5965 E Broad St, Suite 100B Columbus, OH 43212
CF 07-1-2	11/06/06	C. M-Street RN, IBCLC	Lakeland Lactation Center W3985 County Rd NN Elkhorn, WI 53121
CF 07-1-3	11/20/06	M. Truesdale Director	Baby Matters mtruesdale@baby-matters.com
CF 07-1-4	11/20/06	Jane Kershaw	Jane.Kershaw@HCAHealthcare.com
CF 07-1-5	11/21/06	Peggy Andrews	AndrewPK@ah.org
CF 07-1-6	11/22/06	Sally Wodicka RN, IBCLC	Community Memorial Hospital W180 N8085 Town Hall Rd. Menomonee Falls, WI 53051
CF 07-1-7	11/22/06	J.B. Beckwith	beckwithbrowning@earthlink.net
CF 07-1-8	11/23/06	Nancy Engle	gengle1@twcny.rr.com
CF 07-1-9	11/25/06	S.E. Skoug	gaapaa@yahoo.com

*Boston
Billow 1***Stevenson, Todd A.**

From: Cable, Bonnie [bcable@mchs.com]
Sent: Thursday, November 02, 2006 3:47 PM
To: Stevenson, Todd A.
Cc: gaapaa@yahoo.com
Subject: infant cushions/pillows ANPR

Hello,

I have been working with breastfeeding mothers for over 20 years. I am a board certified lactation consultant and a registered nurse. I am writing to express my support for the Boston Billow nursing pillow product. We have sold and used the pillow for 5 years and have never had any negative feedback or experiences with the pillow. I use the pillow daily in my practice, and mothers love it. I love it also. It is the best nursing pillow I have ever found, and I think we have tried them all.

I find it hard to imagine what the problem is. I cannot see how the product could pose any danger. It supports the baby when the baby is nursing. It is not used for sleep, or any other purpose. The Billow is a super product. It's flexibility allows it to fit around women of all shapes and sizes. It is washable, durable, and light weight. I find the phrase "much ado about nothing" coming to mind when I try to understand all the hoopla about the possibility of injury from this product. How is the world is that possible?

I love the Billow. I have used it for years and continue to love it. Nursing support type billows are widely available in stores, through catalogs, and through online sources. They have been available for years. Products of this typed are helpful. The Billow is the best of the bunch. I cannot imagine why in the world anyone would need a prescription for any product of this type.

Please know that I would never use or recommend any product that could be dangerous to any mother or baby. The billow is in no way a dangerous product. I think it is a wonderful, unique product that is tremendously helpful to nursing mothers.

Thanks you.

Bonnie Cable RN,IBCLC

Mt. Carmel Health Outpatient Lactation

5965 E. Broad St., Suite 100B

Columbus, OH 43213

11/9/2006

614-234-8130

bcable@mchs.com

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"This electronic message transmission contains confidential or privileged informati
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Kosh, Martha A.

From: Stevenson, Todd A.
Sent: Monday, November 06, 2006 11:03 AM
To: [REDACTED]
Subject: FW: Nursing Pillows
Importance: High

From: carol.mcshane-street@aurora.org [mailto:carol.mcshane-street@aurora.org]
Sent: Sun 11/5/2006 2:52 PM
To: Stevenson, Todd A.
Subject: Nursing Pillows

To Whom It May Concern,

I am writing in regard to the CPSC request for public comment on the use and purchase of nursing pillows.

I am a board certified Lactation Consultant working in a hospital in the state of Wisconsin. I have been working in Obstetrics for over 20 years and specialized in the field of lactation for over 10 years. It is common knowledge for those of us working with nursing mothers that comfortable positioning of the mothers' arms and shoulders is a crucial aspect of successful breastfeeding. I have seen mother's using several different types and brands of pillows over the years and in my opinion the Boston Billow Pillow is superior to the others on the market for ease of positioning of the mother.

I have never recommended to a mother that she use a pillow as something to position the baby on. **Babies at the breast are cradled in the mother's arms** and the support of a pillow is *under* the mother's arm. This is true of any pillow - even a common bed pillow. I am aware of one nursing pillow on the market that includes in its marketing use as a support pillow for the infant. To my knowledge, the Boston Billow company has never advertised in this way and Lactation Consultants don't condone the propping of babies on any pillow. Evidently this is where the concern of the CPSC has been directed and I believe the concerns should be focused on any company that advertises propping babies on a pillow rather than focusing on a product that is to be expressly used by mothers. I understand you have described the Boston Billow nursing pillow as an "infant cushion". If you look at the major competitor's advertising I think you will find they are the ones that describe their own product for use by the infant and not Boston Billow.

Not all Lactation Consultants are working in a practice with retail sales of products. It would greatly diminish our ability to advise the mother on what may provide the best support for her if the sale of certain nursing pillows is restricted to a medical sales facility or by prescription. Convenience of obtaining any product as well as cost are huge factors for most new parents. As professionals, you would be restricting the way we advise our patients if we cannot reasonably assure them that the product is available in their area for purchase at a reasonable cost. Physicians have little interest in the process to become successful at breastfeeding, let alone taking time for prescribing a nursing pillow. Insurance providers will probably not cover the cost of an item of this nature. This seems like an unreasonable request.

11/6/2006

The current wording of the proposed amendment would eliminate board certified Lactation Consultants to recommend a particular nursing pillow. At the very least, you should add to the proposed amendment request, "and other qualified professionals".

Just because one company in the United States has become very well-known and popular for producing a nursing pillow does not mean they produce the best nursing pillow. It is certainly not in the best interest of the consumer - new mothers - for one company to have a monopoly on the market. The company that I suspect brought forward the concerns due to competition in the first place is one that I would never recommend to a new mother for breastfeeding. It simply doesn't work well for the mothers and then they resort to using it to place the baby on (as indicated in the photos with the product at purchase) rather than for their own arm support. Below is a link to the specific use indicated by the largest seller of nursing pillows in the U.S. I have never seen this indication for use from any other nursing pillow manufacturer and never from Boston Billow.

<http://www.boppy.com/howitwork.asp?sts=11%2F5%2F2006+12%3A44%3A17+PM&mscssid=QBH6TT3P5WA29GRHMG2S3J4JL2ME6QL2>

I believe in this particular issue the CPSC has been misled in their concerns for safety regarding the Boston Billow Nursing Pillow. Nursing pillows should not be for use by the infant, but for use by the mother. ALL pillows on the market, regardless of the shape or content, should be labeled "Not for use by infants". Unless you are planning to restrict the sale of every pillow on the market used by adults, I believe your energies would be better spent on this focus.

Sincerely,
Carol A. McShane-Street, RN, IBCLC
Lakeland Lactation Center
W3985 County Road NN
Elkhorn, WI 53121-1002
(262) 741-2814
carol.mcshane-street@aurora.org

Stevenson, Todd A.

*infant
cushion
ANPR
3*

From: Marguerite Truesdale [mtruesdale@baby-matters.com]
Sent: Monday, November 20, 2006 2:31 PM
To: Stevenson, Todd A.
Cc: gaapaa@yahoo.com
Subject: infant cushion/pillows ANPR

I am a certified parent educator and I teach breastfeeding classes. I have been a big fan of the Billow Nursing pillow. It is a flexible nursing pillow and as such serves tall, medium, and short women very well as opposed to the more set height of most nursing pillows. I would very much like to have this nursing accessory back in circulation so I could recommend it to my clients.

Thank you for your attention to this matter.

Marguerite Truesdale, RN,BS,CCE

Director: Baby Matters- Birthing Basics and Beyond

*Janet
Christine
ANPR 4*

Stevenson, Todd A.

From: Kershaw Jane [Jane.Kershaw@HCAHealthcare.com]

Sent: Monday, November 20, 2006 2:49 PM

To: Stevenson, Todd A.

Subject: Infant cushions/pillows ANPR

I believe infant support pillows should be marketed appropriately. Let the marketplace decide on their effectiveness, as long as they do not harm. Infant pillows are still sold, pillows of all types are still sold and adults will sometimes use them inappropriately. Do we ban all pillows because some adults use them incorrectly with babies? As a lactation consultant and the manager of a support service that markets breastfeeding aids, I have used several different types of support pillows with babies. Our mothers and babies seem to like the Boston Bellow the best because of its ability to be conformed to the shape of the mother and adjusted to provide firm support to the baby, regardless of its weight or size. I don't want to restrain free trade of other brands of pillows, but I don't think it's so much a health and safety jeopardy issue as it a preference issue. If we were discussing breast pumps, I would be much more stringent on requirements! The Boston Bellow is an important adjunct to helping mothers, but it is not a medical device and causes no harm. The only thing I would think that would drive others to ban it would be a wish to restrain free trade and reduce competition.

Jane Kershaw, RN, BA, IBCLC
Coordinator, Lactation Support Services
Centennial Medical Center

11/20/2006

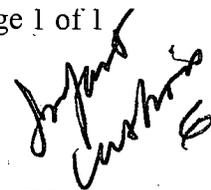
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cushions
5*

Stevenson, Todd A.

From: Peggy Andrews [AndrewPK@ah.org]
Sent: Tuesday, November 21, 2006 1:39 PM
To: Stevenson, Todd A.
Subject: infant cushions/pillow

I am a lactation consultant, labor, delivery and nursery RN. I recommend the Boston Billow for positioning breastfeeding infants especially in situations where latch is difficult. and infants are frail. This is the best positioning tool I have found in 39 years of helping new moms. Please look at the logic of laws and do not include this product in your "infant sleeping pillow" legislation.

11/21/2006

**Stevenson, Todd A.**

From: Sally Wodicka [swodicka@communitymemorial.com]**Sent:** Wednesday, November 22, 2006 1:45 PM**To:** Stevenson, Todd A.

"Infant cushions/pillows ANPR"

11/22/06

I am responding to an email I received regarding the use of the Boston Billow Nursing Pillow and all of the legal brick walls it has had to contend with. I am so sick of the bureaucracy surrounding this issue I could scream. Is this America, or not? The Boston Billow is a superior product for use as a nursing pillow. It is flexible, light weight, easily transportable, washable, and affordable. With all of the 'Back to Sleep' campaign promotion going on, I believe it is clear to new parents NOT to use this or any item similar to it (Boppy, My Breast Friend, etc.) as a head supporting pillow in the crib or anywhere near where baby sleeps. Not only do I not recommend or endorse in any way any pillow competitor, I now boycott the Boppy based on their business ethics. If your product cannot stand alone on it's own merit, than it should swim with the fishes and take its chances like all other fair market products! The nonsense that a Physician or LC must order the Pillow is outrageous! It is not a durable medical equipment item, and should not be treated as such. There are many physicians that are not even up to date on breastfeeding much less, breastfeeding accessories. Many LC's do not or cannot carry retail items so may run into trouble ordering that a mom get a billow. These should be available wherever infant products are sold. What's next? Must we have every new mom obtain a doctors' order to purchase a nursing bra? Let's leave the educated choice up to the moms, and take it out of the hands of the government. Aren't there more important issues to be dealing with? Please let's move along on this issue and get us back the best nursing pillow on the market, the Boston Billow Nursing Pillow!!!!

Sincerely,

Sally Wodicka, RN, IBCLC
Lactation Services
Community Memorial Hospital
W180 N8085 Town Hall Rd.
Menomonee Falls, WI 53051
(262)257-5030

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11/24/2006

Stevenson, Todd A.

infant pillow 7

From: Bruce Beckwith and Nancy Browning [beckwithbrowning@earthlink.net]
Sent: Wednesday, November 22, 2006 11:21 AM
To: Stevenson, Todd A.
Subject: Boston Billows

I am writing to add my voice to those asking you to cease delaying tactics and remove your ban on the sale and use of the Boston Billows nursing pillow. I am a pediatric pathologist with extensive experience with Sudden Infant Death Syndrome (SIDS) and other natural and unnatural causes of sudden death in infants. For 20 years I was responsible for the autopsy and investigation of every case of sudden unexpected infant death in King County, Washington. During that period not a single infant expired unexpectedly during breast feeding. SIDS is a phenomenon that occurs during sleep, and this product has no relationship to infant sleep-its design would make it difficult if not impossible for an infant to assume a sleeping position. Its surface characteristics make it impossible to mold to the infant face. It is not surprising that no case of infant death has been documented during use of this product.

The Boston Billows pillow has been shown to be a popular and effective means of encouraging and facilitating breast feeding. Breast feeding has been consistently shown to be associated with a reduced risk of SIDS. By preventing access to this product you are in fact doing the opposite of protecting infants.

Lest you suspect that my reaction is motivated by any pecuniary or other interest in this product, I assure you I have never received compensation of any sort, nor have I any expectation of such compensation in the future. I was given an example of the product to examine and keep, but that is the only thing I have ever received, or intend ever to receive, from the manufacturers of this product. My only interest and motivation in this matter is the protection and welfare of infants through the encouragement of breast feeding.

Respectfully,
J. Bruce Beckwith MD

*infant cushions***Stevenson, Todd A.**

From: Nancy Engle [gengle1@twcny.rr.com]
Sent: Thursday, November 23, 2006 4:08 PM
To: Stevenson, Todd A.
Subject: [Possibly SPAM (k):] - Infant cushions/pillows ANPR - Found word(s) drugs in the Text body

I have been following the decisions related to the Boston Billow nursing pillow over the past few years. Prior to the ban and recall of this pillow, I carried this pillow in my inventory, and found it to be very helpful to nursing mothers.

I am confused over the controversy with these pillows, as they were designed and marketed for use while mothers were breastfeeding their babies. This means that they are only used when the mother and the baby are together, not when the baby is by itself (unlike some of the other nursing pillows which are advertised for use to prop baby other than in the parent's arms). Because of this, I would not define it as an infant cushion, but a nursing pillow, .

If there is still concern about the use of this pillow, I would think that written cautions on the tag as well as other packaging regarding not using it without competent adult supervision (similiar to safe sleep recommendations as far as adult not under the influence of alcohol or drugs, etc.). In addition to to this, education and recommendation for use by a healthcare professional would, I believe, reduce the risk of injury or death.

Although as a Maternity Nurse and Lactation Consultant, I would love to be able to direct every new mother to purchase only what she really needs to care for her baby, and the safest products to accomplish that, I'm not sure that it would be practical to require that there be a written recommendation or prescription for such products. Perhaps limiting the distribution and sale of infant cushions/pillows to healthcare product companies or medical professionals would add to the safety of this product. In a specialty company as opposed to mass marketing, the employees should theoretically have a greater knowledge of the product and recommendations for use. This would provide another opportunity to educate the purchaser individually regarding safety issues.

In conclusion, I look forward to hearing that an ammendment has been made to the 1992 Federal Regulations to allow an exception to the ban on infant cushions/pillows when the product is specifically designed, intended and promoted for mothers to use when breastfeeding. If these items were available when recommended by a physician, a board certified lactation consultant, or other qualified medical personnel as mentioned above, this would allow pillows such as the Boston Billow nursing pillow to be safely used to help breastfeeding mothers and babies.

Sincerely, Nancy M. Engle, RN, IBCLC, RLC
Owner, Feedemright (Breastfeeding help and supplies)
Lowville, NY

*Infant
cushions 9***Stevenson, Todd A.**

From: S. Erik Skoug [gaapaa@yahoo.com]
Sent: Saturday, November 25, 2006 12:49 PM
To: Stevenson, Todd A.
Subject: Infant cushions/pillows ANPR

Sirs:

There are numerous types of nursing pillows available in the market. Strangely enough the CPSC has not taken action against nursing pillows filled with polyester fiber. Healthcare research has long established that such fibers may cause infant allergies and be a cause of asthma development. This will be so especially when wet, something that will be the case with babies breastfeeding and urinating etc. Under such circumstances, and otherwise, polyester fiber and similar fillings may harbor dust mites and other microscopic insects where feces will build up over time and cause these allergies or induce asthma developments. The sale of such infant cushions/pillows should therefore be restricted. (See comments below.) Nursing pillows filled with beads that are not water permeable can be washed. Washing pillows filled with polyester fiber is difficult and inefficient, at best.

Limiting the sale of infant cushions/pillows:

Health issues with infant cushions is best countered by limiting the sale to stores in, or directly associated with, hospitals and to sales by medical professionals like pediatric offices, lactation consultants etc. Single unit Internet purchases should be permitted provided a purchase is recommended by a named lactation consultant.

Recommendations by medical professionals:

Medical professionals are the only ones with the background to determine if an infant cushion/pillow is needed for a mother with a newborn baby and which type of infant cushion/pillow will be best for the mother and her baby. Requiring a written recommendation will be accepted by the medical community and will work although we question whether it will be practical or even effective.

Sincerely,

S.E.Skoug.

"Injury or death" in connection with nursing pillows

Everyone is raving about [the all-new Yahoo! Mail beta](#).

11/27/2006