



United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: December 13, 2005

TO : HSHS

Through: Todd A. Stevenson, Secretary, OS 

FROM : Martha A. Kosh, OS

SUBJECT: Petition HP 05-1, Petition Requesting Amendment to Ban
on Infant Pillows

ATTACHED ARE COMMENTS ON THE CH 06-1

<u>COMMENT</u>	<u>DATE</u>	<u>SIGNED BY</u>	<u>AFFILIATION</u>
CH 06-1-1	11/16/05	Susan Brown President	The Boppy Company 560 Golden Ridge Road Suite 150 Golden, CO 80401
CH 06-1-2	11/29/05	Alan Korn Director of Public Policy & General Counsel	Safe Kids Worldwide tross@safekids.org
CH 06-1-3	12/08/05	S. Erik Skoug President	Boston Billows, Inc. 28 Charron Ave. Nashua, NH 03063
CH 06-1-3a	2/07/06	S. Erik Skoug	Address same as above
CH 06-1-4	01/23/06	Heather Anderson	hyrubyslippers@yahoo.com
CH 06-1-5	02/07/06	Matt Day	gibbiss@yahoo.com

Boston Billows, Inc.

December 8, 2005

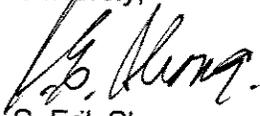
Division of Information Management
(Office of the Secretary)
Room 502
Consumer Product Safety Commission
4330 East West Highway
Bethesda
Maryland 20814

Petition HP 05 – 1.
Petition Requesting Amendment to Ban on Infant Pillows.

Enclosed please find, in 5 copies, letters of support of our petition for an amendment
To the Federal Regulations, reference HP 05-1.

Also, we enclose a list with the name and address of the individuals who have written
Letters of support.

Sincerely,



S. Erik Skoug
President.

Enclosed: 5 binders with letters of
support.
List with names and addresses.

28 Charron Avenue, Nashua, N.H. 03063.
Telephone: 603-598-1200 * E-mail: Contact@bostonbillows.com
www.bostonbillows.com.

Boston Billows, Inc.

December 8, 2005

Division of Information Management
(Office of the Secretary)
Room 502
Consumer Product Safety Commission
4330 East West Highway
Bethesda
Maryland 20814

Petition HP 05 – 1.
Petition Requesting Amendment to Ban on Infant Pillows.

Names and addresses of the individuals who have written letters of support.
(Alphabetically listed.)

Beth Allen, BSN, RNC, IBCLC
Northside Hospital
1000 Johnson Ferry Road
Atlanta
GA 30342
Tel: 404-303-3966

J. Bruce Beckwith, MD
88 Brookside Way
Missoula
MT 59802
Telephone: 406-549-4247

Marylee Brigham, RN, BNS, IBCLC
University of Washington Medical Center
1959 North East Pacific Street
Seattle
Washington 98195
Tel: 206-598-4628

Cable, Bonnie, RN, IBCLC
Mount Carmel Women's Health Center.
5965 E. Broad street
Suite 100
Columbus, OH 43213-0970
Tel: 614-234-8130

28 Charron Avenue, Nashua, N.H. 03063.
Telephone: 603-598-1200 * E-mail: Contact@bostonbillows.com
www.bostonbillows.com.

Karin Cadwell, Ph.D. RN, FAAN, IBCLC
Healthy Children
8 Sebastian Way
East Sandwich
MA 02537
Tel: 508-888-8044

Diane DiSandro, BA, IBCLC
Audubon,
PA
Tel: 610-539-4476

Debi Page Ferrarello, RN, MS, IBCLC
Director Emeritus
Breastfeeding Resource Center
117 North Easton Road
Glenside
PA 19038
Tel: 215-886-2433

Rebecca Gorus, IBCLC
St. Mary's Medical Center
P.O.B. 1477
Walla Walla
WA 99362
Tel: 509-529-3320

Brenda Hallmark, RN, IBCLC
Medical Center East Hospital
50 Medical Park East Drive
Birmingham
AL 35235
Tel: 205-838-3457

Opal Horvat, IBCLC, RLC
197 Phelps Avenue
Bergenfield
NJ 07621-1452
Tel: 201-387-1601

Jane Kershaw, RN, BA, IBCLC
A Mother's Place Lactation Support Services
Women's Hospital
Centennial Medical Center
3304 Briley Park
Nashville
TN 37203
Tel: 615342-5650

Annette Leary, BSN, IBCLC, RLC
Arnold Palmer Hospital
1414 Kuhl Avenue
Orlando
FL 32806
Tel: 321-843-2229

Linda McGee, RNC, IBCLC
Baptist Memorial Hospital for Women
6225 Humphreys Boulevard
Memphis
TN 38120
Tel: 901-227-9621

Jessica Minnick, RN, IBCLC
Lactation Department
St. Joseph Medical Center
Franciscan Breast Feeding Services
1717 South J. Street
Tacoma
WA 98401
Tel: 253-627-4100

Virginia Moore, RN, RLC, IBCLC
PHELPS Memorial Hospital Lactation Center
701 North Boulevard
Sleepy Hollow
Terrytown
NJ 10591
Tel: 914-366-2394

Mary Nettles, RN, BS, IBCLC
Northern Dutchess Hospital
10 Springbrook Road
Rhinebeck
NY 12572
Tel: 845-871-3365

Patsy Sanders, RN, BSN, IBCLC
Comanche County Memorial Hospital
Breastfeeding Resource Center
3401 W. Gore Boulevard
Lawton,
OK 73505
Tel: 580-355-8620

Carol A. McShane-Street, RN, IBCLC
Lakeland Lactation Center
W 3985 Country Road NN
Elkhorn
WI 53121-1002
Tel: 262-741-2814

Boppy

Boston
Billow
Pet

November 16, 2005

Consumer Product Safety Commission
Office of the Secretary
4330 East-West Highway, Room 502
Bethesda, Maryland 20814

Re: Petition HP 05-1, Petition Requesting Amendment to Ban on Infant Pillows

Dear Sir or Madam:

I am writing on behalf of The Boppy Company ("Boppy") to provide comments on why the Consumer Product Safety Commission ("CPSC") should reject Petition HP 05-1, Petition Requesting Amendment to Ban on Infant Pillows (Petition), filed by Boston Billows, Inc. on July 17, 2005. Boppy is the maker of the Boppy® infant nursing and support pillow and many other products for infants and children. Boppy has sold millions of nursing and support pillows. We are vigilant in ensuring the safety of its products. Infant safety is a priority of Boppy and, we believe, should be a priority and guiding principle for the entire infant products industry.

For more than a decade, the CPSC has maintained a ban prohibiting the sale of any infant support pillow that has the following characteristics: (1) a flexible fabric cover, (2) is loosely filled with granular material, including but not limited to, polystyrene beads or pellets, (3) is easily flattened, (4) is capable of conforming to the body or face of an infant, and (5) is intended or promoted for use by children under one year of age. *See* 16 C.F.R. 1500.18(a)(16)(i). Based on this criteria, the CPSC recently banned the Boston Billow nursing pillow. Specifically, the CPSC found that "[i]f infants are placed on these pillows and left unattended, there is a risk of suffocation." *See* CPSC Recall Announcement of the Boston Billows nursing pillow attached as Exhibit A.

In the Petition, Boston Billows requests that the CPSC compromise infant safety in order to advance Boston Billows' economic interests. Specifically, Boston Billows asks that the CPSC relax its prohibition on unsafe infant pillows to allow the use of otherwise banned pillows if they are "specifically designed, intended and promoted for mothers for use when breastfeeding and requested by a Pediatrician or a Board Certified Lactation Consultant." The CPSC should reject the Petition for several important reasons.

If granted, the Petition inevitably would expose infants to dangerous pillows during infant playtime and other non-breastfeeding activities. Even if a particular infant pillow is "specifically designed, intended and promoted for mothers for use when breastfeeding," this will not prevent parents from using the pillow for non-breastfeeding activities. It is widely known in the baby products industry that countless parents use infant support pillows for playtime. In particular, parents use infant support pillows for "tummy time" where parents will rest a baby's chest and stomach on a pillow to allow the baby to develop upper body strength. Given this usage, it is inevitable, in our view, that some parents unknowingly would use the otherwise banned infant pillow for tummy time or other playtime activities. Such usage of the pillow would create the substantial threat of suffocation already identified by the CPSC.

Moreover, the fact that Boston Billows claims in the Petition that its infant pillow is used safely for breastfeeding *in hospitals* does nothing to ensure that its pillows would be exclusively used for breastfeeding when parents return home. As the CPSC undoubtedly is aware, use of equipment by parents in a hospital under the supervision of highly trained doctors and nurses is not the same environment as parents (and infants) encounter at home. Because there is no way to ensure that parents will only use infant support pillows for breastfeeding, the CPSC should maintain its ban on all unsafe infant pillows regardless of whether manufacturers specifically design and promote them for breastfeeding.

Further, the criteria proposed in the Petition would be impossible to implement and enforce. Nothing in the Petition sets out standards that infant pillows must attain to be "specifically designed, intended and promoted for mothers for use when breastfeeding." Because of this, any manufacturer could argue that its infant support pillow falls under this exception if the pillow is used for breastfeeding. Additionally, the Petition does not set forth any mechanism to determine when a particular support pillow is "requested by a Pediatrician or a Board Certified Lactation Consultant." Does this mean that in order to buy an otherwise unsafe infant pillow, a parent needs a specific request from a pediatrician or board certified lactation consultant? Does this request need to be written, and, if so, in what form? More importantly, who would ensure this requirement was satisfied? These questions, and many more, are left unanswered by the Petition, and leave the Petition wholly unworkable.

We expect that the safety of infants alone is sufficient reason for maintenance of the ban. However, even if evaluated purely from an economic perspective, there is no justification for the relief sought by Boston Billows. From the consumer's perspective, there are a number of infant support pillows on the market other than the Boston Billows product. These other products are designed to meet the breastfeeding needs of parents and are required to comply with the CPSC's safety standards. There is no consumer need for the Boston Billows product, certainly none sufficient to warrant risking the lives of infants. In addition, the harm to the industry from just one incident with a child resulting from an unsafe pillow could create a cloud over the industry far more serious and important than the narrow economic interests of Boston Billow. Thus, there is absolutely no reason to risk exposing infants to unsafe pillows.

Consumer Product Safety Commission

November __, 2005

Page 3

For these reasons, Boppy strongly encourages the CPSC to reject the Petition in its entirety and maintain its present safety standards for infant support pillows. If you have any questions, or would like additional input from Boppy on this matter, please do not hesitate to contact me. Thank you for your time and attention.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Susan Matthews Brown', with a large, sweeping flourish extending to the right.

Susan Matthews Brown
President

Enclosure

60633226 v2

NEWS from CPSC

U.S. Consumer Product Safety Commission

Office of Information and Public Affairs

Washington, DC 20207

FOR IMMEDIATE RELEASE

September 1, 2004

Release # 04-205

Firm's Hotline: : (877) 274-4606

CPSC Consumer Hotline: (800) 638-2772

CPSC Media Contact: (301) 504-7908

CPSC, Boston Billows Inc. Announce Recall of Nursing Pillows

WASHINGTON, D.C. - The U.S. Consumer Product Safety Commission announces the following recall in voluntary cooperation with the firm below. Consumers should stop using recalled products immediately unless otherwise instructed.

Name of product: Boston Billows Nursing Pillows

Units: About 8,000

Manufacturer: Boston Billows Inc., of Nashua, N.H.

Hazard: If infants are placed on these pillows and left unattended, there is a risk of suffocation. Infant pillows and cushions are banned under the Federal law. Infant pillows have a flexible fabric covering, are loosely filled with plastic beads, easily flattened, intended for use by infants under 1 year old, and capable of conforming to the body or face of an infant.

Incidents/Injuries: None reported.

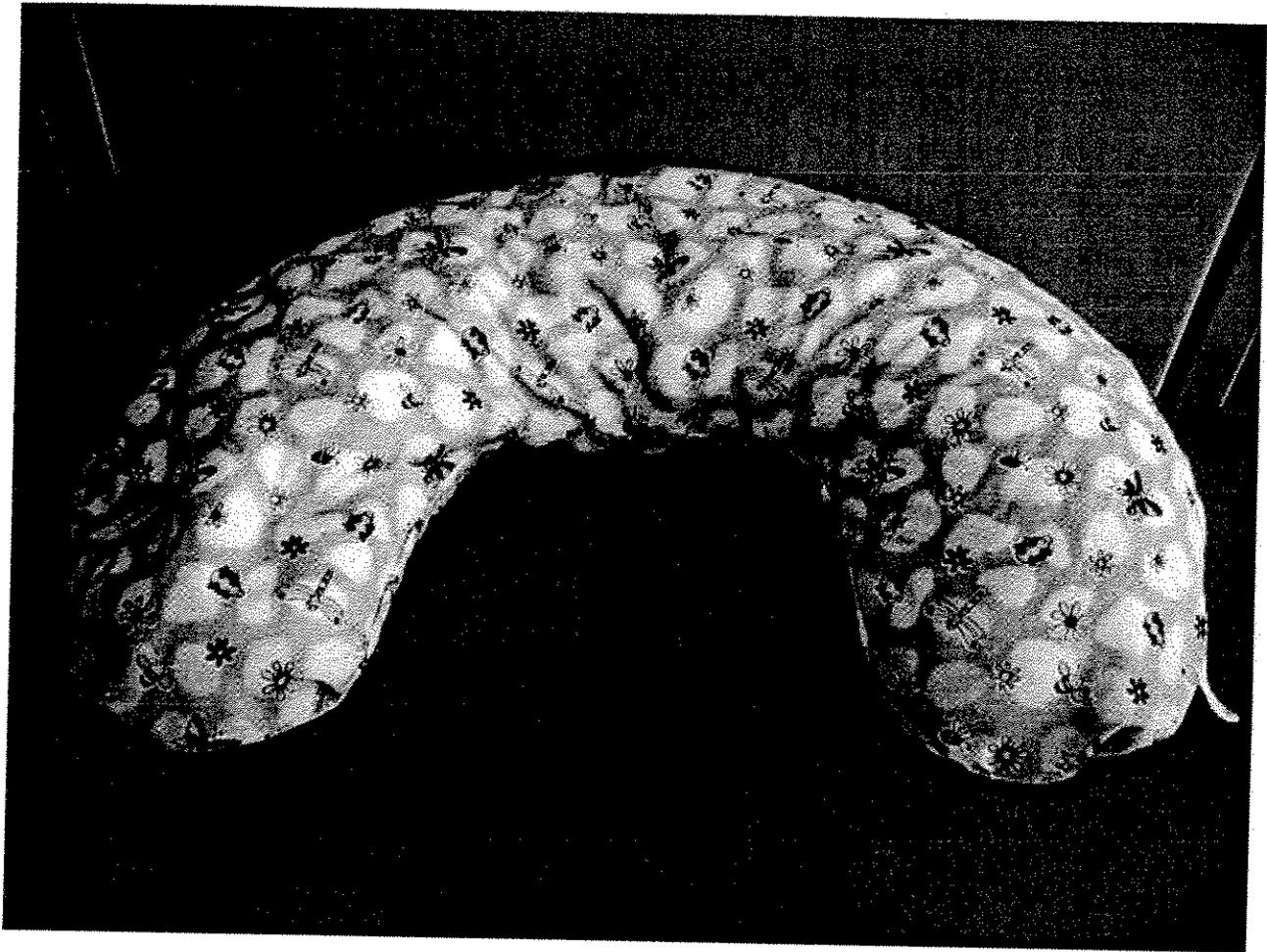
Description: The "C"-shaped pillows are about 36-inches long, 10-inches wide and 5-inches deep. There is a 100 percent cotton hypoallergenic cover of various colors and prints over the white pillow. The outer cover is removable. The whole pillow is washable. The fabric tag on the pillow reads, "Boston Billows, Inc."

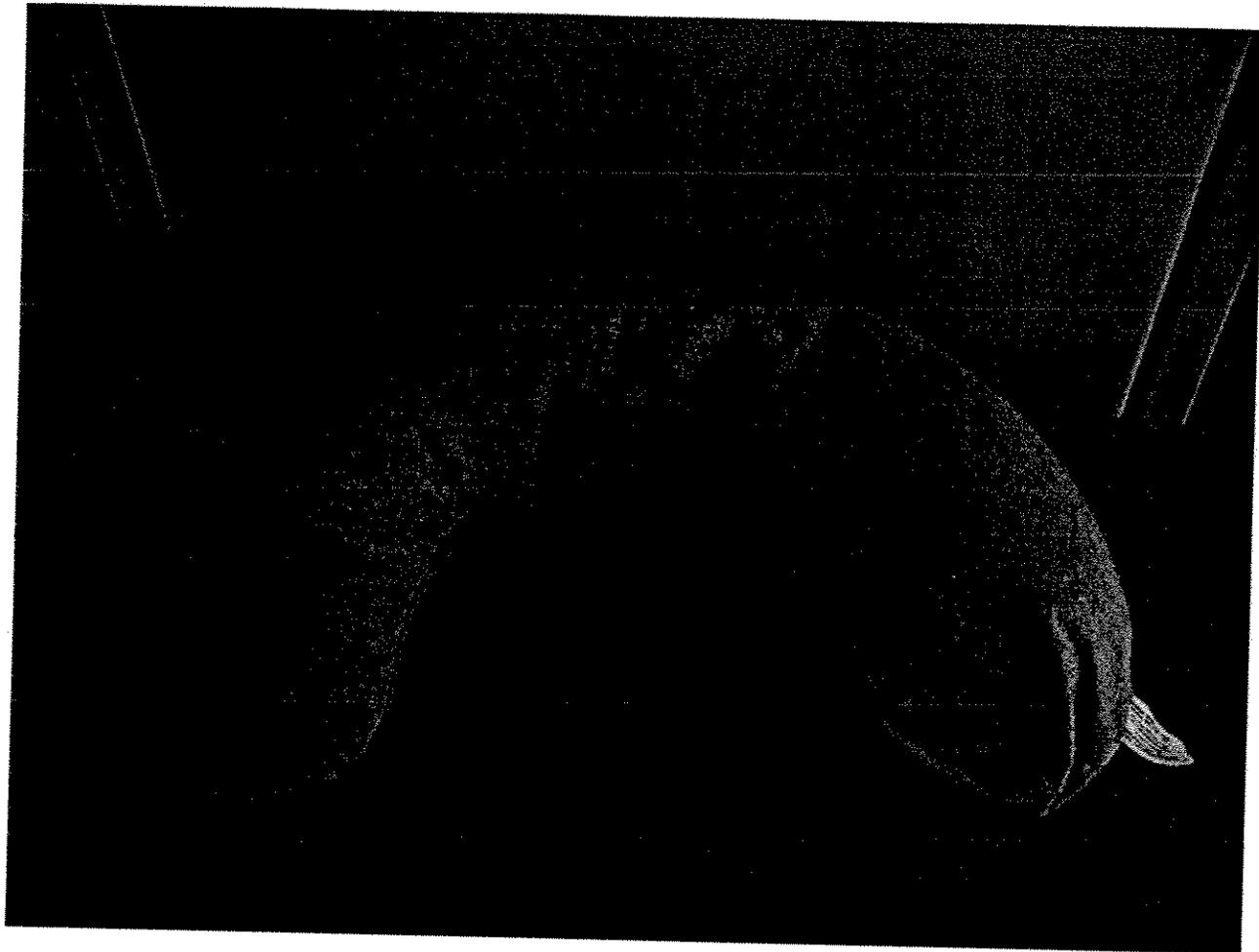
Sold at: Hospitals and independent specialty stores from February 2000 through December 2003 for between \$34 and \$38.

Manufactured in: U.S.A. Materials of U.S.A. and Philippines origins.

Remedy: Consumers should stop using these pillows immediately and contact the firm for information on receiving a refund.

Consumer Contact: Consumers can contact the Boston Billows Inc. at (877) 274-4606 between 9 a.m. and 5 p.m. ET Monday through Friday.





Send the link for this page to a friend! The U.S. Consumer Product Safety Commission is charged with protecting the public from unreasonable risks of serious injury or death from more than 15,000 types of consumer products under the agency's jurisdiction. Deaths, injuries and property damage from consumer product incidents cost the nation more than \$700 billion annually. The CPSC is committed to protecting consumers and families from products that pose a fire, electrical, chemical, or mechanical hazard or can injure children. The CPSC's work to ensure the safety of consumer products - such as toys, cribs, power tools, cigarette lighters, and household chemicals - contributed significantly to the 30 percent decline in the rate of deaths and injuries associated with consumer products over the past 30 years.

To report a dangerous product or a product-related injury, call CPSC's hotline at (800) 638-2772 or CPSC's teletypewriter at (800) 638-8270, or visit CPSC's web site at www.cpsc.gov/talk.html. To join a CPSC email subscription list, please go to www.cpsc.gov/cpscclist.asp. Consumers can obtain this release and recall information at CPSC's Web site at www.cpsc.gov.

Boston
Billows



November 29, 2005

Todd Stevenson
Secretary
U.S. Consumer Product Safety Commission
Washington, D.C. 20207

RE: Petition HP 05-1, Petition Requesting Amendment to Ban on Infant Pillows

Dear Mr. Stevenson:

On behalf of Safe Kids USA, a member of Safe Kids Worldwide (hereinafter "Safe Kids"), I am writing in response to a request for comments, published in the October 13, 2005 issue of the *Federal Register*, for petition HP 05-1 that proposes a specific product amendment to the ban on infant pillows. Safe Kids believes that the U.S. Consumer Product Safety Commission (CPSC) should exhibit the utmost of caution before granting this requested exemption, if at all, because the exemption and accompanying introduction of this product in the marketplace could increase the likelihood of infant suffocation.

Safe Kids believes that the following points should be considered when the CPSC deliberates whether or not to grant the petition. First, the Boston Billow was voluntarily recalled in September, 2004 for being in violation of the federal infant cushion banning rule. Under the rule, cushions that have a flexible fabric covering, are loosely filled with plastic beads, are easily flattened, are capable of conforming to an infant's body or face, and are intended or promoted for children under one year of age, are banned from being sold. If infants are placed on these types of pillows and left unattended, there is a risk of suffocation. Accordingly, the Boston Billow was recalled for meeting all these conditions. It is our understanding that the product today has not been re-engineered or otherwise changed in any way and still has all the characteristics that the CPSC found so dangerous in 2004. While Safe Kids is supportive of products in the marketplace that promote effective breastfeeding, we believe that the risk of suffocation may outweigh any convenience factor that the cushion might bring to a nursing mother.

Furthermore, the CPSC and organizations like Safe Kids consistently tell parents and caregivers to remove soft bedding, such as pillows, quilts, comforters and sheepskins, from the crib environment in order to prevent Sudden Infant Death Syndrome (SIDS) and suffocation-related deaths. If the petition is granted, the possibility exists for a parent/caregiver to place the Boston Billow in their child's crib and consequently, endanger that child's life. It is estimated that as many as 900 infants whose deaths are attributed to SIDS each year are found in potentially suffocating environments, frequently on their stomachs, with their noses and mouths covered by

soft bedding. Soft bedding in any form is completely unacceptable in the crib environment and CPSC approval of the petition may inadvertently promote this dangerous practice.

Safe Kids believes that any decision to amend the infant cushion banning rule should be taken very seriously as airway obstruction injury (including choking, suffocation and strangulation) is the leading cause of accidental injury-related death among infants under age one. I am available to answer any questions that the CPSC might have relating to our comments. As always, Safe Kids looks forward to working with the CPSC on this and other issues in the future.

Sincerely,

A handwritten signature in black ink, appearing to be 'Alan Korn', with a long horizontal line extending to the right.

Alan Korn, J.D.
Director of Public Policy & General Counsel

Stevenson, Todd A.

From: Chin Ross, Tanya [tross@safekids.org]

Sent: Tuesday, November 29, 2005 2:58 PM

To: Stevenson, Todd A.

Subject: Petition HP 05-1, Petition Requesting Amendment to Ban on Infant Pillows

Please see attached letter regarding Petition HP 05-1, Petition Requesting Amendment to Ban on Infant Pillows.

Thank you and please let me know if you have any questions,

Tanya

Tanya Chin Ross
Senior Public Policy Associate
Safe Kids Worldwide
Phone 202/662-0606
Fax 202/393-2072
www.safekids.org

Boston Billows, Inc.

December 7, 2005

Division of Information Management
(Office of the Secretary)
Room 502
Consumer Product Safety Commission
4330 East West Highway
Bethesda
Maryland 20814

Petition HP 05-1
Petition Requesting Amendment to Ban on Infant Pillows.

Enclosed please find, in 5 copies, letters of support for an amendment
To the Federal Regulations, reference HP 05-1.

Also, we enclose a list with the name and address of the individuals who have written
letters of Support.

Sincerely,


S. Erik Skoug
President.

28 Charron Avenue, Nashua, N.H. 03063.
Telephone: 603-598-1200 * E-mail: Contact@bostonbillows.com
www.bostonbillows.com.

Boston Billows, Inc.

December 8, 2005

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(Office of the Secretary)
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Names and addresses of the individuals who have written letters of support.
(Alphabetically listed.)

Beth Allen, BSN, RNC, IBCLC
Northside Hospital
1000 Johnson Ferry Road
Atlanta
GA 30342
Tel: 404-303-3966

J. Bruce Beckwith, MD
88 Brookside Way
Missoula
MT 59802
Telephone: 406-549-4247

Marylee Brigham, RN, BNS, IBCLC
University of Washington Medical Center
1959 North East Pacific Street
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Washington 98195
Tel: 206-598-4628

Cable, Bonnie, RN, IBCLC
Mount Carmel Women's Health Center.
5965 E. Broad street
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Karin Cadwell, Ph.D. RN, FAAN, IBCLC
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8 Sebastian Way
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Diane DiSandro, BA, IBCLC
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Tel: 610-539-4476

Debi Page Ferrarello, RN, MS, IBCLC
Director Emeritus
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117 North Easton Road
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St. Mary's Medical Center
P.O.B. 1477
Walla Walla
WA 99362
Tel: 509-529-3320

Brenda Hallmark, RN, IBCLC
Medical Center East Hospital
50 Medical Park East Drive
Birmingham
AL 35235
Tel: 205-838-3457

Opal Horvat, IBCLC, RLC
197 Phelps Avenue
Bergenfield
NJ 07621-1452
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Jane Kershaw, RN, BA, IBCLC
A Mother's Place Lactation Support Services
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3304 Briley Park
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1414 Kuhl Avenue
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6225 Humphreys Boulevard
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701 North Boulevard
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Carol A. McShane-Street, RN, IBCLC
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W 3985 Country Road NN
Elkhorn
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Division of Information Management
(Office of the Secretary)
Room 502
Consumer Product Safety Commission
4330 East West Highway
Bethesda, Maryland 20814

Petition HP 05-1.
Petition Requesting Amendment to Ban on Infant Pillows.

J. Bruce Beckwith, M.D.
88 Brookside Way, Missoula, MT 59802
Phone: (406)549-4247
E-mail: beckwithbrowning@earthlink.net

Re: Proposed CPSC amendment concerning Boston Billow Nursing Pillow

I support in the strongest possible terms your proposed amendment to CPSC rules excluding it from general use on the basis of allegedly unsafe features. I have examined your nursing pillow carefully, and can see no reason for concern about its safety. It is clearly not a device intended for use during prone infant sleep. Its shape would make such sleep virtually impossible. Even if an infant were somehow to fall asleep prone on this device, its firmness and surface characteristics would prevent any molding to the infant face. I find it amazing that such concerns would even occur to anyone who had examined this product.

I was principal investigator on the first NIH-supported research program to investigate causes of sudden unexpected death in infants, and have more than 40 years of experience with both natural and unnatural sudden deaths of infants and children. I have authored numerous publications on this topic in peer-reviewed journals. I am familiar with the extensive medical and scientific literature dealing with concerns related to unsafe sleeping practices in infants, and can see no relevance of any of that literature to the design or intended use of this product.

I have no connection whatsoever with Boston Billows, Inc., and have not received, nor do I expect ever to receive, any financial or other compensation for my support of your cause. My only motivation is to facilitate access to this fine product, because of its demonstrated ability to encourage and support the breast feeding of infants.

Respectfully submitted,

J. Bruce Beckwith MD

Division of Information Management
(Office of the Secretary)
Room 502
Consumer Product Safety Commission
4330 East West Highway
Bethesda,
Maryland 20814

Petition HP 05-1.
Petition Requesting Amendment to Ban on Infant Pillows.

I am writing about the breastfeeding aid, the Boston Billow nursing pillow. We use it exclusively to aid mothers in positioning the baby at breast because it is the only product that can be individually shaped to accommodate the mother's anatomy and the baby's ability.

For example, with a grant from the March of Dimes, we studied the issue of establishing breastfeeding in the community after babies had been born prematurely and had spent weeks or months in the hospital. These babies have poor muscle tone so are often unable to hold their heads in the appropriate position. Also, they lack subcutaneous layers of fat and that includes the fatty pads that term babies have in their cheeks. This means that they cannot hold the nipple in the mouth by themselves; the mother has to use her hands to keep the baby in position. We found that only the Boston Billow was able to aid the mother because it maintained the desired and appropriate position. We were able to assist all of the mothers to breastfeed and the babies will have the advantage of getting their own mother's milk.

I understand that you have concerns about what other uses the mother and other caregivers may have for the pillow after she has used it for breastfeeding. Certain, there are many "innocent" items in the home including stuffed animals, pails, pillows and recliners that have proved lethal to babies and toddlers. I hope that you will find a way, perhaps by attaching a "billow" use tag to the product that will protect the consumer and allow us to continue to use this unique and irreplaceable product.

Thank you for your attention to my concern.

Karin Cadwell, PhD, RN, FAAN, IBCLC
Healthy Children. A non-profit research and educational institution.
East Sandwich, MA 02537
508-888-8044

Division of Information Management
(Office of the Secretary)
Room 502
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4330 East West Highway
Bethesda, Maryland 20814

Petition HP 05-1.
Petition Requesting Amendment to Ban on Infant Pillows.

I am outraged to find out that the Boston Billow is still on hold. We need it for breastfeeding mothers. About 30% of mothers deliver by C-section these days and the Boston Billow allows mom to breastfeed with a light weight pillow that does not put pressure on her incision. The baby is fully supported and mom does not have to strain to hold the infant. It is the most useful pillow, in fact, for all new mothers.

The Boston Billow is safe and there is no reasonable explanation for its ban from marketing except that a large corporate bully that makes another nursing pillow must have seen the brilliance of the product and is trying to put a small company out of business for their own profit. It is un-American. Boston Billow is a perfectly good product. No one has been hurt by it and someone in Washington who made this error should rectify the situation and lift the ban/ restriction to selling the product.

I am a Board Certified Lactation Consultant and I think I know more about this product and its safety and usefulness than do lawyers in Washington, DC.

Opal Horvat, IBCLC, RLC
Bergenfield, NJ
201 387-1601

Division of Information Management
(Office of the Secretary)
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4330 East West Highway
Bethesda,
Maryland 20814

Petition HP 05-1.
Petition Requesting Amendment to Ban on Infant Pillows.

I am quite distressed about the recall of the Boston Billow nursing pillow.

We have safely used this product and its use is for the mothers arm while the infant is lying against the mother's upper arm. Pillow should not be used for infants and we educate our hospital clients and employees about this fact.

In our hospital setting we use a wipeable cover while seeing our baby and mother clients. However, the regular Boston Billow nursing pillow must be made available again because mothers need them.

Virginia CV. Moore, RN, RLC, IBCLC
Phelps Memorial Hospital Lactation Center
914-366-2394

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(Office of the Secretary)
Room 502
Consumer Product Safety Commission
4330 East West Highway
Bethesda,
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Petition HP 05-1.
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Here is why the Boston Billow nursing pillow must be made available again:

I worked with a mother who had to have her gall bladder removed when she was 37 weeks pregnant. The next day she went into labor and was delivered by cesarean section.

This poor mom could not find a position in which to nurse her baby. She had 4 incisions along her abdomen, from the gall bladder surgery and the c-section. She could not stand to have the weight of a pillow on her lap. She could not stand to have anything even touch her abdomen.

We decided to try the Boston Billow nursing pillow.
It worked like a charm !

It was light weight enough for her. We were able to position it about an inch away from her skin, but it still held securely enough that we could get the baby close enough to nurse in a good position without irritating the mother.

Thank you so much for making a wonderful product.

Diane DiSandro, BA, IBCLC
Audubon, PA
ddisandro@comcast.net

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(Office of the Secretary)
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Petition HP 05-1.
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We are with the Franciscan Health System in Washington State.

We were shocked, to say the least, when we heard of the recall for Boston Billows. We were one of the first West Coast Hospitals to start using the Billow. It is actually the only breastfeeding pillow we recommend or sold to our mothers. Breastfeeding is what it is designed for and used as, an aide to help mothers nurse their babies.

It would stand to reason that a competitor would lodge a complaint, especially when it had a corner on the market. The Billow is a superior nursing pillow and it probably would outsell the competitor.

We believe if you reevaluate your decision and actually see and use the Billow, you will see that your decision is baseless and really should not pertain to this nursing aide.

Jessica Minnick, RN, IBCLC
Lactation Department
St. Joseph Medical Center
Tacoma, WA

Division of Information Management
(Office of the Secretary)
Room 502
Consumer Product Safety Commission
4330 East West Highway
Bethesda,
Maryland 20814

Dear Consumer Product Safety Commission:

I am an RN, an International Board Certified Lactation Consultant, and I have a Master of Science Degree in Health Education. I have been working with mothers and babies in hospitals, in homes, in my office, and in a clinic setting for fifteen years.

Over the years, one of the most helpful products for breastfeeding mothers has been the Boston Billow's nursing pillow. It is light weight, accommodates mothers and babies of all sizes, and is affordable. Mothers find it very useful in successfully positioning babies at the breast. And as you know, successful breastfeeding pays off in healthier moms, babies and communities.

I am an advocate for infant health, and teach parents SIDS protection habits. However, I think that banning the use of Boston Billow's pillows is ridiculous! It is not a sleeping surface, it is a breastfeeding aide. Put a "Do not let your child sleep on or with this pillow" on it if you must, but definitely, use of this product during breastfeeding should be encouraged, not banned!

Please lift the restriction on this valuable, helpful, health-promoting product.

Sincerely,

Debi Page Ferrarello, RN, MS, IBCLC
Director Emeritus, Breastfeeding Resource Center
Glenside, PA, USA

Division of Information Management
(Office of the Secretary)
Room 502
Consumer Product Safety Commission
4330 East West Highway
Bethesda,
Maryland 20814

Petition HP 05-1.
Petition Requesting Amendment to Ban on Infant Pillows.

We first tried the Boston Billow nursing pillow about 5 years ago. We loved it and more importantly, our patients loved it. I have worked with nursing mothers and babies for more than 25 years, and have seen and tried many, many "nursing pillows." In my time, the Boston Billow is my all time favorite.

Mothers do not use this pillow to put babies to sleep. It is used to support the baby during breastfeeding. It helps enormously in positioning a baby comfortably at breast. It fits women of ALL sizes and shapes, unlike most every other pillow out there. The unique design of the Billow allows it to sit comfortably around a women who has recently had a cesarean birth.

It is wonderfully durable, and can be washed over and over. I know this because when the pillow first came out, we liked it so much we used it in our outpatient practice office before the wipeable cover was available. I took it home and washed it every night.

I was very saddened to receive notice that this wonderful product was recalled. It is truly the best nursing pillow available. I feel that the regulations written to protect baby's safety are of the utmost importance. There could not be a subject more near and dear to my heart.

Bonnie Cable, RN, IBCLC

Page -2-

However, there has been a grave injustice done in this case. This pillow was never intended as a sleep aid. It is to be used to support and position a baby at breast while breastfeeding. I cannot see how suffocation could possibly be an issue. I do not see how this product could be deemed unsafe.

Please reconsider. You have no idea how many mothers and babies have benefited from the use of this product. Mothers love it. Lactation Consultants love it. Babies thrive because of it.

Sincerely,

Bonnie Cable, RN, IBCLC
Mt. Carmel Health System
Outpatient Lactation
5965 E. Broad St. Suite 100 B
Columbus, OH 43213
614-234-8130
bcable@mchs.com

Division of Information Management
(Office of the Secretary)
Room 502
Consumer Product Safety Commission
4330 East West Highway
Bethesda
Maryland 20814

Petition HP 05-1.
Petition Requesting Amendment to Ban on Infant Pillows.

I am a lactation consultant who has been in practice for many years, and certified for 18 years. I have used many types of pillows in helping moms. About 3 years ago, our hospital obtained several different types of pillows for our NICU mothers to try. The overwhelming choice by the moms was the Billow Pillow. We also have allowed moms immediately post C-section and at various lengths of time postpartum. They have all expressed great satisfaction with the pillow because of its flexibility and ease of use. The pillow is able to adapt to all ages and sizes of babies due to its moldability. This pillow is significantly different from the product previously banned by the CPSC more than 10 years ago. It is not big enough to be used for a baby to sleep on. It is firmer and holds its shape. I sincerely hope that the CPSC will not cave in to what is really a commercial interest in preventing competition, rather than listening to the voice of reason.

Thank you.

Jane Kershaw, RN, BA, IBCLC
Coordinator
"A Mother's Place"
Lactation Support Services
Women's Hospital @ Centennial

Division of Information Management
(Office of the Secretary)
Room 502
Consumer Product Safety Commission
4330 East West Highway
Bethesda, Maryland 20814

Petition HP 05-1.
Petition Requesting Amendment to Ban on Infant Pillows.

I have been a practicing Lactation Consultant for over 10 years and an OB nurse helping mothers breastfeed for over 20 years. I have probably seen moms using every type of pillow imaginable to position their infant properly at the breast. What we have learned and observed over the past 20 + years is that the real key to successful breastfeeding is proper positioning of the infant at breast. In order for a woman to have her arms comfortably positioned to support the infant, she must use pillows to support her arms and raise the baby up higher to the level of her breast. I would venture to say that any photograph or diagram seen of a mother nursing a newborn infant, pillows are in the picture. One of the worst things a mother can do is lean over to the baby. Unfortunately, not all women are the same size. If they were, everyone would be comfortable using the same pillow and we could easily work with the restrictions you have placed on the use of the Boston Billow Pillow. In reality, the vast majority of women need considerable time to lose body fat accumulated during the pregnancy. This makes the nursing pillows that have not been banned for use impossible for these women to use. I have found that every mother that uses the Billow Pillow is comfortable with its use. It easily conforms to all body shapes and sizes and supports the mother's arms to successfully position the baby at the breast. We have been so pleased with this pillow we carry several of the hospital style Billow Pillows with the wipeable cover for mothers to use while here. They in turn are so pleased with how well it helps to assist with positioning, they ask to purchase one prior to discharge - even if they own another brand of nursing pillow.

I have no doubt that the ban on the use of the Billow Pillow was prompted by one of their competitors. I ask the Commission to be realistic and consider the many letters from professionals in considering the reversal of this ban. The fact is, the medical professionals that recommend this pillow for breastfeeding are recommending it only for use by the mother to help her be more comfortable with her body position while breastfeeding. If you consider the number of hours a newborn is at mother's breast every day, you will understand how important it is for her to be comfortable.

If the mother's body is not comfortably positioned and the baby not correctly positioned at the breast, they are at risk for poor transfer of milk, sore nipples, back and shoulder strain and ultimately lactation failure. No one in the field of Lactation or Medicine would recommend a baby use the Billow Pillow for sleep or while unattended. Any nursing pillow is for use by the mother while nursing her infant for proper position. Mothers nursing their infants are holding the infant - not nursing with their arms off to the side. The fact that one competitor markets its pillow for use as a support pillow for an infant is irresponsible of that company and in no way should indicate that all nursing pillows are marketed that way even if a similar shape. I feel it would be more reasonable to ban that company from marketing it's pillow for use by infants.

You need to consider that there are thousands of pillows, bedding material and toys on the market not intended for use by infants. Parents need to have education that all of these products are potentially harmful for unattended infants. However, to insist they all be taken off the market is unimaginable because they are useful for adults and appropriate aged children.

I respectfully request that you reconsider your original decision and allow the Boston Billow Pillow it's rightful place back on the market as a useful tool for mothers to successfully breastfeed. Our other brands of nursing pillows we have purchased for sale in our Lactation Center are currently sitting dusty on the shelves, unsold for several years. However, we have consistently sold many Boston Billow Pillows over the years and our clients continue to ask for them. It is a gross injustice to ban such a useful item. To suggest that mothers can use alternative means to feed their babies is just a sign of ignorance of the vast health benefits to mother and baby by breastfeeding. I would also venture to say that the majority of parents that do choose to bottle feed their infant will also use a pillow to support their arms, so I believe that argument is totally invalid.

Thank you.

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

Division of Information Management
(Office of the Secretary)
Room 502
Consumer Product Safety Commission
4330 East West Highway
Bethesda,
Maryland 20814

Petition HP 05-1.
Petition Requesting Amendment to Ban on Infant Pillows.

I first came in contact with the Boston Billow nursing pillow in 1999. As a lactation consultant, I found a pillow that was comfortable for all the mothers I worked with, no matter what their shape or size. They could easily conform to raise the baby to breast level and it was not too tight, especially around their waste nor did it create a "crater", as the parents often refer to it. (Many of them had a pillow from another distributor, the "Boppy" where the baby often falls into the area in front, across the mother's waist and slip away from the breast causing nipple damage as the baby slips off the breast.)

Due to the movable filling inside the Boston Billow pillow, the mothers are able to keep the babies at breast level by moving the filling around and bringing and keeping the babies at breast level. The other pillow often left them feeling frustrated, with altered body image ("I thought I was too fat to use my "Boppy" was a common comment) and awkward.

Many of the mothers find the Boston Billow nursing pillow comfortable for themselves to use as a back rest to sit on when they have a sore perineum from delivery. This of course while not breastfeeding the baby.

I work in an area that does about 1,000 deliveries a month and many of the mothers have other nursing pillows. When they use mine during a consult they are very pleased and usually want to purchase a Boston Billow. Our NICU lactation consultant also enjoys using one with her NICU moms and finds them helpful in positioning these fragile babies at breast.

Please accept the petition so that we can get the Boston Billow nursing pillow again.

Sincerely

Annette Leary, BSN, IBCLC, RLC.
Arnold Palmer Hospital
Orlando Florida. aleary@orhs.org

Division of Information Management
(Office of the Secretary)
Room 502
Consumer Product Safety Commission
4330 East West Highway
Bethesda
Maryland 20814

Petition HP 05-1.
Petition Requesting Amendment to Ban on Infant Pillows.

I have been using the "Boston Billow" Nursing Pillow in my practice as an International Board Certified Lactation Consultant. I find that it is critical to teach a new mother positioning skills from the moment the baby is born. Using this product has helped me to assist mothers to the best of my ability. It is an exceptional item and its availability is important.

Please consider my request that you allow mothers to have access to such a great product. It's sole use is for mothers to position the baby while breastfeeding when mom is awake and alert and baby is safe.

Respectfully,

Brenda Hallmark, RN, IBCLC
Medical Center East Hospital
50 Medical Park East Drive
Birmingham, AL 35235
205-838-3457

Division of Information Management
(Office of the Secretary)
Room 502
Consumer Product Safety Commission
4330 East West Highway
Bethesda
Maryland 20814

Petition HP 05-1.
Petition Requesting Amendment to Ban on Infant Pillows.

Office of the Secretary
Consumer Product safety Commission

This letter is in support of the amendment that asks that the regulation be changed regarding the Boston Billow Nursing Pillow (regarding Petition HP 05-1 requesting amendment to ban on infant pillows). I am in support of the amendment that asks that the regulations be changed: "to permit the use of the banned infant pillows, such as the Boston Billow Nursing Pillow, when the pillow is designed, intended and promoted for a mother's use during breastfeeding and when such pillows are requested by a pediatrician or a board certified lactation consultant."

I am a lactation consultant who instructs mothers in breastfeeding and the safe and proper use of the Boston Billow Nursing Pillow. I recommend the Boston Billow Nursing Pillow to all my nursing moms, especially those who have problems with positioning and latch to the breast which also includes premature infants, multiple birth infants, and those with congenital or inborn defects that make nursing at the breast a challenge. The Billow is unique and there are no suitable substitutes available on the current market. The Billow is the ONLY nursing pillow that makes it possible for the close contact necessary for those women who have had a cesarean birth (30% nation-wide) to position the baby for breastfeeding avoiding pressure on the incision. The Billow is the only nursing pillow that will comfortably fit around a mom with a large waist size. One of the unique features of the Billow is the firmness of the Billow when a baby is placed on its surface. It is impossible for a baby to sleep on a Billow as the baby would simply roll off. I warn new mothers against putting the baby to sleep in soft bedding, and I do not consider the Billow to fall in that category.

Patsy Sanders

Page -2-

The Boston Billow Nursing Pillow is a marvelous tool to aid mothers to have a successful breastfeeding experience. I have many, many requests for this Billow from my breastfeeding clients. I believe that the views of health professionals such as myself should prevail in your decision to request an amendment to the regulations so that the Billow can again be sold as a nursing pillow.

Thank you for your consideration in this matter.

Patsy Sanders, RN, BSN, IBCLC
Board Certified Lactation Consultant
Comanche County Memorial Hospital
Breastfeeding Resource Center
3401 W. Gore Blvd.
Lawton, Ok. 73505

Division of Information Management
(Office of the Secretary)
Room 502
Consumer Product Safety Commission
4330 East West Highway
Bethesda,
Maryland 20814

We use the Boston Billow pillows in both our lactation exam rooms. They mold perfectly to fit nursing mothers and babies during breastfeeding no matter what position they use. It would be a shame not to have these available to anyone who wants to use them. Cautionary warnings can certainly be included. There are many other products that may do harm if not used in the correct manner. Common sense suggests that parents would use them responsibly if informed.

We desperately need some in our NICU since most of our chairs have arms on them and don't allow for other types of nursing pillows to be used.

I hope the ban will be lifted. We love the product!

Sincerely,

Merilee Brigham, RN, BSN, IBCLC
Lactation Consultant
Seattle, Washington

Division of Information Management
(Office of the Secretary)
Room 502
Consumer Product Safety Commission
4330 East West Highway
Bethesda,
Maryland 20814

Petition HP 05-1.
Petition Requesting Amendment to Ban on Infant Pillows.

I have used the Boston Billow nursing pillow in my lactation practice for several years now, and also offered it for sale to moms. My clients report very favorably about the ease of positioning that the pillow helps them achieve. They feel the light weight of the filler material is comfortable next to their body as they breastfeed and some moms have used the pillow for support of their back during pregnancy while they sleep.

This product is for use by the nursing mothers and very useful in that capacity. Please restore the Boston Billow nursing pillow to its rightful place.

Sincerely,

Rebecca Gorus, IBCLC
St. Mary's Medical Center
Walla Walla,
WA
509-529-3320 x 5727

Division of Information Management
(Office of the Secretary)
Room 502
Consumer Product Safety Commission
4330 East West Highway
Bethesda,
Maryland 20814

Petition HP 05-1.
Petition Requesting Amendment to Ban on Infant Pillows.

Maternal and Infant safety is ever hospitals number one concern. Our facility has successfully and safely used the Boston Billow to assist mothers with breastfeeding for six years. Mothers receive instruction on the utilization of the product.

I am outraged that such a claim could be made against this product. I urge you to rescind this decision.

Beth Allen, BSN, RNC, IBCLC,
Northside Hospital
Atlanta, GA
404-303-3966

Division of Information Management
(Office of the Secretary)
Room 502
Consumer Product Safety Commission
4330 East West Highway
Bethesda,
Maryland 20814

Petition HP 05-1.
Petition Requesting Amendment to Ban on Infant Pillows.

I am writing in support of the Boston Billow nursing pillow.

I have used it with clients for the last four to five years.
No complaints or problems have been reported.
Not all pillows are alike and repeatedly the clients choose
the Boston Billow pillow. The proper support during nursing
is very important and decreases some potential problems.

Thank you,

Linda McGee, RNC, IBCLC
Baptist Memorial Hospital for Women
6225 Humphreys Bld.
Memphis, TN 38120
901-227-9621

Division of Information Management
(Office of the Secretary)
Room 502
Consumer Product Safety Commission
4330 East West Highway
Bethesda,
Maryland 20814

Petition HP 05-1.
Petition Requesting Amendment to Ban on Infant Pillows.

I have been using the Boston Billow for 5 years so I know
Its usefulness to nursing mothers.

I have only gotten positive feedback from my clients.

I strongly urge you to exempt the Boston Billow nursing pillow
From the 1991 regulations.

Mary Nettles, RN, BS, IBCLC
Northern Dutchess Hospital
New York.
845-871-3365

*Late
comment
Billows
Pillow***Stevenson, Todd A.**

From: Heather Anderson [hyrubyslippers@yahoo.com]
Sent: Monday, January 23, 2006 11:47 AM
To: Stevenson, Todd A.
Subject: Nursing Pillow Ban

Dear Mr. Stevenson,

I just spoke with one of your wonderful staff members regarding the recent ban on a nursing pillow called the "Boston Billows". Even though the deadline for submitting comments of December 12 has passed, she thought that it might be useful to still send you my comments as a consumer. I hope that you will find them insightful, and will present them to the committee who is reviewing this ban.

First, let me say that I have carefully reviewed the Consumer Product Safety Alert issued by the CPSC in 1991 and I think that it was well warranted for the product that it referred to. There is no question that an infant is in serious danger of suffocation if left to sleep on a soft pillow that would conform to their face.

What puzzles me is that the nursing pillow in question is a completely different product. It is shocking that something can be banned based on a couple of similarities to a dangerous product without reason. It seems to me that a child placed to sleep and left unattended on a nursing pillow like the one in question would be in more danger of injury by falling off, or to be honest by being in the care of someone stupid enough to place them there! Under that rationale, we should really ban all pillows and everything soft that could be considered a hazard. More people still put comforters and stuffed animals in cribs than they do their nursing pillows, so maybe we should ban those too. Let's start with teddy bears. Rather than educating the public maybe we should just protect them from their own ignorance.

I think that you have plenty of letters from experts stating the usefulness of an innovation in the nursing pillow market. The only nursing pillows available now fall short of what is obviously needed and I wonder if the ones calling for a ban of this product may be those two big companies who see innovation as a threat.

As a consumer, in particular a consumer that is more concerned about the safety of children than anything else, I have a greater concern for you to take into consideration. By allowing these bans to apply to such an unreasonable spectrum of products, you are watering down the effect that a safety ban should have. It's like Mc Donald's having to put a disclaimer on their coffee cups warning that their coffee might be hot, just because some idiot spilled it on her lap and sued them. No consumer takes that warning seriously because of its ridiculousness. These bans and warnings are becoming the material of stand-up comics, and completely losing the intended and vital effectiveness for products that are, in fact, a danger. Before long, the public will not even take your agency seriously, which would be such a disservice.

As I said, I hope that you will give serious consideration to these points. Feel free to contact me if needed.

Best Regards,

Heather Anderson

1/23/2006

718-383-8854

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Boston Billows, Inc.

*Billow
Comm*

February 7, 2006.

Mr. Hal. D. Stratton, Chairman
Consumer Products Safety Commission
4330 East West Highway
Bethesda
MD 20814

Ref: Boston Billow Nursing Pillow.

Dear Mr. Stratton:

We refer to earlier communications, including our Petition to the CPSC for an amendment to the Federal Regulations under which the CPSC issued a ban on our nursing pillow. That petition was submitted to you on July 17, 2005, soon 7 months ago!

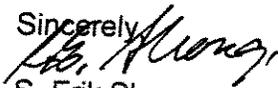
In the meantime, we have been informed through the media (copy enclosed) that the CPSC has solicited certain organizations to issue letters opposing our petition. We have checked out these organizations and the basis for their compliance with the CPSC request. It turns out that the statement issued by Nancy Cowles, executive director of Kids in Danger, was based on her opinion (!) that our nursing pillow was dangerous and should remained banned. Evidently she had not made any research or de facto evaluation of our product. The Consumer Federation of America ignored our request as to the basis of their support. Consequently, we could ascertain the factual basis for their anonymous participation. That in itself makes their support suspect. The third negative statement participant was the Danny Foundation, an organization that is now defunct! Really impressive support of the CPSC staff.

For over two years now, hardly a week passes by without a hospital or a lactation consultant calling us to find out when our nursing pillow will again be available. They need the pillow for C-section mothers or mothers facing problems with breastfeeding. We can only refer to the CPSC lack of action.

A week ago, the Fortune Magazine Small Business Edition published an article about The CPSC and the Boston Billow nursing pillow situation. A copy is enclosed. The issue went out to over 1 million subscribers and has resulted in numerous letters and emails of support.

The issue of this unique nursing pillow will not go away. The reason is that the medical community keeps telling us that they need it as this is the only product – the ONLY product – that can really help new mothers who have problems with breastfeeding to nurse their babies. And the close to 30 percent of women with a Cesarean delivery. Outraged lactation consultants tell us that the number 1 killer of infants, latex balloons has not been banned by the CPSC. And then your organization bans a product that the medical community need to help babies survive. Go figure.

Sincerely,



S. Erik Skoug,
President.

28 Charron Avenue, Nashua, N.H. 03063.
Telephone: 603-598-1200 * E-mail: Contact@bostonbillows.com
www.bostonbillows.com.

WASHINGTON

Nursing pillow ban: Oversight or overzealous?

By LISA ZAGAROLI
McClatchy Newspapers
January 01, 2006

WASHINGTON - When new moms have difficulty getting their arms in the right position to breastfeed their babies, Rebecca Garcia steps in with nursing aids that often solve the problem.

So the lactation consultant from Walla Walla, Wash., was stunned to learn that one of her most popular nursing cushions was pulled from the market by a government agency that decided it could be a suffocation risk to sleeping babies.

"It'd be hard to get a baby to balance on that thing even if you were to try to," said Garcia. "It seemed like a bogus threat."

The Boston Billow hadn't been linked with any injuries or deaths when it was recalled in 2004. But the Consumer Product Safety Commission decided the "nursing pillow" was too similar in design to an "infant pillow" that was associated with baby deaths more than 15 years ago.

Now the product manufacturer and some health care professionals who think the ban was overzealous and unwarranted are petitioning the safety agency to reconsider letting parents buy it.

The case sheds light on the sometimes controversial business of safety regulation and identifying possible risks before they become crises.

"You don't need a body count in order to protect the public," said R. David Pittle, one of the original appointees of the CPSC who served from 1973 to 1982. "You try to act to reduce it before it actually materializes."

At the core of the case is whether a nursing pillow - made to help moms breastfeed their babies - should be treated the same as an infant pillow, which was designed as a sleeping aid for kids before 35 lifeless little bodies were found stomach-down on them in the late 1980s.

Sudden Infant Death Syndrome by definition is a diagnosis of exclusion. Young babies who die for reasons that can't be pinpointed with an autopsy are put into the SIDS classification; in 2003, there were about 2,000 nationwide.

The babies who died in the 1980s were initially listed as SIDS cases until health officials noticed the presence of infant pillows, about a million of which were in American households.

Statistically, the likelihood of a baby dying on one was tiny, but the Consumer Product Safety Commission launched an aggressive investigation, recalled all makes of the bead-filled cushions and came up with a very specific regulatory definition to make sure they were never made and sold again in the United States.

Armed with studies that show children fed with nutrient-packed breast milk can be healthier and more developmentally advanced than their bottle-fed counterparts, an estimated 70 percent of U.S. moms try nursing. Many of them stop within a few weeks or months for a variety of reasons ranging from having to return to work or school to pain and discomfort.

A common, early deterrent is that mothers can't find a position comfortable enough for both them and their children to nurse.

The Boston Billow, made in Nashua, N.H., is a C-shaped cushion that nursing moms wrap around their bodies to provide a platform to help support their babies. There are other popular brands, such as the Boppy Pillow, on the market.

What distinguished the Boston Billow, a niche product sold mostly in birthing centers and specialty shops, is that it is soft and filled with beads, like a bean bag, that allow it to be molded to fit moms and kids of all sizes.

Because of those features, the hospitals that carried them often recommended the Boston Billow to moms who can't tolerate a firm pillow because they have had Caesarean sections.

The pillows also are used by women who have carpal tunnel syndrome, multiple sclerosis, cerebral palsy or rheumatoid arthritis, said Karin Cadwell, executive director and lead faculty member at the Healthy Children Project in Massachusetts, which runs a breastfeeding center that trains health care providers.

Cadwell's organization studied premature babies with poor muscle tone to try to increase their success in breastfeeding. The researchers found the Boston Billow was the only product that helped because it could be individually shaped to accommodate the mother's anatomy and the baby's ability, she said.

"These pillows are malleable and stay in that shape for you to provide support," she said.

Those very features that distinguished the Boston Billow were what got the product into trouble.

It shares some indisputable characteristics with banned "infant pillows" - it has a flexible fabric covering and is loosely filled with beads and can easily be flattened.

The Consumer Product Safety Commission also said the Boston Billow meets the two other criteria that make it synonymous with an infant pillow from a regulatory standpoint - it is capable of conforming to the body or face of an infant, and "intended for use by infants under 1 year old."

S. Erik Skoug, president of Boston Billows Inc., said there can be no confusing the use of the two products.

"It can't be used as a pillow," Skoug insisted. "The reason is this - it's quite round and when a baby is put on the pillow, it immediately firms up because of the amount of beads and type of beads in the pillow. It's ridiculous because if you try to put the baby on one of the pillows, it would roll off.

"The 1991 infant cushion was designed to put a baby on to sleep and leave the baby alone," Skoug added. "Ours is designed and promoted for use by mothers when breastfeeding."

To some safety advocates, the original purpose of the product is largely irrelevant because it's used around babies.

A baby might nestle face-first into the soft Boston Billow but wouldn't be able to with firmer breastfeeding pillows, said Nancy Cowles, executive director of Kids in Danger, a group that promotes child product safety and is opposing the exemption that Boston Billows has petitioned for from the government.

She and two other safety watchdog groups, the Consumer Federation of America and the Danny Foundation, told the CPSC in a letter that "the risk of suffocation outweighs any convenience factor that the cushion might bring to a nursing mother."

"While the Boston Billow is not intended for any other use than breastfeeding, it is easily conceivable that the product would find its way into the sleeping environment of a baby - even if it is just that the mother and baby doze off while nursing in a rocking chair," their letter said.

Skoug was successful in persuading the commission to let him keep selling a version of the Boston Billow with a washable cover for hospital use only because it is used in a controlled environment and not taken home by patients.

Still, new orders dried up and the recall has virtually destroyed Boston Billows Inc., which has gone from eight employees to two and struggling to survive.

In the petition filed earlier this month with the CPSC, Skoug and supporters have tried to get the commission to allow sales of the pillow if a pediatrician or lactation nurse recommends it to a patient.

Julie Vallese, director of public affairs for the CPSC, said the commission is reviewing the petition. The public comment period on the request closed Dec. 12.

Though the agency doesn't have to wait for deaths to occur to recall a product, it doesn't always ban something even when it is directly involved in a death.

For example, more than 100 babies have drowned while using bath seats, but the commission ignored public pressure to ban them and instead issued mandatory safety standards for how they should be built.

The agency has been aggressive in trying to dissuade parents from exposing babies to sleeping-related hazards such as faulty crib designs.

Skoug said that without products like his, parents might just use something else the CPSC warns against putting near babies - adult pillows and bedding.

Cadwell said she agrees that babies should never be placed on pillows, but she notes that a lot of other products not meant for babies to sleep on have killed children but aren't banned.

"Are we going to ban recliners or rugs or sofas?" she said. "We don't have a ban on fancy sofa pillows in houses with children."

(Distributed by Scripps Howard News Service.)

TOTALR

➤ **After a company's product was arbitrarily deemed unsafe by the government, it had two choices: Go out of business—or fight back.**
By Maggie Overfelt



RECALL

RED TAPE

THE SOUND of packing tape being torn from its roll echoes through the nearly empty warehouse of Boston Billows, a maker of nursing pillows based in Nashua, N.H. Only two executives—the co-founders—remain at the company, which last year employed seven. Having laid everyone else off, they struggle to sew and ship the pillows, which support newborn babies as they breastfeed. Over the past two years, annual revenues at Boston Billows have shrunk from \$750,000 to less than \$15,000. “We just canceled our UPS account,” says co-founder Ken Igoe, 57. The cash-strapped company could no longer afford the \$40-a-month fee required for daily pickup.

Boston Billows’ decline stems from a single catastrophic event—a 2004 decision by the U.S. Consumer Product Safety Commission (CPSC) that forced the company to recall its pillows. Company president Erik Skoug, 73, claims that the recall was unwarranted and that his nursing pillows have never been linked to any deaths or injuries. Ten hospitals still order and use them in neonatal intensive-care units—including Children’s Hospital in Boston and the Cincinnati Children’s Hospital Medical Center. (Hospitals are exempt from the recall.)

The CPSC is the federal agency charged with ensuring the safety of household wares. In 2005 it issued 400 recalls affecting more than 330 companies. Congress established the CPSC in 1972 to reduce injuries caused by products such as kitchen gadgets and toys, but the agency has been controversial virtually since its creation. Consumer advocates say it doesn’t do enough to get unsafe products off the market quickly. Business owners consider it a meddlesome, heavy-handed bureaucracy. Yet the Boston Billows case shows that the rules under which the CPSC operates often favor big corporations over small businesses. Companies with



PILLOW FLIGHT:
Co-founders Ken Igoe
(left) and Erik Skoug, at
the Boston Billows ware-
house in Nashua, N.H.

> In January 2004, saying it was TIPPED OFF by a competitor, the CPSC sent Boston Billows a recall letter. It did not name the competitor.



PAPER CHASE: Skoug (left) and Igoe with documents relating to the recall

deep pockets and in-house counsel can negotiate virtually every step of the process—even dispute whether a recall should happen at all. But a small business under CPSC scrutiny often finds itself in a fight it can't afford and usually has no choice but to comply.

Boston Billows has been contesting the recall of its product for two years. Skoug and Igoe, angered by the CPSC's inefficiency and what they consider its disregard for their arguments and evidence, say they don't have the money to hold out much longer. (The CPSC, through a spokeswoman, declined to speak about the specifics of the Boston Billows case.) "We just want to continue to sell our product," says Skoug. "We know from the medical community that it helps save lives." Before the recall, the U.S. Department of Agriculture bought the company's pillows for low-income communities where mothers weren't properly breastfeeding. "It's a needed product," Skoug says. "That's why we'll continue to fight."

❖ **SKOUG** was born in Norway and studied at Harvard on a Fulbright scholarship in the 1960s. He spent more than 30 years in management and marketing positions with Siemens, Volkswagen, and finally Nashua Corp., an imaging-technology company in Nashua. While there he hired Igoe, and the two hit it off.

By the mid-1990s both had quit the company and shared office space in Nashua, working on consulting projects. They realized that before retiring, they wanted to launch an entrepreneurial venture.

On a tip from a childhood friend in Norway who runs a pillow company, Skoug bought the license for a nursing pillow that had proved popular in European hospitals for more than 25 years. In the U.S. about a dozen firms sell a similar product, mostly in major retail chains. The market leader is Boppy Co., based in Golden, Colo., which posts about \$18 million in annual sales. Boppy sells its nursing pillow in chains such as Target and Toys "R" Us.

Most nursing pillows are filled with foam or polyfiber, but the European pillow used plastic beads, which are denser and designed to firm up under the weight of a baby. According to several lactation consultants (nurses who work with new mothers in hospitals), Boston Billows' pillow makes it easier for a baby—especially one born prematurely—to latch onto its mother's breast. "Boston Billows provides more support under a baby's head" than competing pillows, says Diane DiSandro, a lactation consultant for 25 years who is based in Audubon, Pa. "It holds shape. There's nothing else out

there that does that." Other products, DiSandro says, compress under the newborn's weight, so the mother has to support the baby's weight with her arms. Because their pillow's design was already popular in European hospitals, Igoe and Skoug decided to market it through lactation consultants and hospital retail shops in the U.S.

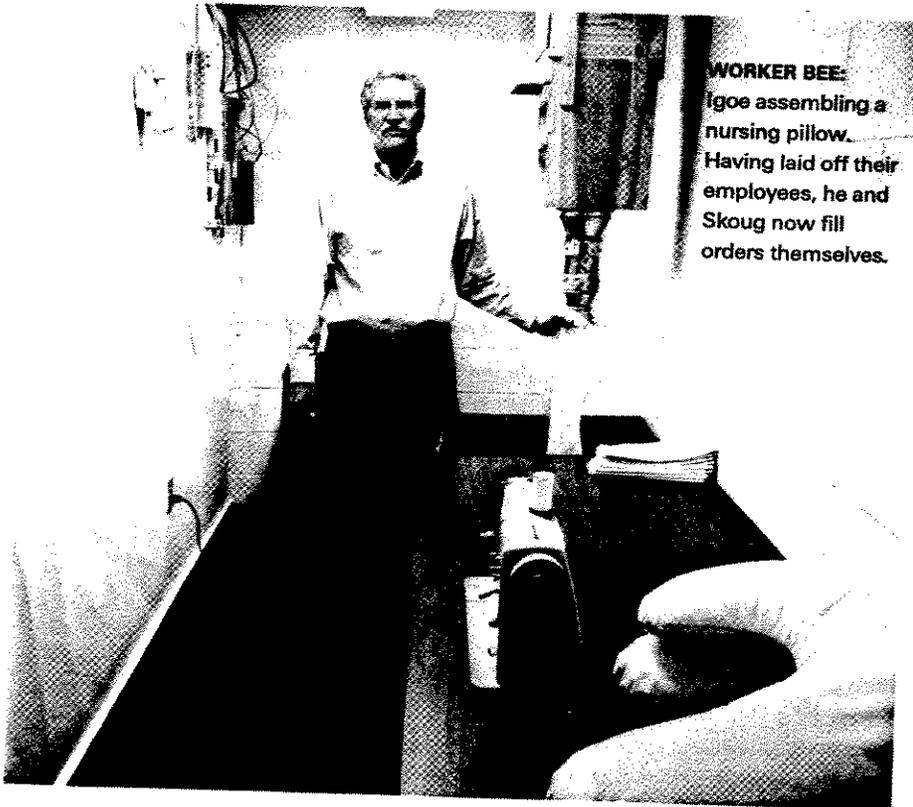
By 2003, after five years in business, Boston Billows was selling its product in more than 70 hospital retail shops, and its revenues hit \$750,000. That June, Skoug and Igoe received a letter from Boppy Co. claiming that the filling in Boston Billows' pillow could be dangerous. "Boston Billows' nursing pillow contains 'poly-beads,'" the letter read. "Such a filling has been found to be unsafe for use with infants and small children." Not long after, in January 2004, Boston Billows received a recall letter from the CPSC, noting that it had been tipped off by a competitor. The CPSC wouldn't divulge the competitor's name. When asked if Boppy Co. had notified the CPSC, Boppy spokeswoman Nancy Bartley declined to answer directly but said, "There are a lot of pillow products out there—I don't know that you could pin it on just one company."

The CPSC hears about unsafe products through a number of

channels, including consumer hotlines and insurance investigations, and it's not unusual for competitors to turn each other in. Recalls are technically voluntary, meaning the CPSC asks a company to cooperate. But if it doesn't, the agency can sue to force it to comply. (The CPSC estimates that less than 1% of its recalls involve a court case.) If a company agrees to a recall, it meets with CPSC staff to negotiate the next steps: notifying retailers to pull the product from shelves, retrieving defective items already purchased by consumers, tracking repairs, and issuing refunds. The CPSC publishes a press release, but the company is responsible for all other costs, which can range from \$10,000 to \$10 million. Because of the bad publicity and potential losses involved, companies sometimes drag their feet when faced with evidence that their products are unsafe.

During the 1980s, for example, ATV manufacturers argued with the federal government for years over the safety of three-wheeled ATVs, even after more than 100 riders had been killed in accidents. (The manufacturers agreed to stop selling three-wheeled ATVs in 1988.) More recently, baby-gear maker Graco Children's Products, based in Exton, Pa., paid a \$4 million fine to the CPSC last March for failing to report injuries with about 12 million items sold from 1994 to 2001. "Graco currently has a good working relationship with the CPSC," says a Graco spokeswoman.

■ IN THE CASE of Boston Billows, however, its product was not linked to any injuries or deaths. Skoug and Igoe had researched pillow fillings for about two years prior to launching their company, and the poly-bead fillings they decided on have been used for decades without problem in Europe—not exactly a slacker in the regulation of business. Hoping to persuade the CPSC to change its mind, Skoug and Igoe flew to Bethesda, Md., where the CPSC is based, to contest the decision in February 2004.



WORKER BEE: Igoe assembling a nursing pillow. Having laid off their employees, he and Skoug now fill orders themselves.

> WHAT YOU CAN DO

HOW DO SMART manufacturers minimize the risk of a recall? The U.S. government sets rules for a few products, such as cigarette lighters, but most others are governed by voluntary standards. A nonprofit called ASTM International (American Society for Testing and Materials) issues standards for about 12,000 consumer products in 130 industries. For example, the standards for stroller manufacturers are updated twice a year by a committee of Consumer Product Safety Commission staffers, manufacturers, retailers, and product testers assembled by the ASTM. (To download standards for your product, go to astm.org and click on Technical Committees; cost: \$25 to \$50.)

The CPSC also suggests getting your product tested by an independent lab for qualities such as durability and fire resistance. The Underwriters Laboratories (ul.com) is probably the best known; basic testing starts at about \$500.

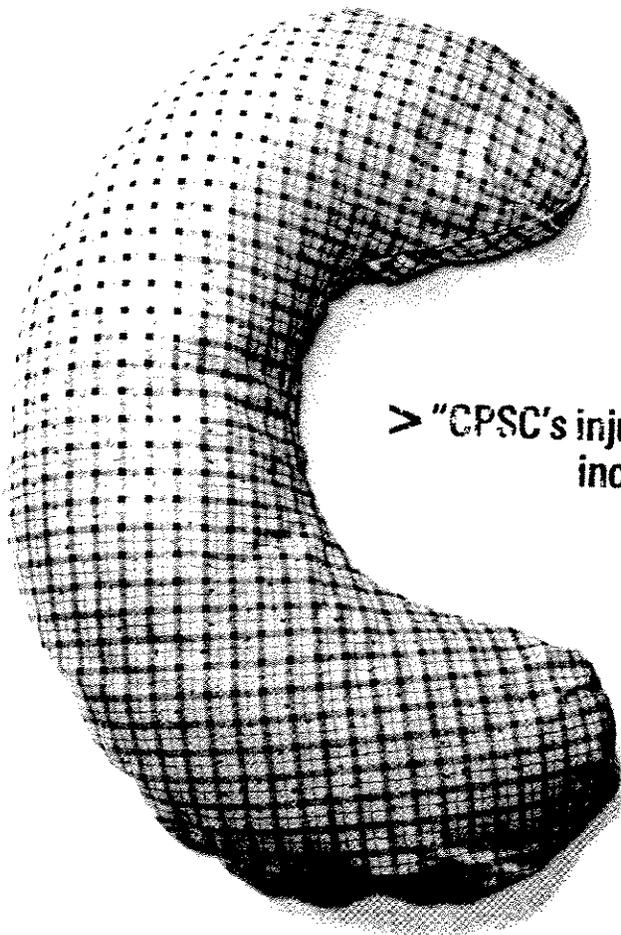
Some business owners splurge on product-liability insurance, which covers them even if their product uses components made by other manufacturers. "A \$4 part could cause a recall that becomes a \$100 million problem, and you're responsible," says Bill Harrison, managing director at AON, a risk-management firm in Chicago. Costs range widely; expect to pay \$15,000 at least.

—M.O.

With their lawyer on speakerphone, the two sat at a conference room table, across from CPSC staff, lawyers, and engineers. According to Skoug's notes from the meeting, the CPSC staffers said that they had spent three weeks examining the pillow in the agency's lab, and that its design and filling were too similar to those of several infant mattresses made by a dozen companies in the 1980s and early '90s. Those mattresses were banned by law in 1992 after 35 infants were found dead on them. (The cause of the deaths—possibly suffocation—was never conclusively determined and is still debated among pediatricians.)

Skoug and Igoe didn't think the comparison was fair. The filling in the two products was the same, but nothing else was similar. Their pillow was crescent-shaped and designed to support a nursing infant. Skoug says that even if a baby were left unattended on the pillow, he would roll off. Conversely, the infant mattresses banned in 1992 were flat, soft slabs on which babies were put to sleep. The CPSC decision was akin to recalling a car because it shared a part with the Corvair.

The agency told Boston Billows to take two weeks and modify the pillow so it could possibly be sold in the future (Skoug says he was given no guidance on how to alter it), and it demanded the recall of those already on the market. "I asked what would happen if we didn't follow through with the recall," says Skoug. "The CPSC said it would bring all the resources of the U.S. government down on us." Without the money for costly legal fees, Billows issued the recall in March 2004, spending about \$10,000 to contact retailers, write letters to customers, and issue refunds.



> "CPSC's injury and death data allow at best an incomplete view—at worst a **DISTORTED** one."

theory, including an updated report by the pediatrician who conducted the original CPSC study, Dr. James Kemp. "Beanbags stood out," says Kemp, now an associate professor of pediatrics at St. Louis University. "But soft bedding like comforters and pillows, not unusual to find in beds, increase the risks too." Other researchers reached similar conclusions. "Ten years ago, people were looking at polystyrene vs. this and that," says Dr. Rachel Moon, a pediatrician at the Children's National Medical Center. "But the thinking right now is that fillings are probably irrelevant."

In the company's notes of the meeting, Stratton is quoted as saying, "I'm not sure I would have voted for this in 1992 if I had been here, but now we're stuck with it." Stratton advised Skoug to get him "off the hook" by asking his Congressman to tweak the 1991 legislation and allow Boston Billows' pillows back on the market. (Gregg wrote a letter on Skoug's behalf asking the CPSC to expedite the process.) In August, Boston Billows resorted to its final option, filing paperwork to get the agency to reverse its decision. An answer will probably take two years.

Big companies often have other options. After the CPSC issues a recall, such heavy-hitting corporations can dispute specific aspects of it, and they have time on their side. (The product under dispute stays on the market while a case is being resolved.) If negotiations break down, the agency can take the manufacturer to court. "Suing is very rare," says Patty Davis, a spokeswoman for the CPSC. Still, it happens: Household-goods manufacturer Sunbeam (now a division of Jarden, a conglomerate in Rye, N.Y.) put off recalling a line of fire sprinklers for two years. The CPSC claimed the sprinklers were defective and would fail to operate during a fire. The CPSC sued Sunbeam in 2001, but the recall wasn't launched until mid-2003. Jarden declined to comment on the incident.

■ **FOR MOST** of 2004 and 2005, Boston Billows tried to persuade the CPSC to overturn its decision. Igoe made the pillow smaller and more compact, but he says the CPSC ignored his modified version. Next he recruited Senator John E. Sununu and Congressman Judd Gregg, both Republicans from New Hampshire, to write letters on behalf of the company. That prompted a meeting with CPSC chairman Hal Stratton and seven CPSC lawyers in April 2004, at which Skoug and Igoe explained how their pillow was different from, and safer than, the mattresses banned in 1992.

They had done their homework. According to medical reports cited by the CPSC in its 1992 ban, a baby's face might sink into a mattress filled with polystyrene beads, suffocating him. But Skoug and Igoe presented recent research that strongly disputed that

The CPSC's job is not easy—it is responsible for the safety of more than 15,000 household objects—but critics ranging from the Consumer Federation of America to the Government Accountability Office (the investigative arm of Congress) say that its recall process is deeply flawed. "CPSC's injury and death data allow at best an incomplete view—at worst, a distorted one—of the incidents that result from consumer product hazards," the GAO stated in a 1997 study. E. Marla Felcher, an adjunct lecturer at Harvard's Kennedy School and the author of *It's No Accident: How Corporations Sell Dangerous Baby Products*, says CPSC relies too much on information supplied by large companies. Because it can't possibly write guidelines for the manufacture of thousands of products, it asks industries to set their own standards. (See box, "What You Can Do.") Felcher says that small companies often can't afford to attend the meetings and thus have to react to new rules only after they are published. "Little companies are excluded from the big manufacturer collusions," says Felcher. "This makes little companies easier to pick on." Unfortunately, the situation is only likely to get worse. Among the smallest of all government agencies, the CPSC has seen its budget (now \$62 million) and headcount (480 employees) trimmed by almost half since 1975, and more cuts are looming. "I find it hard to believe that the commission will be able to continue to fully serve its mission in the face of such budget cuts," Stratton told Congress in April.

Back in New Hampshire, Skoug and Igoe stitch up pillows when orders from hospitals trickle in. They say the monthly \$2,000 rent for the warehouse—one of their last business expenses—might force them to close up shop soon. Both have already taken management consulting projects on the side, hoping to hear good news before the company goes under. □

For links to Boston Billows and other companies mentioned in this story and to give feedback, please visit fsb.com.



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Office of Hazard Identification and Reduction

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March 3, 2006

Mr. S. Erik Skoug
Boston Billows, Inc.
28 Charron Avenue
Nashua, NH 03063

Dear Mr. Skoug:

Chairman Stratton has asked me to respond to your letter of February 7, 2006 regarding the Boston Billow Nursing Pillow and Petition HP 05-1, which requests an amendment to the ban of infant pillows.* I have asked the Office of the Secretary to enter your letter into the docket as a comment on the Petition. The staff will consider the information you provided as we prepare our briefing package for Commission consideration.

Sincerely,

A handwritten signature in cursive script that reads "Jacqueline Elder".

Jacqueline Elder

* The comments in this letter are those of the CPSC staff, have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

*Pillow
pet***Stevenson, Todd A.**

From: Hammer, Catherine R.
Sent: Friday, March 03, 2006 3:31 PM
To: Stevenson, Todd A.
Subject: FW: [Possibly SPAM (k):] - About Boston Billows - Found word(s) no risk in the Text body

From: Matt Day [mailto:gibbiss@yahoo.com]
Sent: Friday, March 03, 2006 2:54 PM
To: Chairman Stratton
Subject: [Possibly SPAM (k):] - About Boston Billows - Found word(s) no risk in the Text body

Dear Chairman Stratton,

I recently read an article in the Fortune Small Business magazine. It discussed your agency's recall of the Boston Billow baby pillow. It appears that there is no real reason for this recall. The article stated that recent studies have indicated that there is virtually no risk to the child. Not to mention that there have been no reported incidents of injury. Even you indicated that had you been chairman in 1992 you would not have voted for this. Mr. Stratton it is imperative that you rescind the recall. This is obviously not an issue of product safety. This is an issue of a competitor, i.e. Boppy Co., using their government connections to eliminate a successful competitor. It is quite obvious that Boppy Co. was infact the company that made the complaint and was the driving force behind this product recall. It is not fair to small business owners who obviously can not compete with the resources of larger companies in matters like this. Regulations such as these are aimed at small time competitors for the simple fact that they do not have the additional resources to fight these battles and must obey or be wiped out. What's even more appalling is the fact that due to your agency's limited budget you permit the larger corporations to write up the regulations that will impact their industry with little input from smaller companies within that industry. I realize it is common place for companies to use legislation and regulatory agencies to solidify their place in the market at the expense of smaller competitors and consumers as a whole. But please.....do not let this happen. It is unfair and un-American. I believe you know full well that government agencies lack the resources to properly regulate and as a result the system gets abused from those companies who have the excess resources to spare on political favors such as these. Regulation in these matters is quite unnecessary. Are we really to believe that consumers are too dumb to decide what is or isn't safe? I do not believe this is the case. Let the market sort this out. If in fact these products are unsafe consumers will eventually stop buying them. Besides, what reason do we have to believe that your agency's criteria for what is or isn't safe is any better than what we as consumers use to determine that for ourselves? This decision is wrong and I hope that by doing the right thing you will rescind this recall and allow this product, which has hurt no one, to be permitted back on the market.

-Matt Day
Concerned citizen

Relax. Yahoo! Mail virus scanning helps detect nasty viruses!

3/3/2006