



131 Coolidge St., Ste 102, Hudson, MA 01749 Phone: 978.212.3376

May 22, 2024

The Hon. Richard L. Trumka Jr. Commissioner U.S. Consumer Product Safety Commission 4330 East West Highway Bethesda, MD 20814

Re: Request to immediately retract your public statements as they pertain to Nested Bean, its products, and our safety record

Commissioner Trumka:

I am writing to correct the record regarding your recent unfounded attacks on Nested Bean, a Massachusetts based immigrant minority woman-owned small business, and its products.

Safety is our number one - and only - priority. Your speculative, unsupported allegations and actions have not only caused great harm to our small business and our employees, but more important, have made it much more difficult for parents to access alternatives that promote safe sleep practices and help with their baby's sleep challenges.

Simply put, your statements made on the CPSC site¹ and your letter to the retailers², as they relate to Nested Bean products, are misleading and ignore a series of facts, including:

- <u>Nested Bean's products have a long, proven track-record of safety.</u> Nested Bean stands by the safety of our products, with over 2.5 million units sold since 2011. Your public comments do not consider our proven safety record, in fact, they ignore it.
- Added weight in the Nested Bean products is equivalent or less to commonly found comparators like car seat buckles or pacifier holders. You wrongly alert consumers to the risk of death while using exaggerated images in video statements³, which aim to create unfounded fear in the minds of the viewers. The "weighted" part of our products for newborns weighs only 30 grams, equivalent to car seat buckles, pacifier holders, or a small stuffed toy. Broad categorization of our light-weight product into a category of weighted infant blankets and swaddles ignores this critical distinction in your "recommendation" to retailers.
- Official public reports demonstrate that Nested Bean is not associated with multiple deaths. The death of a child is an unfathomable tragedy. It is disturbing to use such an incident to further false statements. Your statements to retailers falsely allege that a Nested Bean product played a role in the Kansas state infant death. The State Coroner's official report⁴ found that to be false. In fact, the coroner's report found

¹ See https://www.cpsc.gov/About-CPSC/Commissioner/Richard-Trumka/Statement/Beware-Weighted-Infant-Swaddles-and-Blankets-Are-Unsafe-for-Sleep-Retailers-Should-Consider-Stopping-Sales

² See https://www.cpsc.gov/s3fs-public/Trumka Statement Weighted Infant Products 4 26 24 with attachments.pdf?VersionId=iK5EDmatuGu9 z2jKt8t8BaWndFKwWCh

³ See <u>https://x.com/TrumkaCPSC/status/1779951952559751190</u>

⁴ See https://wycokck.nextrequest.com/documents/25987141

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that an infant lounger – the very kind of product banned by the CPSC⁵ – and several unsafe sleep practices were involved in this tragic incident.

- <u>CPSC staff evaluated Nested Bean products and found them safe.</u> In April 2023, CPSC's own internal Compliance staff completed an investigation of Nested Bean's products, sending the company a closing letter stating that no further action was warranted [Attachment A closing letter]. Your statements ignored CPSC's own careful staff analysis.
- Not one CPSC Commissioner supported rulemaking for weighted wearables. The Commission is made up of five Commissioners, to ensure balance and rigor in decision-making. The Commission, as a body, spoke when not one Commissioner voted in favor of your motion⁶ to start rulemaking for weighted wearable infant blankets and swaddles, which you had proposed during the 2024 Operating Plan Review⁷. Pressuring retailers in this manner you ignored the process. CPSC is also staffed with excellent and dedicated technical experts, but you ignored their data driven findings.

Independent Study for Baselines

Right from birth, an infant's body receives pressure from many objects, from swaddles to car seat buckles, and blankets to winter jackets. Yet we found that there was no evidence, standard tests or regulation of what pressure was acceptable. To inform the industry decisions, Nested Bean undertook an independent fundamental research study aiming to create baselines. The pilot study used a broad spectrum of weights - from 30 grams of weight concentration to almost 10 times that, spread over the same area and location to create incremental pressure.

This study was shared with your office in our letter dated Feb 16, 2024. There has been no substantive response to date, to the material we shared.

Results of this pilot study indicate that using concentrations of 30 grams or lower over the specified area, as used in Nested Bean products, show no health risk particularly to the pulse rate, oxygen saturation and heart rate. This is contrary to your broad citations of risk without the specifics of weights, duration, baby's weight, or age at which the hypothesized negative impact may occur.

Nested Bean's product design uses light pressure to simulate parental touch.

In 2011, Nested Bean applied the concept of parental touch simulation with proven benefits⁸ in a line of infant sleepwear to offer alternative solutions to parents struggling with their infants' sleep challenges. The sleepwear applied very light mass of 30 grams (one ounce) or lower, spread over a specific area on the

⁵ See https://www.cpsc.gov/About-CPSC/Commissioner/Richard-Trumka/Statement/Dockatot-Deluxe-is-Unsafe-for-Sleep-CPSC-Issues-Notice-of-Violation

⁶ *See* https://www.cpsc.gov/s3fs-public/Comm-Mtg-Min-FY-2024-Operating-Plan-Decisional.pdf?VersionId=GDwWSUy29P7SN9MpqVVWdX5Nn9xe36Vm.

⁷ See https://youtu.be/LHemQpZZBN0?list=PLPbI8bR243fHmCYA1a7pZ4l4wzhYjla V&t=1041

⁸ See https://cdn.shopify.com/s/files/1/2582/8162/files/Neuroprotective Core Measure 2 publication.pdf?v=1588033406

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infant's chest, where babies are used to feeling the calming palm of a parent. This application of light mass to our sleepwear was tested for associated risks and verified by Human Factors safety experts.

Nested Bean remains committed to having a close working relationship with public safety officials and their staff. But that requires an open dialogue. And yet, neither you nor your staff provided any substantive response to the research, data and findings provided in our letter dated February 16, 2024.

Further, you ignored our request for documentation of your meeting with an advocate, including for a copy of the request you should have made to the Executive Director when you failed to provide the required seven-day public notice of that meeting.

Our request for a public meeting to present our actual safety record and discuss steps to increase standards remains. You and your staff have my email. In the meantime, I respectfully request that you immediately retract your recent public statements as they pertain to Nested Bean, its products, and its safety record.

Respectfully,

Manasi Gangan



Nested Bean Inc.

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Attachment A

CPSC Closing Letter After Review of Nested Bean Products



April 05, 2023

Email: boaz@nealcohenlaw.com

Boaz Green Nested Bean, Inc. Neal Cohen Law LLC 6930 Carroll Ave., Suite 423 Takoma Park, MD 20912

Re: CPSC File No. PI220138

Nested Bean, Inc.

Zen Sack weighted wearable blanket

Dear Mr. Green:

The staff of the Office of Compliance and Field Operations of the U.S. Consumer Product Safety Commission ("Commission") has completed its review of the information you provided on behalf of Nested Bean, Inc. ("Firm") in response to our request regarding Zen Sack weighted wearable blankets ("Subject Products") rising over an infant's face and posing a potential suffocation risk. Based upon the information you provided, the staff does not believe the problem identified necessitates further action by the Commission under section 15 of the Consumer Product Safety Act, 15 U.S.C. § 2064.

The Firm has a continuing obligation to inform the Office of Compliance and Field Operations of defects associated with the Subject Products which could create a substantial product hazard and of information that reasonably supports the conclusion that the Subject Products create an unreasonable risk of serious injury or death. If the Firm receives or learns of any information complaints, claims, incidents, or injuries that the Firm did not report, or other information affecting the scope, prevalence, or seriousness of the reported problem, issue, or potential defect or hazard, the Firm must report that information to the Office of Compliance and Field Operations.

This staff conclusion is based upon the information that the Firm provided to us. The staff will assess any new information concerning the Subject Products, including new information that the Firm may provide, to determine if action should be taken to protect the public. Should the staff decide to investigate further, we will notify the Firm.

If you have any questions, please contact me at (301) 504-7656 or RBThomas@cpsc.gov.

U.S. Consumer Product Safety Commission 4330 East-West Highway Bethesda, MD 20184 cpsc.gov National Product Testing & Evaluation Center 5 Research Place Rockville, MD 20850

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Sincerely,

Rosalee Thomas

Trial Attorney Division of Enforcement and Litigation

Rosalee Thomas.