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JUDICIARY

VETERANS' AFFAIRS

United States Senate
WASHINGTON, DC 20510

706 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510
(202) 224-2823
FAX: (202) 224-9673

90 STATE HOUSE SQUARE, TENTH FLOOR
HARTFORD, CT 06103
(860) 258-6940
FAX: (860) 258-6958

915 LAFAYETTE BOULEVARD, SUITE 304
BRIDGEPORT, CT 06604
(203) 330-0598
FAX: (203) 330-0608
<http://blumenthal.senate.gov>

December 6, 2023

Ms. Manasi Gangan
Nested Bean
131 Coolidge Street, Ste. 120-D
Hudson, MA 01749

Dear Ms. Gangan,

I write today regarding the weighted sleep sacks and swaddles developed and sold by your company, Nested Bean. The Nested Bean website claims that these products were developed in consultation with doctors and pediatric pulmonologists.¹ However, the American Academy of Pediatrics (AAP) recently shared their opposition to weighted sleep products for infants explicitly stating that “weighted swaddle clothing or weighted objects within swaddles are not safe and therefore not recommended.”² That is why I am deeply concerned by your company’s decision to continue selling these products to vulnerable and unsuspecting parents who are sleep-deprived, stressed and desperate for help, all while lacking reputable research to back the safety of these items.

In June 2023, the AAP sent a letter to the U.S. Consumer Product Safety Commission (CPSC) urging oversight of weighted sleep products for infants and children. In this letter, they outlined significant health concerns with the use of these products, including the fact that an infant’s ribcage is flexible and not fully ossified so prolonged weight and pressure from these types of products may compress their chest, affecting their breathing and heart rate.³ Pediatricians have also linked Sudden Infant Death Syndrome (SIDS) to infants’ inability to startle themselves awake and re-stabilize their system.⁴ The deep sleep that is promoted by

¹ Nested Bean, <https://www.nestedbean.com/pages/our-story>

² Moon, Rachel, “Sleep-Related Infant Deaths: Updated 2022 Recommendations for Reducing Infant Deaths in the Sleep Environment.” (July 2022). <https://publications.aap.org/pediatrics/article/150/1/e2022057990/188304/Sleep-Related-Infant-Deaths-Updated-2022?autologincheck=redirected>

³ Khimm, Suzy “Weighted sleep sacks are unsafe for infants, national pediatricians’ group says” (June 16, 2023). <https://www.nbcnews.com/news/us-news/weighted-sleep-sacks-american-academy-pediatrics-rcna89469>

⁴ Kirchner, Lauren “Pediatricians Warn That Weighted Baby Blankets, Sleep Sacks, and Swaddles Are Not Safe” (July 26, 2023). <https://www.consumerreports.org/babies-kids/child-safety/weighted-baby-blankets-sleep-sacks-swaddles-are-not-safe-a6236206799/>

weighted sleep products may inhibit their natural ability to rouse themselves, putting them at a greater risk for SIDS. Further, infants have small stomachs and are supposed to wake up every few hours to eat. According to the CDC, in their early months, parents should expect infants to feed every 2 to 5 hours.⁵ Telling a parent that it is safe for their baby to sleep uninterrupted for hours on end using your products is misleading and harmful.

In addition to the serious health concerns that have already been raised by the AAP, the lack of comprehensive research and testing into the safety of weighted sleep products for infants is troubling. Your website claims that Nested Bean “worked with multiple safety laboratories, all of whom are accredited by the [CPSC]...to ensure safety in both design and quality.” It also says that “all Zen Sleep products have undergone extensive tests to meet both mandatory and voluntary safety standards.” The CPSC does not have an existing standard for the use of weighted sleep products for infants.⁶ Further, your website has an “experts speak” webpage which cites various studies on the importance of human touch in regulating stress.⁷ However, the one study that cited the importance of human touch for infants was conducted in a clinical setting in a hospital where infants were under constant supervision. This study was also released thirty-five years ago in 1988.⁸ The majority of these studies focused on human, not simulated, touch and the benefits they had on *adults*. In fact, there has been little to no evidence, in peer-reviewed scientific literature evaluating the safety of weighted sleep products on infants and there have been no published studies regarding their use in an unmonitored setting.⁹ Yet your company is actively selling these products, marketing them as safe.

One of the more recent, and widely cited, studies was published in 2020 and examined the safety and efficacy of weighted sleep products for infants but the focus was specifically on patients in the neonatal intensive care unit (NICU) who were suffering from neonatal abstinence syndrome. The sample size in this study was small, consisting of 16 infants who were under the weighted blanket for 30-minute sessions with constant supervision.¹⁰ This study did not explain how infants would respond to this pressure over a longer period or time, namely the overnight sleep sessions the weighted sleep sacks are marketed for or how weighted sleep products would affect infants without an underlying condition. The study also acknowledged that additional research with larger sample sizes were necessary, but most importantly, it never advocated or promoted the use of weighted sleep products outside of a hospital setting.

You have even underscored the lack of adequate research into these products yourself. In response to the AAP’s strong opposition to weighted sleep products, you stated that you were

⁵CDC “How Much and How Often to Breastfeed”

<https://www.cdc.gov/nutrition/infantandtoddlernutrition/breastfeeding/how-much-and-how-often.html#:~:text=First%20Weeks%20and%20Months&text=On%20average%2C%20most%20exclusively%20breastfed,on%20the%20time%20of%20day>

⁶ Nested Bean, <https://www.nestedbean.com/pages/faq>

⁷ Nested Bean, <https://www.nestedbean.com/pages/experts-speak>

⁸ Goleman, Daniel “The Experience of Touch: Research Points to a Critical Role”

<https://www.nytimes.com/1988/02/02/science/the-experience-of-touch-research-points-to-a-critical-role.html>

⁹ AAP letter to the CPSC, <https://www.documentcloud.org/documents/23849624-aap-letter-61523>

¹⁰ Hernandez, Joe “Weighted infant sleepwear is meant to help babies rest better. Critics say it’s risky” (July 27, 2023), <https://www.npr.org/2023/07/27/1190263995/weighted-infant-sleepwear-safety>

hopeful the AAP would change its position *once they were researched more thoroughly*.¹¹ It is clear that there is not yet enough information on the potential impacts weighted sleep products can have on infants and they should not be marketed as ‘safe’ especially since medical professionals have expressed such serious concerns.

To better understand the research conducted and safety precautions taken during the development of this product, I request answers to the following questions by December 21st, 2023:

- 1) Have you received reports or reviews of incidents, injuries, or deaths resulting from the use of your products, including those that have not been formally reported to the CPSC? If so, please provide the reports for each category of complaints along with the dates of their reporting.
 - a. Have you shared any reports of incidents, injuries, or deaths with the CPSC. If so, when?
 - b. How do you follow up with consumers who experienced negative incidents?
 - c. Have consumers returned products due to incidents or perceived hazards? If so, how many and what were the reasons listed for the return?
- 2) Which medical experts did you consult with when developing these products?
 - a. How many medical experts did you consult?
 - b. What background and qualifications do these experts possess?
 - c. What was the nature of the consultation?
 - d. Did this consultation include a safety assessment? If so, what did the assessment involve?
 - e. What were the specific conclusions reached by the experts you consulted?
- 3) If you have conducted research or studies into the efficacy and safety of weighted sleep products of infants please provide details of the process and outcomes including the following: the structure of the study and duration of the study periods, whether these studies were conducted with or without supervision, the pediatric experts who led the research, and any findings or reports that may illustrate the rigor of the study.
- 4) What information have you relied on to market these products as safe? If sales without injury are one source of information, please explain what safety metrics were used to determine safety when the products were first introduced?
- 5) How many Nested Bean products are currently in circulation? What levels of growth do you predict in the next fiscal year?
- 6) Your website claims that your products are “backed by multiple studies for design and breathing safety.” Please provide information on these studies and the qualifications of the experts who conducted them.
- 7) Does your product include any information for consumers that would remind them that young infants need to wake up every few hours to feed?

¹¹ Khimm, Suzy “Weighted sleep sacks are unsafe for infants, national pediatricians’ group says” (June 16, 2023). <https://www.nbcnews.com/news/us-news/weighted-sleep-sacks-american-academy-pediatrics-rcna89469>

Thank you for your attention to this important matter.

Sincerely,

A handwritten signature in blue ink, reading "Richard Blumenthal". The signature is fluid and cursive, with the first name "Richard" being the most prominent.

Richard Blumenthal
United States Senate