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December 6, 2023

Tara Williams
Dreamland Baby
3338 Deer Hollow Drive
Danville, CA 94506

Dear Ms. Williams,

I write today regarding the weighted sleep sacks and swaddles developed and sold by your company, Dreamland Baby. The Dreamland Baby website claims that these products were developed in partnership with pediatricians.¹ However, the American Academy of Pediatrics (AAP) recently shared their opposition to weighted sleep products for infants explicitly saying 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,”³ 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 type of products may compress their chest, affecting their breathing and heart rate.⁴ Pediatricians have also linked Sudden Infant Death Syndrome (SIDS) to infants’ inability to startle themselves awake and re-stabilize their system.⁵ The deep sleep that is promoted by weighted sleep products

¹ Dreamland Baby, <https://dreamlandbabyco.com/pages/faq-producty-safety-and-care>

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 Dreamland Baby, <https://www.dreamlandbaby.co.uk/blogs/news/the-key-benefits-of-weighted-sleep-sacks-for-babies>

⁴ 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>

⁵ 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/>

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.⁶ 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 company website claims that the weighted sleep sacks and swaddles are rigorously tested and “exceed all CPSC standards.” The CPSC does not have an existing standard for the use of weighted sleep products on infants. Further, the website states that you are working with researchers on a comprehensive study on the safety and efficacy of weighted sleep products.⁷ As you know, the results have not been published or verified. In fact, there has been 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.⁸ Yet your company is actively selling these products, marketing them as safe.

One of the studies highlighted on your website 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.⁹ This study did not explain how infants would respond to this pressure over a longer period of 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.

The lack of adequate research into these products has even been underscored by the founder and president of Nested Bean, another weighted sleep sack company, who stated that they were hopeful that the AAP would change its position on the products *once they were researched more thoroughly*.¹⁰ It is clear that there is not yet enough understanding of the impact

⁶ CDC “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>

⁷ Dreamland Baby, <https://dreamlandbabyco.com/pages/safety>

⁸ AAP letter to the CPSC, <https://www.documentcloud.org/documents/23849624-aap-letter-61523>

⁹ 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>

¹⁰ 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>

of weighted sleep products 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 experience 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 for infants, please provide details of the process and outcome 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 Dreamland Baby products are currently in circulation? What levels of growth do you predict over the next fiscal year?
 - a. What hospitals are currently using Dreamland Baby products in their NICU?
 - b. Have you received any outreach from hospitals using Dreamland Baby products looking to dissolve the partnership given AAP’s recommendations?
 - c. Are hospitals recommending the use of Dreamland Baby products to parents or caregivers outside of the hospital setting? (See Exhibit A)
- 6) A Google search on November 1, 2023 for “Dreamland Baby weighted blanket” resulted in an advertisement that asserts the following: “Dreamland Baby is the world’s first *safety certified* weighted blanket designed for infants.” [See Attachment] Who certified this product and to what standard were they certified?
- 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?

- 8) Your design distributes weight throughout the front of the sleep product, up to 10% of the recommended user's weight. What medical research do you point to that shows that 10% of *a newborn's or infant's weight* is safe in a weighted product?

Thank you for your attention to this important matter.

Sincerely,



Richard Blumenthal
United States Senate

Attachment

The image shows a Google Shopping search results page for 'dreamland baby weighted blanket'. The search bar at the top contains the text 'dreamland baby weighted blanket' and has a search icon on the right. Below the search bar, there are navigation options: 'All', 'Shopping', 'Images', 'Videos', 'Books', and 'More'. The 'Shopping' tab is selected. On the left side, there is a 'Filter by' section with several filters: 'Nearby', 'On sale', 'Get it fast', 'Color' (with options for Pink, Blue, Gray, Green, and a 'See 3 more' link), 'Material' (with options for Cotton, Fleece, Sherpa, and Faux Fur), 'Price', 'Fabrication', and 'Stores'. The main content area shows 'About 576,000 results (0.50 seconds)'. Below this, there is a 'Sponsored' section with five product listings. Each listing includes an image of the product, the brand name 'Dream Weighted...', the price, the product name 'Dreamland ...', and a star rating with the number of reviews. The products are: 1. Blue quilted blanket, \$99.00, 5 stars (163 reviews). 2. White quilted blanket, \$99.00, 5 stars (163 reviews). 3. Teal quilted blanket, \$89.00, 5 stars (3k+ reviews). 4. Pink quilted blanket, \$99.00, 5 stars (163 reviews). 5. Green quilted blanket, \$89.00, 5 stars (3k+ reviews). Below the sponsored listings, there is another 'Sponsored' section for 'Dreamland Baby' with the URL 'https://www.dreamlandbabyco.com'. The text reads: 'Dreamland Baby Co - Weighted Blankets & Swaddles' and 'Dreamland Baby is the world's first safety certified **weighted blanket** designed for infants'. Below this, there is a section titled 'How It Works' with the text: 'Evenly Distributed Gentle Weight. Asleep Faster, Asleep Longer.'