



LIBERTY
JUSTICE CENTER

February 13, 2025

VIA EMAIL

Dorothy A. Fink, M.D., Acting Secretary
The U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Dorothy.fink@hhs.gov

Re: Request to rescind unsupported guidance from health agencies NIH and CDC against weighted infant sleep products that has irreparably damaged small businesses

Dear Secretary Fink,

We are writing on behalf of **Nested Bean, Inc.** to urgently demand rescission of the specific statements in the **Safe Sleep Guidance** issued by the **Department of Health and Human Services (HHS)**, the [Centers for Disease Control and Prevention \(CDC\)](#), and the [National Institutes of Health \(NIH\)](#), which, without any scientific or statutory support, strongly advises *against* the use of weighted infant sleep products, including weighted sleepers, swaddles, sleep sacks, and blankets.

This guidance represents an egregious overreach of the federal government in the absence of any statutory authority granted to HHS, CDC, or NIH to regulate consumer products. The CDC and NIH were the first agencies to warn against the use of weighted infant sleep products. However, the Consumer Product Safety Commission (“CPSC”) is the *only* agency statutorily authorized to determine if a consumer product presents an unreasonable risk of injury or death. There is no legal backing for HHS, CDC, or NIH to lead the charge and recommend to the public that a consumer product is unsafe *before* the CPSC has made any hazard determination or followed proper rule making. The HHS, CDC, and NIH are not following a directive from the CPSC.¹ The Safe Sleep Guidance on weighted infant sleep products is not based on any rule, standard, recall, ban, or stop sale issued by the CPSC, because there is none.²

Moreover, the guidance is not based on any scientific evidence demonstrating harm from these products.³ On the contrary our client’s products have helped millions of families for the last 14 years, and thousands of parents continue to rely on them to this day. It is the CPSC’s responsibility to research potential product hazards, and to date it has not identified a hazard

¹ Instead the CPSC is following the HHS, CDC, and NIH guidance. **“This guidance is based on information from the Centers for Disease Control and the National Institutes for Health. Please go to [CDC.gov](#) and [NIH.gov](#) for more information.”** Available at <https://www.cpsc.gov/SafeSleep>.

² **“There are currently no safety standards for weighted swaddles and blankets beyond the general rules for children’s products.”** Available at <https://safetosleep.nichd.nih.gov/reduce-risk/FAQ> (under drop-down tab “Why are weighted swaddles or blankets not recommended for babies?”).

³ Emily Oster, *New AAP Guidelines on Breastfeeding and Safe Sleep: A case study in bad use of data*, Parent Data (July 5, 2022), <https://parentdata.org/new-aap-guidelines-on-breastfeeding-and-safe-sleep/>.

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pattern associated with weighted infant sleep products available on the market. In fact, no studies or safety standards currently exist that would justify such an aggressive public stance.

This guidance made under the Biden Administration directly contradicts the policies set forth by **President Trump's** executive orders, which explicitly called for the freezing of regulatory actions until they were properly reviewed, including agency-issued guidance documents. These orders emphasize the need for transparency, scientific integrity, and due process, none of which have been followed in the issuance of this damaging guidance. Additionally, these executive orders provide enough authority for the HHS, CDC, and NIH to rescind this unscientific guidance made under the previous administration. The guidance against weighted infant sleep products is not a promulgated rule, instead it is merely an agency statement that can be rescinded by executive or agency action without the need for adherence to the rule-making procedures.

The Trump administration's clear mandate — to end government overreach and restore economic opportunity — underscores the imperative need for action. **This guidance stands in direct conflict with President Trump's policies**, which prioritize the creation of jobs, the support of small businesses, and the protection of American citizens from unjustified and unfounded regulatory barriers. The ongoing advocacy *against* weighted infant sleep products **without adequate scientific or statutory support** is inconsistent with these objectives and harmful to businesses like **Nested Bean, Inc.**, which has served American families since 2011, selling millions of products and maintaining an impeccable safety record.

During the prior administration we brought these concerns to the *only* agency statutorily authorized to opine on the safety of a consumer product, the CPSC. And, while we are prepared to bring a lawsuit against the HHS, CDC, and NIH for their *ultra vires* actions, we believe that given the change in administration and President Trump's policies, we are hopeful that these agencies can be brought into statutory conformance through executive action. The **rescission of this unscientific and overreaching guidance** would immediately restore due process and save a critical industry that has been unfairly targeted.

We respectfully request that the current administration act swiftly to **rescind the guidance against weighted infant sleep products**, in line with President Trump's executive orders, and rectify this instance of **unwarranted government overreach**.

We remain committed to engaging with your office to resolve this matter expeditiously, and we are confident that the **Trump administration** can restore balance and fairness to this issue.

Very truly yours,



Loren A. Seehase

Senior Counsel

CC: HHS Chief of Staff, Heather Melanson, Heather.melanson@hhs.gov