



AAP Headquarters

345 Park Blvd
Itasca, IL 60143
Phone: 630/626-6000
Fax: 847/434-8000
www.aap.org

Reply to

AAP Washington Office

601 13th St NW, Suite 400N
Washington, DC 20005
Phone: 202/347-8600
E-mail: kids1st@aap.org

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June 15, 2023

The Honorable Alexander Hoehn-Saric, Chairman
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, Maryland 20814

Mr. Donald Mays
Chair
F15 Committee on Consumer Products
ASTM International

RE: ASTM F15.19 Weighted Infant Products

Dear Chairman Hoehn-Saric and Mr. Mays:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of 67,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents, and young adults, I am writing to express our concerns about the possible development of a voluntary safety standard for weighted infant sleep products, including weighted blankets, weighted sleepers, and weighted swaddles.

Safe infant sleep is a critical AAP priority. Sleep-related infant deaths, after an initial decrease following implementation of the Back to Sleep campaign in the 1990s, have not declined in the last 10 years. Approximately 3,400 infants each year experience sleep-related death — and many of these deaths in otherwise health infants are preventable.¹ Policies promoting safe sleep environments and preventing dangerous sleep practices are critical for preventing sleep-related infant deaths.

The AAP recommends that infants always sleep on their back, on a separate, flat and firm sleep surface without any bumpers or loose bedding. AAP's recommendations for a safe sleep environment also include room-sharing without bed-sharing, and the avoidance of soft bedding and overheating.

The AAP's [most recent recommendations](#) for safe sleep, issued in 2022, state "it is recommended that weighted blankets, weighted sleepers, weighted swaddles, or other weighted objects not be placed on or near the sleeping infant." The AAP's recommendations further states that "weighted swaddle clothing or weighted objects within swaddles are not safe and therefore not recommended." The evidence available at this time does not indicate that weighted swaddle products are safe, nor does it demonstrate that they are effective in helping babies sleep longer or with fewer disruptions. Further, it is hypothesized that impaired arousal may contribute to risk of Sudden Infant Death Syndrome (SIDS), so a product that decreases arousal may increase the risk of SIDS.

The AAP is concerned that ongoing efforts to develop a voluntary safety standard for these weighted infant products through ASTM International will send parents and caregivers the incorrect message that these unnecessary products are safe. The AAP believes these weighted swaddles and related products are unsafe for infants and does not recommend these products. While voluntary standards are appropriate for certain products, given the AAP's clear policy regarding the danger of weighted infant sleep products, we oppose the development of any voluntary standard for these products.

There is no evidence in the peer-reviewed scientific literature evaluating the safety of weighted sleep products on typical, healthy infants, and there is also nothing published regarding their use in an unmonitored setting. Even preliminary, non-peer-reviewed data under discussion in ASTM International proceedings suggest these products are associated with concerning reductions in oxygen saturation levels in infants. This means there is evidence that the use of weight sleep products on infants can lead to lower oxygen levels, which if sustained, may be harmful to the developing infant's brain. A lack of substantial evidence about the possible harms of weighted sleep products should not serve as evidence that they do not cause harm.

Parents expect that products available for purchase at reputable retailers are thoroughly tested for safety. CPSC and ASTM International should both take a precautionary approach to these and other novel infant sleep products to avoid a repeat of what happened with inclined sleepers, in-bed sleepers, and other novel sleep-related products. These products ultimately were associated with over 100 infants' deaths—all of which would have been prevented if these products were not kept on the consumer market. Waiting for the emergence of confirmatory data about these concerns while these products proliferate is an unacceptable outcome when each of those data points will be a family whose lives are forever marked by unfathomable tragedy of their infant dying from a sleep-related death.

The AAP urges you to conduct vigorous oversight on all weighted sleep products, especially those marketed for infants and children. Thank you for this opportunity to comment on this important issue and for your work to better protect children from dangerous products. If the AAP can be of any further assistance, please do not hesitate to contact Zach Laris in our Washington, D.C. office at 202/347-8600 or zlaris@aap.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Sandy L. Chung'.

Sandy L. Chung, MD, FAAP
President

SC/zml

ⁱ U.S. Centers for Disease Control and Prevention (2022). About SUID and SIDS. Retrieved from <https://www.cdc.gov/sids/data.htm>.