IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NESTED BEAN, INC., *Plaintiff,* v. UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION; PETER A. FELDMAN in his official capacity as Acting Chair of the Consumer Product Safety Commission; RICHARD L. TRUMKA, JR., in his official capacity as Commissioner of the Consumer Product Safety Commission; ALEXANDER HOEHN-SARIC in his official capacity as Commissioner of the Consumer Product Safety Commission; DOUGLAS DZIAK in his official capacity as Commissioner of the Consumer Product Safety Commission; MARY T. BOYLE in her official capacity as Commissioner of the Consumer Product Safety Commission; DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR. in his official capacity as Secretary of Health and Human Services; CENTERS FOR DISEASE CONTROL AND PREVENTION; SUSAN MONAREZ in her official capacity as Acting Director of the Centers for Disease Control and Prevention; NATIONAL INSTITUTES OF HEALTH; and JAY BHATTACHARYA in his official capacity as Director of the National Institutes of Health, *Defendants.*	CIVIL ACTION NO._____ **COMPLAINT FOR DECLARATORY RELIEF**

COMPLAINT FOR DECLARATORY RELIEF

INTRODUCTION

1. This challenge is brought to stop the unlawful and unfounded public statements against weighted infant sleep products made by Defendants Consumer Product Safety Commission ("CPSC" or "Commission"), CPSC Commissioner Richard Trumka, Jr., the

Department of Health and Human Services ("HHS"), the Centers for Disease Control and Prevention ("CDC"), and the National Institutes of Health ("NIH"). Defendants have issued inaccurate, misleading, and unlawful public advisories, maligning weighted infant sleep products as deadly and hazardous, – including the products developed, designed, produced, and sold by Nested Bean, Inc. ("Plaintiff" or "Nested Bean") – and advocating that parents and caregivers refrain from using such products. These unlawful actions have severely damaged Nested Bean's relationships with retailers and investors, destroyed its reputation, and decimated the company.

2. The CPSC is the only agency charged with protecting consumers from unreasonable risks of injury from consumer products. The authorizing law provides a regulatory framework for the CPSC to: conduct product safety research, investigations, and testing; assist with the development of voluntary product safety standards; promulgate mandatory consumer product safety standards; collect, maintain, and analyze incident data; file suit to seize imminently hazardous products; and ban hazardous products. All consumer product safety determinations made by the CPSC must follow the rigorous science and data driven process set forth by federal law.

3. Weighted infant sleep products have been around for nearly 15 years. In 2011, Nested Bean was founded by a mother struggling with newborn sleepless nights, who happened to have an engineering background and over a decade of developing consumer facing products. Determined to provide relief for other parents, Nested Bean rigorously researched, designed, and developed its product for child safety before bringing it to market. Nested Bean is deeply committed to infant safety. It continues to invest and undergo safety testing and scientific research, even though it is under no obligation to do so. Nested Bean has actively participated and cooperated with the CPSC to create voluntary safety standards for weighted infant sleep

products to protect consumers from unscrupulous manufacturers. Nested Bean's safety record speaks for itself. It has sold over 2.5 million products and has not had a single known incident or CPSC investigation report concluding that any of its products are hazardous.

4. To date, the CPSC has not: adopted any voluntary or mandatory product safety standards for weighted infant sleep products; adopted a definition of weighted infant sleep products; identified a hazard pattern with Nested Bean's products or weighted infant sleep products; nor issued a recall, stop sale, or ban for Nested Bean's products.

5. Despite the fact that the CPSC has not made any determinations regarding weighted infant sleep products, sometime in 2023, the HHS, and its subagencies CDC and NIH, amended their Safe Sleep guidance for the public to advocate *against* the use of weighted infant sleep products. Then the CPSC, rather than following their own statutory requirements for making consumer product safety determinations, simply followed and echoed the unlawful HHS guidance.

6. Compounding the unlawful actions, one Commissioner made it his personal mission to destroy the industry of weighted infant sleep products. Even though the CPSC has not identified a hazard pattern associated with weighted infant sleep products and the CPSC admitted that it did not have enough data necessary to begin the rule making process for a mandatory product safety standard, Commissioner Trumka wrote letters to major retailers and announced publicly that weighted infant sleep products were dangerous and presented an unreasonable risk to consumers.

7. Because of Trumka's actions, major retailers dropped Nested Bean's products thereby decimating Nested Bean's business.

8. Defendants will continue these unlawful actions unless and until a Court upholds

the rule of law. Therefore, this Court should grant Plaintiff's requested relief.

PARTIES

9. Plaintiff Nested Bean, Inc. ("Nested Bean") is a corporation incorporated in Delaware, primarily engaged in the business of designing, manufacturing, and selling infant and toddler products, including weighted infant sleepwear.

10. Defendant Consumer Product Safety Commission ("CPSC" or "Commission") is the federal agency given limited authority to regulate consumer products. Its headquarters are in Bethesda, Maryland.

11. Defendant Peter A. Feldman is sued in his official capacity as Acting Chair of the Consumer Product Safety Commission. He was nominated by President Trump and began serving a seven-year term on October 5, 2018.

12. Defendant Commissioner Richard L. Trumka Jr. is sued in his official capacity as Commissioner of the Consumer Product Safety Commission. He was nominated by President Biden and began serving a seven-year term on October 27, 2021.

13. Defendant Alexander Hoehn-Saric is sued in his official capacity as Commissioner of the Consumer Product Safety Commission. He was nominated by President Biden and began serving a seven-year term on July 13, 2021.

14. Defendant Douglas Dziak is sued in his official capacity as Commissioner of the Consumer Product Safety Commission. He was nominated by President Biden and began serving on March 25, 2024 to complete a seven-year term that expired on October 27, 2024.

15. Defendant Mary T. Boyle is sued in her official capacity as Commissioner of the Consumer Product Safety Commission. She was nominated by President Biden and began serving a seven-year term on June 22, 2022.

16. Defendant Department of Health and Human Services ("HHS") is a Cabinet-level agency within the Government of the United States. It is headquartered in Washington, District of Columbia.

17. Defendant Robert F. Kennedy, Jr. is sued in his official capacity as Secretary of Health and Human Services.

18. Defendant Centers for Disease Control and Prevention ("CDC") is an operating division of HHS and an agency under 5 U.S.C. § 551(1). It is headquartered in Atlanta, Georgia and maintains offices in Washington, District of Columbia.

19. Defendant Susan Monarez is sued in her official capacity as Acting Director of the Centers for Disease Control and Prevention.

20. Defendant National Institutes of Health ("NIH") is an operating division of HHS and an agency under 5 U.S.C. § 551(1). It is headquartered in Bethesda, Maryland.

21. Defendant Jay Bhattacharya is sued in his official capacity as Director of the National Institutes of Health.

JURISDICTION AND VENUE

22. Plaintiff seeks declaratory relief (28 U.S.C. §§ 2201, 2202; 5 U.S.C. § 706) against the Commission for its actions in adopting and failing to rescind the Safe Sleep Guidelines that recommend against weighted infant sleep products, and its actions in publishing and failing to retract inaccurate and misleading statements by Trumka because such actions violate Section 6(b) of the Consumer Product Safety Act ("CPSA") (15 U.S.C. § 2055(b), 16 C.F.R. § 1101.1-1101.52); is not authorized by the CPSA (5 U.S.C. § 706(2)(A)); exceeds statutory authority (5 U.S.C. § 706(2)(C)); failed to follow procedure (5 U.S.C. § 706(2)(D)); is arbitrary and capricious (5 U.S.C. § 706(2)(A)); and thereby entitles Plaintiff to attorneys' fees

(28 U.S.C. § 2412, 42 U.S.C. § 1988 – attorneys' fees).

23. Plaintiff also seeks declaratory relief (28 U.S.C. §§ 2201, 2202) against Commissioner Trumka for his letters to major retailers and his public social media statements recommending against Nested Bean products and the class of weighted infant sleep products because it is *ultra vires* (5 U.S.C. § 702); violates the Fifth Amendment right to due process (42 U.S.C. § 1983 – constitutional rights); and thereby entitles Plaintiff to attorneys' fees (28 U.S.C. § 2412, 42 U.S.C. § 1988 – attorneys' fees).

24. Plaintiff also seeks declaratory relief (28 U.S.C. §§ 2201, 2202; 5 U.S.C. § 706) against Defendants HHS, Robert F. Kennedy, Jr., CDC, Susan Monarez, NIH, and Jay Bhattacharya for their actions in adopting the Safe Sleep Guidelines that recommend against weighted infant sleep products because none of those agencies have the authority to make consumer product safety determinations and as such the actions are *ultra vires* (5 U.S.C. § 702).

25. Plaintiff is also seeking to hold unlawful and set aside the Safe Sleep Guidelines that recommend against weighted infant sleep products (5 U.S.C. § 706).

26. The federal government has waived sovereign immunity to this action under 5 U.S.C. § 702.

27. This Court has jurisdiction over these federal claims (28 U.S.C. § 1331), review of agency action (5 U.S.C. § 702), and redress for deprivation of civil rights (28 U.S.C. § 1343(a)(3)) against these federal Defendants (28 U.S.C. §§ 1346).

28. Plaintiff Nested Bean has exhausted administrative remedies; the Commission's response to plaintiff's letter demanding retraction on December 20, 2024 is a final agency action that is judicially reviewable under the Administrative Procedure Act. 5 U.S.C. §§ 704, 706.

29. Venue is proper in this Court under 28 U.S.C. § 1391(e)(1) because (1)

Defendants are United States agencies or officers sued in their official capacities, (2) Plaintiff's place of incorporation is Delaware, (3) no real property is involved, and (4) a substantial part of the events or omissions giving rise to the Complaint occurs within this judicial district.

LEGAL BACKGROUND

The Consumer Product Safety Commission

30. The Consumer Product Safety Act ("CPSA"), 15 U.S.C.S. § 2051 et seq., enacted in 1972, established the Consumer Product Safety Commission ("CPSC" or "Commission") and gives the Commission authority to develop product safety standards, to ban products under certain circumstances, and to pursue recalls of products that present a substantial product hazard. 15 U.S.C. §§ 2056, 2057, 2058.

31. The CPSA was enacted to address concerns that "consumer products which present unreasonable risks of injury" were available to consumers and that the existing regulatory framework was either inadequate or burdensome to manufacturers. 15 U.S.C. § 2051(a)(1), (4), and (5).

32. The Commission's purpose is: "(1) to protect the public against unreasonable risks of injury associated with consumer products; (2) to assist consumers in evaluating the comparative safety of consumer products; (3) to develop uniform safety standards for consumer products and to minimize conflicting State and local regulations; and (4) to promote research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries." 15 U.S.C. § 2051(b).

33. To fulfill its purpose, the CPSA authorizes the Commission to: collect, maintain, and analyze incident data; assist in development of voluntary product safety standards; conduct product safety research, investigations, and product tests; promulgate consumer product safety

standards establishing performance or warning requirements; address imminently hazardous products; and ban hazardous products. *See* 15 U.S.C. §§ 2054, 2056, 2058, 2061, and 2064.

34. In promulgating consumer product safety standards, the Commission must follow the procedures set forth by both the CPSA and the Administrative Procedure Act ("APA").

35. A product safety standard requirement "shall be reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product." 15 U.S.C. § 2056(a).

36. "A consumer product safety rule shall express in the rule itself the risk of injury which the standard is designed to eliminate or reduce." 15 U.S.C. § 2058(e).

37. "In promulgating such a rule the Commissioner shall consider relevant available product data including the results of research, development, testing, and investigation activities conducted generally and pursuant to this Act." 5 U.S.C. § 2058(e).

38. "Prior to promulgating a consumer product safety rule, the Commission shall consider, and shall make appropriate findings for inclusion in such rule with respect to – (A) the degree and nature of the risk of injury the rule is designed to eliminate or reduce; (B) the approximate number of consumer products, or types or classes thereof, subject to such rule; (C) the need of the public for the consumer products subject to such rule, and the probable effect of such rule upon the utility, cost, or availability of such products to meet such need; and (D) any means of achieving the objective of the order while minimizing adverse effects on competition or disruption or dislocation of manufacturing and other commercial practices consistent with the public health and safety." 15 U.S.C. § 2058(f)(1).

39. "The Commission shall not promulgate a consumer product safety rule unless it has prepared, on the basis of the finding of the Commission under paragraph (1) and on other information before the Commission…" 15 U.S.C. § 2058(f)(2). Also, on the basis of those

findings, the final regulatory analysis must describe the potential benefits, costs, and alternatives.

40. The CPSA also permits the Commission to ban hazardous products which present "an unreasonable risk of injury" but such action requires the same evidence and data-backed determination. 15 U.S.C. § 2057.

41. CPSC may not promulgate a rule banning a product unless it finds "that no feasible consumer product safety standard under this Act would adequately protect the public from the unreasonable risk of injury associated with such product." 15 U.S.C. § 2058(f)(3)(c).

42. The CPSA also dictates how the Commission, the individual commissioners, and CPSC staff may publicly discuss consumer products. *See* 15 U.S.C. § 2055.

43. No less than 15 days prior to public disclosure of information, where the identity of the manufacturer is readily ascertainable, the Commission must notify the manufacturer about the information to be disclosed and must provide the manufacturer the opportunity to comment on such information. 15 U.S.C. § 2055(b)(1).

44. A manufacturer is "readily ascertainable," requiring notice before disclosure, "when a reasonable person receiving the information in the form in which it is to be disclosed and lacking specialized expertise can readily ascertain from the information itself the identity of the manufacturer or private labeler of a particular product." 16 C.F.R. § 1101.13.

45. Then before it publicly discloses information "from which the identity of such manufacturer . . . may be readily ascertained," the Commission must "take reasonable steps to assure" that the disclosure is (1) accurate, (2) fair in the circumstances, and (3) reasonably related to effectuating the purposes of the Consumer Product Safety Act. *Id*. In other words, if the CPSC, or an individual Commissioner, is going to disclose to the public information that would enable an average person to easily identify the manufacturer, then the CPSC must provide

that manufacturer with notice and opportunity to comment on the proposed disclosure. Then the CPSC must include in the disclosure any comments or other information provided by the manufacturer in response to the information. 15 U.S.C. § 2055(b)(1).

46. If the CPSC is going to disclose to the public information that reflects on the safety of a specific consumer product or a class of consumer products, then the CPSC still has an obligation to make sure that the information is not inaccurate or misleading regardless of whether the identity of the manufacturer is easily identifiable. 15 U.S.C. § 2055(b)(6).

47. The disclosure responsibilities under the CPSA apply to both the Commission and individual Commissioners. The public disclosure procedure "shall apply whenever information is to be disclosed by the Commission, *any member of the Commission*, or any employee, agent, or representative of the Commission in an official capacity." 15 U.S.C. § 2055(d)(2) (emphasis added).

48. Likewise, a retraction can be requested for statements made by individual commissioners. "Any manufacturer, distributor or retailer of a consumer product or any other person may request a retraction if he/she believes the Commission or *an individual member*, employee, agent, contractor or representative of the Commission has made public disclosure of inaccurate or misleading information, which reflects adversely either on the safety of a product with which the firm deals or on the practices of the firm." 16 C.F.R. § 1101.52(b) (emphasis added).

49. Then "[i]f the Commission finds that, in the administration of the Act, it has made public disclosure of inaccurate or misleading information which reflects adversely upon the safety of any consumer product or class of consumer products, or the practices of any manufacturer, private labeler, distributor, or retailer of consumer products, it shall, in a manner

equivalent to that in which such disclosure was made, take reasonable steps to publish a retraction of such inaccurate or misleading information." 15 U.S.C. § 2055(b)(7).

50. Commissioners may only be removed by the President for "neglect of duty or malfeasance in office but for no other cause." 15 U.S.C. § 2053(a).

Advancing Standards Transforming Markets

51. Advancing Standards Transforming Markets International ("ASTM"), formerly known as American Society for Testing and Materials, is an organization that develops technical standards for a wide range of materials, products, systems, and services.

52. Since the 1970's CPSC has collaborated with ASTM to create standards for emerging hazards. ASTM is a private voluntary consensus standards development organization which creates and maintains product standards using a rigorous approach to assure that standards are developed in an open, fair, and balanced system with input from all stakeholders. ASTM Committee F15 on Consumer Products was established in 1973 at the request of CPSC.[1]

53. "CPSC has about 500 employees and is responsible for overseeing safety issues relative to thousands of product categories. ASTM technical committees provide stakeholder expertise that could not otherwise be found among CPSC staff."[2] "The development of a new or revised ASTM International standard is often initiated when CPSC approaches ASTM regarding the need for a particular safety standard. CPSC staff will provide a list of people who might be interested in developing the standard. If the stakeholders agree, ASTM will then establish a committee or subcommittee and solicit people and organizations to become involved. When a

[1] Committee F15 on Consumer Products, https://www.astm.org/membership-participation/technical-committees/committee-f15.
[2] Alan Earls, *The CPSC and ASTM Collaboration*, Standardization News, January/February 2011, https://sn.astm.org/features/cpsc-and-astm-collaboration-jf11.html.

committee is organized, ASTM staff explains the ASTM system and how it works to the participants. Assuming the participants decide to move ahead, they will then work on different aspects of the subject such as safety performance provisions, labeling and testing protocols. When the CPSC feels it appropriate, the ASTM standard will be incorporated by reference and any additional safety provisions are then added to the CPSC mandatory rule." *Id*.

54. The ASTM Subcommittee F15.19 on Infant Bedding,[3] which includes weighted infant sleep products, has not reached a consensus on voluntary product standards for this category of consumer products.[4]

The Public Health Service Act

55. The Public Health Service Act ("PHSA") authorizes the Secretary of HHS to "develop, support, or maintain programs or activities to address sudden unexpected infant death and sudden unexpected death in childhood[.]" 42 U.S.C. § 300c-11(a). Such programs and activities include: supporting CDC registries collecting certain data; awarding grants or cooperative agreements to States, Indian Tribes, and Tribal organizations to, among other things, improve data collection, develop best practices, and educate health care professionals and the public about risk factors. 42 U.S.C. § 300c- 11(a)(2). The purpose of these programs is data collection.

56. The Secretary of HHS must make sure that there are adequate funds applied to leads and findings from research "in order to make maximum feasible progress toward identification of infants at risk of sudden infant death syndrome and prevention of sudden infant

[3] Subcommittee F15.19 on Infant Bedding, https://www.astm.org/membership-participation/technical-committees/committee-f15/subcommittee-f15/jurisdiction-f1519.
[4]Proposed voluntary standards failed to pass resolution, https://www.astm.org/membership-participation/technical-committees/workitems/workitem-wk81176.

death syndrome." 42 U.S.C. § 300c-12.

57. The Secretary of HHS must continue activities related to still birth, sudden unexpected infant death, and sudden unexplained death in childhood, such as collecting data, educating the public, and collaborating with federal and state agencies. 42 U.S.C. § 300c-13.

58. Then the Secretary of HHS must make regular reports to Congress describing all the activities being carried out by the HHS, CDC, and NIH, data collection, and assessment of various approaches related to stillbirth, sudden unexpected infant death, and sudden unexplained death in childhood. 42 U.S.C. §§ 300c-13(b), 300c-14.

FACTUAL ALLEGATIONS

Plaintiff - Nested Bean

59. Plaintiff Nested Bean, Inc. ("Nested Bean") develops, designs, manufactures, and sells infant and toddler products, including infant swaddles, sleeping bags and pajamas that are lightly weighted to mimic the gentle touch of a parent.

60. Nested Bean is a small immigrant minority woman-owned business founded in 2011. Nested Bean grew out of its founder, Manasi Gangan's, struggle to find a solution to help her own child sleep restfully and independently as a working mother of a baby who would not go to sleep unless a parent placed their hand gently on the child's center. As soon as the parent's hand was removed, her child would wake immediately.

61. Ms. Gangan, a 15-year veteran in the technology industry, set out to create a product that would effectively and safely provide the baby with the proven benefits of the sense of being comforted through touch, in a manner that is consistent with safe sleep guidance, such that it would place babies on their back, in the crib, without any loosely placed aids. Nested Bean's products are designed to foster safe sleep practices by allowing parents, who may

otherwise resort to unsafe practices such as co-sleeping with their baby, or using loungers or inclined products, to instead place them in a safe crib environment with no soft bedding or other objects.

62. Ms. Gangan was inspired by neonatal units in hospitals that were utilizing positional aids with polypropylene filling to simulate the familiar pressure experienced in the womb or from parental touch, mimicking the touch or cradling of a caregiver's hand. Encouraged by a neonatal research study on the soothing effects of simulated touch, Ms. Gangan embarked on a mission to create a solution that would provide restful sleep for both little ones and their parents. Ms. Gangan began her efforts to develop a line of sleepwear that is designed to mimic the gentle touch of a parent to help soothe babies to sleep.

63. Ms. Gangan's experience in product development and risk assessment guided her cautious approach to the design and development of the new innovative sleepwear. In designing Nested Bean's products Ms. Gangan followed the International Organization for Standardization ("ISO") for consumer product safety ISO 10377[5] guidance that safety is "freedom from unacceptable risk"[6] and the CPSC recommendations for best practices that the product "not only meets or exceeds the requirements of federal safety laws, but also is designed and manufactured as safely as possible."[7] She sought advice from sleep safety experts and safety labs to ensure that safety was front and center throughout the design, development, and production phases.

64. Nested Bean shared early designs and prototypes with accredited safety labs for a design evaluation. Based on the safety lab's evaluation and recommendations received during the

[5] ISO 10377:2013(E), available at https://www.iso.org/standards.html.
[6] ISO 10377:2013(E), Section 2 (Terms and definitions).
[7] CPSC Best Practices, available at https://www.cpsc.gov/business--manufacturing/business-education/business-guidance/BestPractices.

design and development phase, Nested Bean made critical design changes. Nested Bean updated the prototype and then shared it with Human Factor Design experts to receive safety evaluation in case of rebreathing through the parts containing filling. Nested Bean then adopted the experts' safety recommendations. Nested Bean also consulted with an accredited safety lab to receive a comprehensive report of mandatory, and a few voluntary, safety test recommendations using international test methods from major global territories such as the United States, Canada, Europe, China, and Japan. Materials chosen throughout the supply chain underwent applicable mandatory testing, as well as additional voluntary testing. Nested Bean then consulted with safety experts to define the warnings to be added to product labels. All of these safety measures in the design, development, and production were done in 2011-2012 before a single product went to market.

65. Ms. Gangan's unwavering commitment to safety, innovation, and research underpins Nested Bean's success. This is evidenced by the stellar safety record the company has maintained with over 2.5 million products sold. There has been no hazard pattern identified with Nested Bean's products, nor injuries or deaths attributed to them.

66. Nested Bean listens to, supports, and provides valuable insights to parents while advocating best practices for safe sleep. The company has earned widespread acclaim from parents, receiving tens of thousands of positive reviews for its effectiveness in helping their babies sleep, and has actively engaged with the parenting community through social platforms. Nested Bean reviews and analyzes customer comments and anecdotal observations left on its own website, retailers' sites, and the CPSC's publicly searchable consumer database saferproducts.gov to identify possible improvements.

67. Even with its amazing safety record, Nested Bean remains committed to safety

and compliance. Nested Bean frequently reviews CPSC regulations that apply to infant clothing and infant sleepwear. To ensure continued safety, Nested Bean commissioned a preliminary study in 2023 to investigate the potential effects of applying incremental weights to an infant's chest while in a supine position. The results of that study found that the peripheral oxygen saturation and pulse rate for weights between 0g and 30g were in the same statistical grouping. Nested Bean's products are within this range of weight concentration that shows no hazard pattern.

68. Additionally, the CPSC's own review of Nested Bean's products showed no identifiable hazard. In 2023, the Office of Compliance and Field Operations ("Office of Compliance"), the compliance branch of the CPSC, conducted a four-month review of Nested Bean's products to assess the risk of suffocation. After reviewing Nested Bean's products, the CPSC staff found no identifiable hazard pattern, so the compliance staff's attorney sent Nested Bean a closing letter stating that no further action was warranted.

69. Nested Bean uses minimal weight in its products, ranging from 30 to 90 grams depending on the baby's size. This aligns with the 30-50 grams of pressure applied by an infant car seat harness and chest clip or winter clothing found commonly in the market and although they are not marketed as "weighted" they can weigh significantly more than a Nested Bean product. Among CPSC's sample market scan, Nested Bean's products fall in the 25^{th}-55^{th} percentile for weight and are much lighter than many products containing filling meant to add warmth or weight which are not labeled or marketed as "weighted."[8]

70. Nested Bean is committed to creating standards and definitions for the class of

[8] CPSC Staff Comments on Wearable Infant Blankets, transmitted November 16, 2023, https://perma.cc/7H6C-WEE4.

wearable infant sleep products, including the category of filled infant sleep products, to raise the bar on infant sleep safety and protect consumers from unscrupulous manufacturers. Because there is no definition currently, numerous manufacturers are selling infant products with heavy filling making them significantly heavier than Nested Bean products, although these heavier products may not be labeled or marketed as "weighted."

71. Nested Bean has actively contributed to the collaborative process with the ASTM F15.19, the Wearable Infant Blankets Subcommittee, in working towards developing a voluntary safety standard for wearable infant blankets and swaddles. Nested Bean has dedicated significant resources and supported independent research and consumer studies to bring greater insight to how innovation can be balanced with safety.

CPSC Weighted Sleep Research and Rejection of Proposal to Pursue a Mandatory Standard for Weighted Infant Sleep Products

72. The ASTM F15.19 subcommittee for wearable infant blankets has not adopted any voluntary standards or definitions. In October 2023, the ASTM F15.19 subcommittee submitted for administrative ballot F1519000223001 regarding Work Item WK81176 – Draft Standard Consumer Safety Specification for Wearable Blankets Intended for Use by Infants and Toddlers ("Draft Voluntary Standards"). The CPSC staff reviewed the Draft Voluntary Standards and provided feedback to the ASTM F15.19 subcommittee. The CPSC staff rejected the suggested performance requirements specific to weighted features "until additional research and testing and evaluation of the safety can be conducted."

73. To date, CPSC has not promulgated any rules providing mandatory standards and definitions for products that could fall under the marketing category of weighted infant sleep products.

74. On November 8, 2023, the CPSC convened an internal meeting to discuss the upcoming Fiscal Year 2024 Operating Plan Decisional and proposed amendments. During this meeting Commissioner Richard L. Trumka proposed an amendment to require CPSC "staff to initiate rulemaking and issue a proposed rule to address risks associated with weighted infant blankets, sleepers, and swaddles and align the Commission's safe sleep guidance and Centers for Disease Control (CDC) and National Institute of Health (NIH) guidance for weighted products."[9]

75. Commissioner Trumka's proposed amendment was rejected by the Commission in a 3-1 vote. *Id*. In rejecting the proposal Chairman Hoehn-Saric expressed that it was "[his] understanding that [CPSC] staff ha[d] not conducted the research necessary to draft a notice of proposed rulemaking in 2024," and that "simply directing [the staff] to do it or wishing something to happen doesn't reflect the work that has to go into a successful rulemaking that ultimately reflects the science and can be sustained over time."[10] The Chairman went on to explain that "the staff is very aware of the issue and working diligently to assess and quantify safety risks associated with weighted blankets." *Id*. Commissioner Boyle and then-Commissioner Feldman both agreed that rulemaking "at this time [was] premature." *Id*. at 21:52 – 22:05.

76. ASTM Committee F15.19 has been hard at work developing a voluntary safety standard for wearable infant blankets and swaddles alongside CPSC Staff; a subcommittee on Wearable Infant Blankets was formed, as F15.19, after a series of meetings in 2021. The subcommittee set out to provide performance standards for fit and construction as well as sizing and warnings to help address the potential hazard of suffocation resulting from a child slipping below the neck hole (known as "submarining") in any wearable sleep product, regardless of

[9] CPSC, Minutes of Commission Mtg. 13 (Nov. 8, 2023), https://perma.cc/U2P9-CHR4.
[10] See CPSC, Commission Meeting FY24 Operating Plan Decisional 20:28−20:55 (Nov. 9, 2023), https://perma.cc/AU4U-6HVB.

weight. At the time of the 2023 CPSC meeting and well into 2024, the ASTM Committee F15.19 was, and still is, actively researching and analyzing hazard data on wearable infant sleep products in collaboration with CPSC Staff.

77. On November 16, 2023, the CPSC staff cast a negative vote against the F15.19(23-03) draft voluntary standard because it lacked specification about maximum weight limits for weighted wearable infant sleep products. In writing again to the ASTM F15.19 subcommittee regarding the Draft Voluntary Standard, the CPSC staff identified concerns sufficient to warrant voting against adoption of the proposed safety standard, because it did not have an "accompanying specification of maximum weight limits by age." Staff noted the "lack of publicly available research relating to the issue at hand," and thus undertook a "market scan of non-weighted wearable blankets and swaddles as well as a range of products marketed as 'weighted' and ma[d]e comparisons between the two groups." The "staff [] collected and measured a variety of wearable blankets and swaddles marketed as weighted ("weighted") and a variety of those products without any such marketing ("non-weighted") currently sold on the market." The staff found differences in the weight concentration; some products distribute the weight throughout the product while others concentrate it in a specific area. The staff also observed that there was a number of products that did not market themselves as weighted but in fact weighed as much as some of products marketed as weighted and some were heavier than other products marketed as weighted. Therefore, the "CPSC staff recommend[ed that] the Subcommittee consider establishing weight concentration limits given existing scientific research, the differentiation CPSC staff observed, and NIH and CDC concerns about weighted blankets not being safe for infants."

CPSC Safe Sleep Guidelines

78. Sometime after the CPSC Operating Plan Decisional Meeting held on November 8, 2023,[11] the CPSC's website modified the Safe Sleep Guidelines to recommend that the public not use an entire class of consumer products, weighted infant blankets and swaddles.[12] In these guidelines, the CPSC states "Don't use weighted blankets or weighted swaddles." *Id*. Then with a footnote the CPSC deflects responsibility by asserting that statement is made with the caveat that "*This guidance is based on information from the Centers for Disease Control and the National Institutes for Health." *Id*. In other words, the CPSC admits that it has not conducted its own research or made its own determinations as to the safety of these products. The notice on the website read as follows:

> **DON'T:**
> - **Don't add pillows or blankets** to your baby's sleep space.
> - **Don't use weighted blankets or weighted swaddles***.
> - **Don't leave your baby unsupervised in products that aren't designed for safe sleeping.** Inclined products with an angle greater than 10° -such as a rockers, gliders, soothers, and swings- *should never be used for infant sleep.*
>
> *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.

Id. (emphasis in original)

Commissioner Trumka's 2024 Statements on Weighted Infant Sleep Products

79. Disregarding the lack of voluntary or mandatory standards, the lack of a product ban, stop sale, or recall, and the Commission's determination that CPSC lacked the necessary data to propose a mandatory standard on weighted infant sleepwear in fiscal year 2024,

[11] At the Commission's November 8, 2023 meeting to consider its Fiscal Year (FY) 2024 Operating Plan Chair Hoehn-Saric noted that "[CPSC] staff is already working on how to modify safe sleep guidance to account for the fact that both NIH and CDC is warning against the use of ... weighted wearables for infants" and that CPSC would be updating its guidance. CPSC Meeting Minutes, November 8, 2023, https://perma.cc/U2P9-CHR4.

[12] CPSC Safe Sleep Guidelines, available at https://www.cpsc.gov/SafeSleep (last accessed Nov. 27, 2024).

Commissioner Trumka chose to pursue a negative publicity campaign against weighted infant sleep products in public statements, letters to retailers, and social media posts.

Commissioner Trumka's January 26, 2024 Statements

80. On January 26, 2024, Commissioner Trumka used his official X account (formerly Twitter) to post[13] a link to a *Washington Post* article naming Nested Bean explicitly in the second sentence.[14] The post claimed that CPSC is "in agreement" with CDC, NIH, and the American Academy of Pediatrics that weighted infant sleep products "pose serious threats to the lives of babies," and instructed the public: "Do NOT use them for sleep." *Supra* note 17. A true and correct copy of the post is reproduced below:[15]

[13] @TrumkaCPSC, X.com (Jan. 26, 2024 at 12:00 PM), https://perma.cc/XQ9Z-NCJB.
[14] Lauren Kirchner, *Weighted blankets are dangerous for babies, doctors warn*, Washington Post, January 22, 2024, available at https://www.washingtonpost.com/wellness/2024/01/22/weighted-baby-blankets-unsafe/, *last visited* January 10, 2025.
[15] Commissioner Rich Trumka, Jr. @TrumkaCPSC, X.com (Jan. 26, 2024 at 11:00 AM), available at https://x.com/TrumkaCPSC/status/1750926680267333669, *last visited* January 10, 2025.

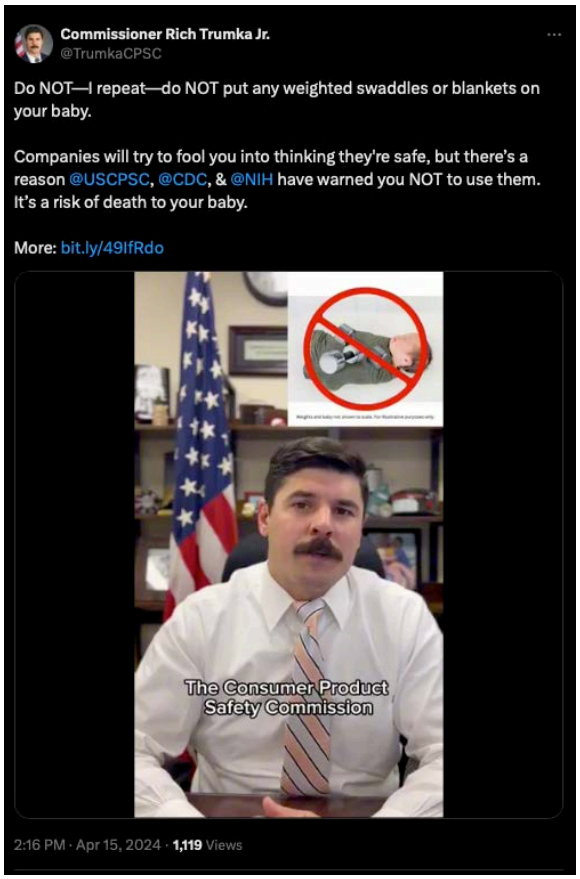
Commissioner Trumka's April 15, 2024 Statements

81. On April 15, 2024, Commissioner Trumka sent identical letters on his official CPSC letterhead to seven major retailers, including Target, Walmart, Nordstrom, and Babylist, asking them to consider removing weighted infant sleepwear from their shelves (collectively "Stop Sale Letters"). In his letter he cited directly to the *Washington Post* article that named Nested Bean in its second sentence, and Trumka claimed that "multiple infant deaths" had been linked to weighted sleepwear products.

82. On the same day, Commissioner Trumka posted a video on X[16] and Instagram[17] with a caption stating "Do NOT – I repeat – do NOT put any weighted swaddles or blankets on your baby. Companies will try to fool you into thinking they're safe, but there's a reason

[16] @TrumkaCPSC, X.com (Apr. 15, 2024 at 3:16 PM), https://perma.cc/G86U-C3ZY.
[17] @trumkacpsc, Instagram.com (Apr. 15, 2024), https://perma.cc/MM4F-ZL8V.

@USCPSC, @CDC, & @NIH have warned you NOT to use them. It's a risk of death to your baby." *Id*. The video also included an intentionally dramatized photo showing a baby with metal dumbbells on its chest. Screenshots of the April 15, 2024, posts on X and Instagram are reproduced below.



83. In the videos Trumka states:

> It seems like a new baby product comes on the market every day. Some new ones that you need to watch out for are *weighted infant swaddles and blankets*. Weighted blankets for adults are one thing, but they have no place in infant sleep. The Consumer Product Safety Commission just updated our safe sleep guidance to warn you NOT to use these products with your babies. This brings us in line with NIH and CDC which warns that *weighted products are unsafe for infants*. And when unsafe comes up in the infant sleep space, let's be clear we're talking about the *risk of death*. You can find our safe sleep guidance at cpsc.gov/safesleep. It has great information on what to do and what not to do.

Id. (emphasis added).

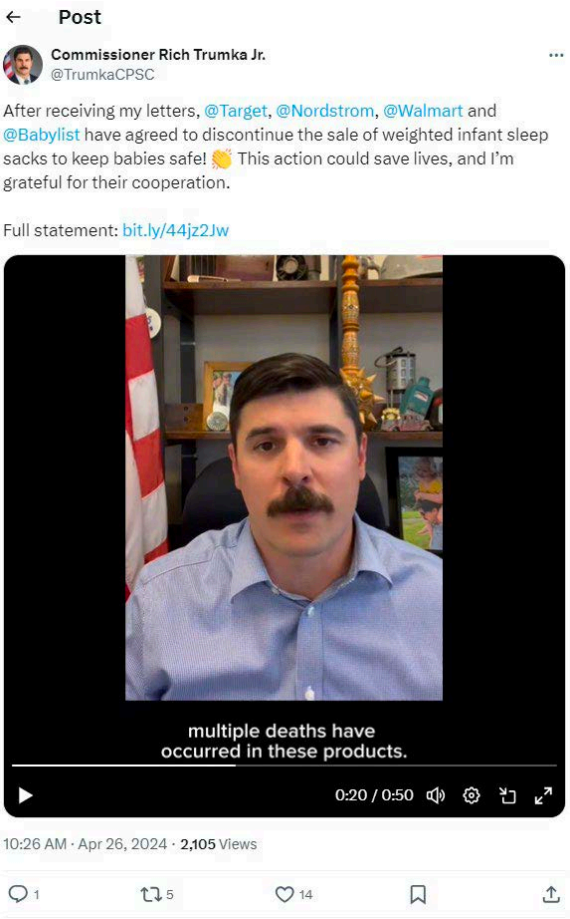
84. That same day, April 15, 2024, CPSC posted Trumka's statement on its website entitled: *Beware: Weighted Infant Swaddles and Blankets are Unsafe for Sleep; Retailers Should Consider Stopping Sales.*[18] The statement purported to speak on behalf of CPSC stating that "CPSC has a clear warning for safe infant sleep: **Don't** use weighted blankets or weighted swaddles for your babies." *Id*. (emphasis in original). The statement also alleges without any citation to proof that "There are multiple infant deaths in these products." *Id*. And it told retailers that "we do not have to wait *for a federal rule*," and that they have "the power to stop sales" and "take precautions today." *Id*. (emphasis added). The CPSC statement page also contains a link to Commissioner Trumka's April 15, 2024 statement video on X, as mentioned *supra*. This statement was published on CPSC's official website and Commissioner Trumka signed his statement "Your consumer advocate at the Consumer Product Safety Commission." *Id*.

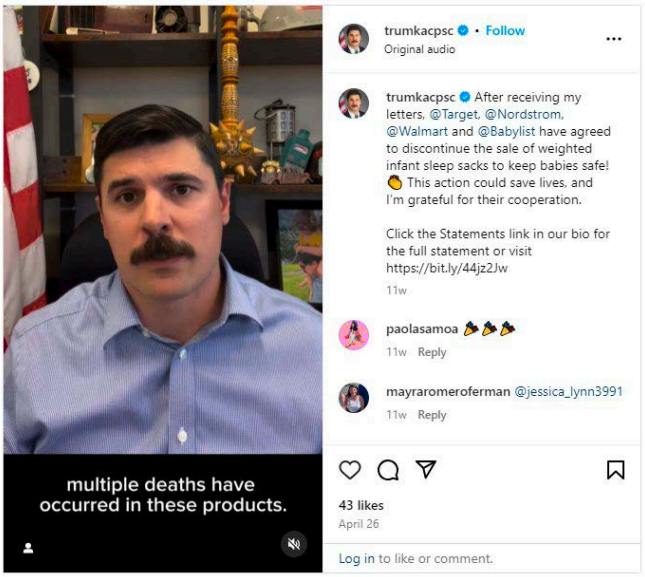
Commissioner Trumka's April 26, 2024 Statements

85. On April 26, 2024, Commissioner Trumka made another statement on the CPSC website,[19] X,[20] and Instagram[21] gloating about the harm he was able to do to Plaintiff's business while skirting procedural requirements. The statement reads, in part, "On April 15, 2024, I wrote to major U.S. retailers informing them of the hazards weighted infant swaddles and blankets pose to babies, and asking them to consider whether they want to continue selling such products. I am

[18] Comm'r Trumka, *Beware: Weighted Infant Swaddles and Blankets Are Unsafe for Sleep; Retailers Should Consider Stopping Sales* (Apr. 15, 2024), available at 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, last visited January 10, 2025.
[19] Trumka Statement, April 26, 2024, available at https://www.cpsc.gov/About-CPSC/Commissioner/Richard-Trumka/Statement/Target-Walmart-Nordstrom-and-Babylist-Commit-to-Stop-Selling-Weighted-Infant-Products#_ftnref1, last visited January 10, 2025.
[20] @TrumkaCPSC, X.com (Apr. 26, 2024 at 10:26 AM), https://perma.cc/4CGR-8VWB.
[21] @trumkacpsc, Instagram.com (Apr. 26, 2024), https://perma.cc/EL23-JDLV.

pleased to announce that Target, Walmart, Nordstrom, and Babylist quickly responded by sharing that they will cease sales of weighted infant products" and "I expect to hear back from additional retailers soon." *Id*. Screenshots of the April 26, 2024, posts on X and Instagram are reproduced below.





86. In his videos Trumka states:

> I have some great news to report. Last week, I wrote to major U.S. retailers and I wanted to talk to them about a product category that I'm concerned about: Weighted infant blankets and swaddles. I wanted to let them know that CPSC, CDC, NIH, and the American Academy of Pediatrics have all warned against their use and that multiple deaths have occurred in these products. Armed with this information, multiple major U.S. retailers decided to stop selling these products out of an abundance of caution and a mind toward safety. And I wanted to take time to commend those companies. Target, Walmart, Nordstrom, Amazon, and Babylist all made the decision to pull sales of these products. I

> have letters out to other retailers as well; I haven't heard back from them quite yet. I'm gonna report to you when I do. Stay safe.

Id.

Responses to Statements of Commissioner Trumka and the Commission

87. Defendants' statements resulted in direct harm to Plaintiff's business. Multiple major retailers, including Target, Amazon, and others discontinued the sale of Nested Bean products in response to Defendants' misleading statements.

88. Most of these retailers kept other brands of weighted infant sleep products that were not mentioned in Trumka's letters available for sale on their platforms.

89. Amazon stopped sales of Nested Bean's products and notified customers who had purchased Nested Bean products in the past 12 months that CPSC had "warned that these products should not be considered safe for use by children and babies."

90. As a result, Nested Bean has experienced a greater than 80% reduction in sales, forcing the layoff of 93% of its workforce. This devastating decline has ruined Nested Bean's relationship with leading retail partners and is risking the company's future and ability to bring effective products to help its customers, which also risks its ability to participate in the ASTM standards creation as a knowledgeable manufacturer to benefit the industry as a whole.

91. On January 22, 2024, Commissioner Trumka sent Nested Bean a letter requesting that it provide information about its product, quality control, safety research, health incidents, and safety messaging compliance by February 5, 2024. But before Nested Bean could respond, and only four days after sending the letter, Trumka posted an article on social media that explicitly named Nested Bean, as discussed above. On February 16, 2024, Nested Bean provided responses to Commissioners Trumka, Hoehn-Saric, Boyle, and Feldman explaining Nested Bean's safety record, research into the product development, and involvement in the ASTM

voluntary standards process.

92. On May 22, 2024, Nested Bean wrote to Commissioner Trumka, to ask him to correct the record regarding his attacks on the company by issuing an immediate retraction of his inaccurate and misleading statements. On July 22, 2024, Commissioner Trumka responded by refusing to retract his statements by falsely claiming that they were his personal statements, even though they were made from his official letterhead and on his official social media account, and posted to the CPSC website. And he tried to shirk his statutory responsibilities by relying on the equally unsupported statements of other health agencies that are *not* tasked with product safety and claimed that he merely echoed the warnings of CPSC in his personal statements.

93. This wasn't the first time that Commissioner Trumka has abused his power. On July 25, 2024, the Chairman of the House Committee on Small Business announced that it was launching an investigation into Trumka's unilateral actions and abuse of power, specifically pertaining to the very actions that Nested Bean is complaining about.[22] This investigation is a result of a pattern of exceeding his regulatory authority by repeatedly going rogue and issuing public statements about a product under the guise of CPSC authority.[23] For example, in January of 2023, Trumka made public statements that the CPSC intended to ban gas stoves.[24] The gas stove debacle was very similar to this situation in that the CPSC had *declined* to adopt Trumka's proposed standards for gas stoves – yet, without any CPSC authority, he publicly stated that the

[22] Congressional Small Business Committee letter to CPSC Chairman, dated July 25, 2024, https://perma.cc/NVR2-MNHW.
[23] GOP panel accuses safety commission's Richard Trumka Jr. of pressuring private businesses, Zack Halaschak, July 25, 2024, available at https://www.washingtonexaminer.com/news/business/3098110/gop-panel-accuses-safety-commissions-trumka-jr-pressuring-private-businesses/#google%20vignette.
[24] Gas stove ban not in the works, agency chairman says amid uproar, Breanne Deppisch, January 11, 2023, available at https://www.washingtonexaminer.com/news/405289/gas-stove-ban-not-in-the-works-agency-chairman-says-amid-uproar/.

CPSC was going to ban gas stoves.[25] This statement was so inaccurate and misleading, and caused such a public backlash, that the Chairman for the CPSC felt it necessary to issue his own statement clarifying that the Commission was not intending to ban gas stoves.[26]

94. On August 1, 2024, Nested Bean again wrote to Commissioner Trumka and demanded that he immediately retract the inaccurate and misleading statements. Nested Bean's letter provided evidence that his letters to retailers telling them to not to sell weighted sleep products, which cited the *Washington Post* article that expressly named Nested Bean and one other company, resulted in most retailers only taking down products of the two companies named in the article. Retailers were still selling weighted sleep products from unnamed manufacturers, just not Nested Bean. Trumka's August 16, 2024 response ignored the retraction request.

95. On August 26, 2024, the ASTM F15.19 subcommittee released report "ASTM F15.19 Data Analysis Task Group Wearable Infant Blanket-Related Incident Data."[27] ASTM completed a Hazard Analysis using CPSC's data on safety incidents involving various infant sleep products from various manufacturers and found that there was no unique hazard pattern associated with weighted infant sleep products. *Id*. The report demonstrated that a combination of hazardous behavioral sleep practices were typically present in each reported fatality case,

[25] The obscure regulator (and political scion) who sparked the furor over gas stoves, Breanne Deppisch, January 12, 2023, available at https://www.washingtonexaminer.com/news/2277854/the-obscure-regulator-and-political-scion-who-sparked-the-furor-over-gas-stoves/.

[26] Statement of Chair Alexander Hoehn-Saric Regarding Gas Stoves, January 11, 2023, available at https://www.cpsc.gov/About-CPSC/Chairman/Alexander-Hoehn-Saric/Statement/Statement-of-Chair-Alexander-Hoehn-Saric-Regarding-Gas-Stoves.

[27] CPSC and ASTM F15.19 Wearable Infant Blankets Data Analysis and Performance Requirements Task Force Meeting Log, Aug. 26, 2024, https://perma.cc/JWN6-LT3H.

including swaddling past rolling age, co-sleeping, incline, soft bedding, use of products that have since been banned, and leaving a bottle unattended for an extended period—all proven unsafe practices. *Id*.

96. The injury to Nested Bean is ongoing as Commissioner Trumka's statements and the Safe Sleep Guidelines remain posted on the Commission's public-facing website and the Commission has declined to retract or correct the statements. Commissioner Trumka's disparaging posts on X and Instagram also remain visible to the public.

97. Nested Bean was not provided notice of any of Commissioner Trumka's statements before they were made public, even though the statements allow the public to readily ascertain Nested Bean's identity.

98. On information and belief, retailers were misled by Commissioner Trumka's letter and communications into believing that the CPSC had made a product safety determination regarding weighted infant sleep products when the Commission had made no such determination and, in fact, lacked data or evidence supporting such an action.

99. As a result of Commissioner Trumka's actions, Nested Bean suffered significant reputational and economic harm, including retailers stopping sale of its products.

Nested Bean Seeks Retraction of CPSC and Commissioner Trumka's Statements

100. On November 11, 2024, and pursuant to 15 U.S.C. § 2055(b)(7), counsel for Nested Bean sent a letter to the Secretary of the Commission seeking a Section 6(b)(7) request for retraction of the inaccurate and misleading statements by Commissioner Trumka and the CPSC ("Retraction Request").[28]

[28] Nested Bean's November 11, 2024 Letter to CPSC, https://libertyjusticecenter.org/other-legal-work/demand-letter-to-cpsc-on-behalf-of-nested-bean/.

101. The Retraction Request asked the CPSC to publicly retract Commissioner Trumka's inaccurate and misleading statements, as detailed *supra*, and retract the provision of the CPSC's Safe Sleep Guidance that advocates *against* the use of weighted infant sleep products. *Id*. The Retraction Request also provided in detail the legal and factual basis for the request. *Id*.

102. Around December 19, 2024, the Commission voted on, and denied, Nested Bean's request for retraction.[29] The outcome of the vote was 0-1-1-2 with 0 commissioners voting for the retraction, 1 and 1 representing separately proposed courses of action, and 2 representing two abstentions. *Id*. Commissioner Trumka recused himself from the vote. *Id*. Chairman Hoehn-Saric proposed delaying a response for 90 days to allow the CPSC more time to consider all the facts and circumstances. *Id*. Commissioner Boyle proposed (1) sending a letter to retailers clarifying that the Commission has not taken any official action, and that Commissioner Trumka's statements were not made on behalf of the CPSC and do not constitute a stop sale, ban, or recall; and (2) directing the CPSC staff to review the Safe Sleep Guidance in light of new information since its posting in 2023. *Id*. Commissioners Feldman and Dziak abstained from the vote and issued a joint statement suggesting that Nested Bean's relief is "best obtained through an Article III court."

CLAIMS FOR RELIEF

Count One

Violation of the Administrative Procedure Act Excess of Statutory Authority (Against CPSC)

[29] https://www.cpsc.gov/s3fs-public/RCA-Request-by-Nested-Bean-Inc-for-Retraction-of-Information-Pursuant-to-Section-6b-7-of-the-Consumer-Product.pdf?VersionId=7WepmZFMBCZl7w_DcA.7ukgp_WInt2t3.

103. Plaintiff incorporates by reference all the preceding material as though fully set forth herein.

104. Under the APA, a court must "hold unlawful and set aside agency action" that is "not in accordance with law" or is "in excess of statutory . . . authority[] or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

105. The CPSC decision to publish the Safe Sleep Guidance advocating against the use of all weighted infant sleep products is a final agency action under the APA.

106. The CPSA provides the framework for determining whether consumer products present an unreasonable risk of injuries. The CPSC may only promulgate a mandatory consumer product safety standard, in accordance with 15 U.S.C. § 2058, that is "reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product." 15 U.S.C. § 2056(a).

107. The Commission may promulgate a rule banning a hazardous product, in accordance with 15 U.S.C. § 2058, but may only do so after finding that the consumer product presents an unreasonable risk of injury *and* there is "no feasible consumer product standard under this Act [that] would adequately protect the public from the unreasonable risk of injury associated with such product[.]" 15 U.S.C. § 2057.

108. The promulgation of a consumer product safety rule, including both a mandatory standard and a product ban, must follow the procedural requirements of 15 U.S.C. § 2058, which includes, among other things, the requirement to identify the degree and nature of the risk of injury associated with the product and how the proposed action is reasonably necessary and is designed to eliminate or reduce the risk of injury. *See* 15 U.S.C. § 2058

109. The CPSA requires the Commission to establish procedures to ensure that the information it publicly releases that reflects on the safety of a consumer product or class of consumer products is accurate and not misleading. *See* 15 U.S.C. § 2055.

110. In order to promulgate a mandatory safety standard, the Commission must first determine the risk of injury then "express in the rule itself the risk of injury which the standard is designed to eliminate or reduce." *Id*. In doing so, the Commission must "consider relevant available product data including the results of research, development, testing, and investigation activities conducted generally and pursuant to [the CPSA]." 15 U.S.C. § 2058(e).

111. The Commission must also "conduct a 'final regulatory analysis'—*i.e.*, a cost-benefit analysis— before promulgating a safety standard. The analysis must detail costs, benefits, and alternatives to the proposed standard, and must address any issues raised by commenters." *Window Covering Mfrs. Ass'n v. CPSC*, 82 F.4th 1273, 1279 (citing 15 U.S.C. § 2058(f)(2)). There must also be a "host of findings" the Commission must make before promulgating a rule, many of which must be supported by data and evidence. *Finnbin, LLC v. CPSC*, 45 F.4th 127, 131 (D.C. Cir. 2022) (citing 15 U.S.C. § 2058(f)).

112. The CPSA also permits the Commission to ban hazardous products which present "an unreasonable risk of injury[.]" 15 U.S.C. § 2057. Banning a product requires the Commission to "find that the product at issue presents an unreasonable risk of injury and that no feasible safety standard would adequately protect the public from it. … In banning products, the CPSC must follow the procedures that govern its general power to promulgate safety standards." *Finnbin*, 45 F.4th at 131 (citing 15 U.S.C. § 2057).

113. The CPSA does *not* provide the CPSC the discretion to adopt the consumer product safety determinations made by other agencies without following the CPSA procedures and requirements.

114. The Commission's Safe Sleep Guidance regarding weighted infant sleep products is a product safety determination.

115. The Commission took none of the required steps before it adopted and repeated CDC's and NIH's unsupported product safety determinations regarding weighted infant sleep products.

116. The product safety determination made by CPSC regarding weighted infant sleep products was not authorized by statute and thus exceeds CPSC's authority under CPSA, which carefully outlines how and when CPSC may regulate consumer products or make determinations about a product's safety. The CPSA does not authorize CPSC to determine the safety of consumer products absent evidence and data.

117. Accordingly, CPSC's Safe Sleep Guidance is a product safety determination that was "not in accordance with" or "in excess of" its statutory authority because it opines on the safety of weighted infant sleep products and directs parents and caregivers not to use weighted infant sleep products.

118. Likewise, CPSC's December 2024 decision not to remove its Safe Sleep Guidance and its decision to take no action with respect to Commissioner Trumka's statements was also made "in excess of" CPSC's statutory authority.

Count Two
***Ultra Vires* Acts (Against HHS, NIH, CDC)**

119. Plaintiff incorporates by reference all the preceding material as though fully set forth herein.

120. Under the APA, a court must "hold unlawful and set aside agency action" that is "not in accordance with law" or is "in excess of statutory . . . authority[] or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

121. A plaintiff may also "institute a non-statutory review action" against an agency head "for allegedly exceeding his statutory authority." *Chamber of Com. of U.S. v. Reich*, 74 F.3d 1322, 1327–28 (D.C. Cir. 1996).

122. Section 702 of the APA permits a party to bring a non-statutory review action against an agency even if the action challenged is not final. *See Apter v. Dep't of Health & Hum. Servs.*, 80 F.4th 579, 589-90 (5th Cir. 2023).

123. Ultra vires review is appropriate under the APA, *see Apter v. Dep't of Health & Hum. Servs.*, 80 F.4th 579, 587 (5th Cir. 2023), and, in the alternative, it is appropriate under the common law, *see Fed. Express Corp. v. U.S. Dep't of Commerce*, 39 F.4th 756, 763-64 (D.C. Cir. 2022).

124. "[A]n agency literally has no power to act, . . ., unless and until Congress confers power upon it. . . . An agency may not confer power upon itself." *Louisiana Pub. Serv. Comm'n v. FCC.*, 476 U.S. 355, 374 (1986).

125. "Where a statute's language carries a plain meaning, the duty of an administrative agency is to follow its commands as written, not to supplant those commands with others it may prefer." *SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 363 (2018).

126. An agency's "power to act and how they are to act are authoritatively prescribed by Congress, so that when they act improperly, . . . , what they do is ultra vires. Because the question – whether framed as an incorrect application of agency authority or an assertion of

authority not conferred – is always whether the agency has gone beyond what Congress has permitted it to do, ..." *City of Arlington v. FCC*, 569 U.S. 290, 297-98 (2013).

127. The PHSA authorizes HHS, and its subagencies NIH and CDC, to "develop, support, or maintain programs or activities to address sudden unexpected infant death and sudden unexpected death in childhood," such as collecting data, educating the public, and collaborating with federal and state agencies. 42 U.S.C. §§ 300c-11(a), 300c-13.

128. The PHSA requires the Secretary of HHS to make regular reports to Congress describing all the activities being carried out by the HHS, CDC, and NIH, data collection, and assessment of various approaches related to stillbirth, sudden unexpected infant death, and sudden unexplained death in childhood. 42 U.S.C. §§ 300c-13(b), 300c-14.

129. Nothing in the PHSA authorizes the HHS, NIH, or CDC to opine on the safety or risk of a consumer product.

130. The issuance of public statements by an agency advocating for or against a particular action by the public are final agency actions subject to judicial review. *See Apter v. Dep't of Health & Hum. Servs.*, 80 F.4th 579, 590 (5th Cir. 2023).

131. The HHS, NIH, and CDC have, as part of their public Safe Sleep Guidance, advised the public to *not* use weighted infant sleep products.

132. Therefore, the CDC's and NIH's actions opining on the safety or risk of a consumer product and advising the public against the use of weighted infant sleep products were *ultra vires*.

Count Three
***Ultra Vires* Acts (Against Commissioner Trumka)**

133. Plaintiff incorporates by reference all the preceding material as though fully set forth herein.

134. Under the APA, a court must "hold unlawful and set aside agency action" that is "not in accordance with law" or is "in excess of statutory . . . authority[] or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

135. A plaintiff may also "institute a non-statutory review action" against an agency head "for allegedly exceeding his statutory authority." *Chamber of Com. of U.S. v. Reich*, 74 F.3d 1322, 1327–28 (D.C. Cir. 1996).

136. Section 702 of the APA permits a party to bring a non-statutory review action against an agency even if the action challenged is not final. *See Apter v. Dep't of Health & Hum. Servs.*, 80 F.4th 579, 589-90 (5th Cir. 2023).

137. Ultra vires review is appropriate under the APA, *see Apter v. Dep't of Health & Hum. Servs.*, 80 F.4th 579, 587 (5th Cir. 2023), and, in the alternative, it is appropriate under the common law, *see Fed. Express Corp. v. U.S. Dep't of Commerce*, 39 F.4th 756, 763-64 (D.C. Cir. 2022).

138. "[A]n agency literally has no power to act, . . ., unless and until Congress confers power upon it. . . . An agency may not confer power upon itself." *Louisiana Pub. Serv. Comm'n v. FCC.*, 476 U.S. 355, 374 (1986).

139. "Where a statute's language carries a plain meaning, the duty of an administrative agency is to follow its commands as written, not to supplant those commands with others it may prefer." *SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 363 (2018).

140. An agency's "power to act and how they are to act are authoritatively prescribed by Congress, so that when they act improperly, . . . , what they do is ultra vires. Because the question – whether framed as an incorrect application of agency authority or an assertion of

authority not conferred – is always whether the agency has gone beyond what Congress has permitted it to do, ..." *City of Arlington v. FCC*, 569 U.S. 290, 297-98 (2013).

141. The CPSA provides the Commission with the authority to determine whether a consumer product presents an unreasonable risk of injury and if so, then it has the authority to create product safety standards. But a mandatory standard must be necessary to prevent or reduce an unreasonable risk of injury. 15 U.S.C. § 2056(a). And if the Commission finds that a consumer product presents an unreasonable risk of injury *and* there is no feasible product safety standard that would adequately protect the public from this unreasonable risk *then* the Commission may create a rule banning the product. 15 U.S.C. § 2057. Both a mandatory standard and a product ban must follow the science and data driven process and procedures prescribed by Congress. *See* 15 U.S.C. § 2058.

142. The CPSC did not follow the rule making process before revising its Safe Sleep Guidance to state its determination that weighted infant sleep products are unsafe. Instead of undertaking the rigorous data- and evidence-driven process designed by Congress, it simply adopted the CDC and NIH's unsupported determinations.

143. Likewise, Commissioner Trumka exceeded, or was without, statutory authority under the CPSA to unilaterally: (1) determine that a product presents an unreasonable risk of injury; (2) advocate for the ban of a product; and (3) make public statements, social media posts, and send letters to retailers which repeated the same statutorily deficient statements.

144. Commissioner Trumka also exceeded, or was without, authority to publish inaccurate and misleading statements about Nested Bean's products, which the public was readily able to ascertain Nested Bean's identity, without providing advance notice and opportunity for the company to respond.

Count Four
Violation of the Administrative Procedure Act Arbitrary and Capricious Agency Action (Against CPSC)

145. Plaintiff incorporates by reference all the preceding material as though fully set forth herein.

146. Under the APA, a court must "hold unlawful and set aside agency action" that is arbitrary or capricious, an abuse of discretion, or without observance of procedure required by law. 5 U.S.C. § 706(2)(A).

147. "An agency may not 'depart from a prior policy sub silentio or simply disregard rules still on the books.'" *Louisiana v. DOE*, 90 F.4th 461, 469 (5th Cir. 2024) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)). "Rather, the agency must 'display awareness that it is changing position.'" *Id*. That means "changes require careful comparison of the agency's statements at T0 and T1 to ensure that the agency has recognized the change, reasoned through it without factual or legal error, and balanced all relevant interests affected by the change." *Id*. "An agency cannot shift its understanding of the law between those two times, deny or downplay the shift, and escape vacatur under the APA." *Wages & White Lion Invs., L.L.C. v. Food & Drug Admin.*, 90 F.4th 357, 381 (5th Cir. 2024) (en banc).

148. That means the Commission was required to "provide a 'detailed justification' for its change" here. *Id*. It did not, so its decision is "arbitrary or capricious." *Id*.

149. The Commission's November 2023 decision to *not* initiate rulemaking of mandatory safety standards and its December 2024 decision to *not* retract the Safe Sleep Guidelines and Commissioner Trumka's statements. The two decisions are irreconcilable. The November 2023 decision to *not* initiate rulemaking of mandatory safety standards for weighted infant sleep products was due to a lack of data identifying a hazard pattern associated with the

products. But the December 2024 decision to *not* retract the Safe Sleep Guidelines and Commissioner Trumka's statements, which claim weighted infant sleep products present an unreasonable risk to consumers, did not provide any data. The CPSC did not acknowledge the existence of the November 2023 decision or attempt to demonstrate why it now rejects its earlier, well-supported conclusion. This is black-letter arbitrary-and-capricious administrative action.

150. Also, failing to engage in "reasoned decisionmaking" renders an agency action arbitrary and capricious. *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 374 (1998) (internal quotation omitted). An "agency action is lawful only if it rests on a consideration of the relevant factors" and "important aspect[s] of the problem." *Michigan v. EPA*, 576 U.S. 743, 750–52 (2015) (internal quotation marks omitted) (requiring "reasoned decisionmaking"). This means agencies must "examine all relevant factors and record evidence." *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 923 (D.C. Cir. 2017).

151. Agency actions are arbitrary or capricious when, as here, the agency has "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

152. Upon information and belief, the CPSC did not engage in reasoned decision-making when it decided to adopt and publish the Safe Sleep Guidance advocating against weighted infant sleep products.

153. Likewise, the Commission did not provide any reasoned decision-making as to why it denied Nested Bean's Retraction Request. The CPSC's December 19, 2024, decision did

not explain why the Commission denied Nested Bean's request for retraction of both CPSC's Safe Sleep Guidance and Commissioner Trumka's statements.

154. Also, if an agency departs from a prior policy or rule still on the books then it "must 'display awareness that it is changing position.'" *Louisiana*, 90 F.4th at 469 (quoting Fox Television Stations, 556 U.S. at 515).

155. The issuance of the Safe Sleep Guidance and its refusal to retract the same is a departure from the longstanding rule that requires the Commission follow the CPSA procedure for determining whether a consumer product presents an unreasonable risk to consumers.

156. The December 2024 decision does not acknowledge, much less explain, its change in position.

157. Each of these failures renders the Commissions' actions arbitrary and capricious under the APA.

Count Five
Violation of the Administrative Procedure Act Failure to Observe Procedure Required by Law (Against CPSC)

158. Plaintiff incorporates by reference all the preceding material as though fully set forth herein.

159. A "reviewing court shall . . . hold unlawful and set aside agency action . . . found to be . . . without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

160. The purpose of the notice-and-comment rulemaking is to give the public the "opportunity to participate in the rule making through submission of written data, views, or arguments . . . ." 5 U.S.C. § 553(c).

161. A foundational premise of administrative law is to provide due process protections to the public when the unelected agencies make decisions, through adjudication or rulemaking, that have the force and effect of law and affect the public's rights and obligations.

162. These requirements "are not mere formalities" but rather "are basic to our system of administrative law." *NRDC v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 115 (2d Cir. 2018). That is why agencies must "subject their substantive rules to notice and comment" otherwise the rules "may not be enforced." *W&T Offshore, Inc. v. Bernhardt*, 946 F.3d 227, 237 (5th Cir. 2019).

163. The Commission did not follow the CPSA's science and data driven process and procedures, nor did the Commission follow the notice and comment requirements for rule-making procedure under the APA and CPSA when it issued its Safe Sleep Guidance determining that weighted infant sleep products present an unreasonable risk to consumers.

Count Six
Violation of the Fifth Amendment (Against Commissioner Trumka)

164. Plaintiff incorporates by reference all the preceding material as though fully set forth herein.

165. "No person shall … be deprived of life, liberty, or property, without due process of law[.]" U.S. Const. Amend. V.

166. This Court is authorized to set aside laws, rules, regulations, and executive actions that are in violation of the constitutionally guaranteed rights of the citizens of the United States.

167. "A fair trial in a fair tribunal is a basic requirement of due process." *In re Murchison*, 349 U.S. 133, 136 (1955).

168. A fair trial in a fair tribunal means the judge has "no actual bias against the defendant." *Bracy v. Gramley*, 520 U.S. 899, 904-05 (1997).

169. As such, "recusal is required when, objectively speaking, 'the probability of actual bias on the part of the judge or decisionmaker is too high to be constitutionally tolerable.'" *Rippo v. Baker*, 580 U.S. 285, 287 (2017) (citation omitted).

170. The question is "not whether a judge harbors an actual, subjective bias, but instead whether, as an objective matter, the average judge in his position is likely to be neutral, or whether there is an unconstitutional potential for bias." *Williams v. Pennsylvania*, 579 U.S. 1, 8 (2016) (quotation and citation omitted).

171. The due process requirement of a fair tribunal "applies to administrative agencies which adjudicate as well as to courts." *Withrow v. Larkin*, 421 U.S. 35, 46 (1975) (citation omitted).

172. "[W]hen an administrator unnecessarily makes prejudicial remarks outside an authorized proceeding, the court is more likely to find a violation of due process." *Zen Magnets, LLC v. CPSC*, 968 F.3d 1156, 1171 (10th Cir. 2020).

173. When an administrator made prior statements during the course of an authorized proceeding then the court is "less likely to consider the prior statements as evidence of prejudgment or its appearance," thereof. *Id.*

174. "But even when statements take place in the course of an authorized proceeding, the statements may reflect prejudgment or its appearance." *Id.* at 1171. "It is conceivable that a decisionmaker can form an opinion of a party so extreme that it renders the decisionmaker impermissibly biased. . . . ." *Id.* (quoting Kristin E. Hickman & Richard J. Pierce, Jr., *Administrative Law Treatise* § 7.7, at 868 (6th ed. 2019).

175. Commissioner Trumka has publicly and repeatedly made inaccurate and misleading statements about weighted infant sleep products. Those statements were not made

during an authorized proceeding. Given his letter and social media campaign against weighted infant sleep products, it is clear that Commissioner Trumka has strong negative opinions on the category of products. As such, Commisioner Trumka has actual bias against weighted infant sleep products and is incapable of neutral unbiased actions concerning these products in the future.

Count Seven
Violation of Separation of Powers (Against CPSC)

176. Plaintiff incorporates by reference all the preceding material as though fully set forth herein.

177. "The executive Power shall be vested in a President," who must "take Care that the Laws be faithfully executed." U.S. Const. art. II, § 1, cl. 1. The President, under the Appointments Clause, has the authority to appoint "Officers of the United States." U.S. Const. art. II, § 2, cl. 2.

178. "[T]he Constitution gives the President 'the authority to remove those who assist him in carrying out his duties.'" *Seila Law LLC v. CFPB*, 591 U.S. 197, 204 (2020) (citation omitted). Generally, the President has unrestricted removal power. *Id.*

179. Challenging the constitutionality of an officer's removal restriction is not limited to cases involving a contested removal. *Id.* at 212. Supreme Court "precedents have long permitted private parties aggrieved by an official's exercise of executive power to challenge the official's authority to wield that power while insulated from removal by the President." *Id.* (citations omitted).

180. There are "only two exceptions to the President's unrestricted removal power. *Id.* at 204. However, if the officer is a principal, as opposed to inferior, and the agency "wields

significant executive power," then statutory removal protections are unconstitutional. *See Id*. at 204.

181. The CPSC's Commissioners are principal officers of the United States and are appointed by the President for a term. *See* 15 U.S.C. 2053 (a).

182. The CPSC wields significant executive power. It can unilaterally conduct administrative hearings, issue rules interpreting its enabling statues, and can seek to impose significant monetary penalties against regulated parties, 15 U.S.C. § 2064(f); 15 U.S.C. § 2051; 15 U.S.C. § 2069.

183. However, the President may only remove a Commissioner for "neglect of duty or malfeasance in office but for no other cause." 15 U.S.C. 2053 (a).

184. Therefore, the for-cause removal protections under the CPSA are unconstitutional and violate the separation of powers.

PRAYER FOR RELIEF

Plaintiffs respectfully request that this Court:

A. Declare that CPSC's product safety determination of weighted infant sleep products in its Safe Sleep Guidance is contrary to law, not authorized by law, and in excess of statutory authority under the APA;

B. Declare that CPSC's product safety determination of weighted infant sleep products in its Safe Sleep Guidance is arbitrary and capricious and unlawful under the APA;

C. Declare that CPSC's product safety determination of weighted infant sleep products in its Safe Sleep Guidance violates the APA because it failed to follow procedure and was promulgated without notice and comment;

D. Declare that CPSC's refusal to retract its product safety determination of

weighted infant sleep products in its Safe Sleep Guidance and Commissioner Trumka's public letters and statements regarding the same

E. Declare that HHS, CDC, and NIH's product safety determination of weighted infant sleep products in its Safe Sleep Guidance is *ultra vires*;

F. Declare that Commissioner Trumka's unilateral product safety determination of weighted infant sleep products in his public letters and statements is *ultra vires* and violated CPSA disclosure requirements;

G. Declare that Commissioner Trumka is impermissibly biased against weighted infant sleep products, including Nested Bean's products, in violation of the Fifth Amendment;

H. Declare that the Commissioner's for-cause removal protections violate the separation of powers;

I. Order Defendants to issue a retraction pursuant to 15 U.S.C.A. Section 2055(b)(7) to correct and clarify Commissioner Trumka's inaccurate and misleading public statements regarding weighted infant sleep products;

J. Enjoin Defendants from making further public disclosures in violation of Section (6)(b) and determining the safety of weighted infant sleep products without adherence to the CPSA requirements;

K. Enjoin Defendant Commissioner Trumka, preliminarily and permanently, from participating in any future CPSC actions pertaining to weighted infant sleep products, including Nested Bean's products;

L. An award of Plaintiffs' reasonable attorneys' fees and costs under 42 U.S.C. § 1988; and

M. Any further relief this Court deems just and proper.

Respectfully submitted this 28th day of March 2025.

Respectfully Submitted,

/s/ William E. Green, Jr.

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