IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DREAMLAND BABY CO.,
1824 Port Margate Place
Newport Beach, CA, 92660,

Plaintiff,

v.

CONSUMER PRODUCT SAFETY COMMISSION
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814;

RICHARD TRUMKA, JR., in his official capacity as Commissioner of the Consumer Product Safety Commission
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814;

DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Ave., SW
Washington, DC 20201;

CENTERS FOR DISEASE CONTROL AND PREVENTION
1600 Clifton Rd.
Atlanta, GA 30329;

NATIONAL INSTITUTES OF HEALTH
9000 Rockville Pike
Bethesda, MD 20892,

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Case No. 1:24-cv-3277

COMPLAINT

NATURE OF THE CASE

Plaintiff Dreamland Baby Co. ("Dreamland") brings this civil action for declaratory and injunctive relief to stop 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") from perpetuating their baseless and unlawful attacks on weighted infant sleep products, including those developed, designed, produced, and sold by Dreamland.

In support, Plaintiff alleges the following:

1. Consumers trust CPSC and other public health agencies such as HHS, CDC, and NIH to base their decisions and statements on evidence and data, rather than speculation and conjecture. But in this case speculation, or something worse, drove these agencies and one rogue CPSC Commissioner to ignore the law and data to unfairly malign a class of consumer products, destroying Dreamland's reputation and pushing its business to the brink of failure.

2. The CPSC is charged with protecting consumers from unreasonable risks of injury from consumer products, assisting consumers in determining the comparative safety of products, developing safety standards, and promoting research into product-related injuries and deaths.

3. The CPSC is controlled by the Consumer Product Safety Act ("CPSA"), which provides a general regulatory framework for many consumer products and authorizes the Commission to fulfill its mission in several ways, including: collecting, maintaining, and analyzing incident data; conducting product safety research, investigations, and testing; assisting with the development of voluntary product safety standards; promulgating consumer product safety standards; filing suit to seize imminently hazardous products; and banning hazardous products.

4. When making product safety determinations the Commission must follow a rigorous process set out by the CPSA.

5. The statutory guardrails placed on the Commission's processes are reinforced by the Commission's implementing regulations. Together, these processes protect consumers and companies alike by encouraging the collaborative development of voluntary standards, providing due process protections for companies, fostering public input in standards development, and supporting a commitment to high quality data and evidence-based determinations. They also place certain limitations on what the Commission, including individual Commissioners or staff, may say when disclosing information and how they may do so.

6. Unfortunately for Dreamland, those statutory guardrails failed when the Commission effectively adopted consumer product safety recommendations made by CDC and NIH which—without any evidence at all, and, in fact ultimately rely on a *lack* of evidence—determined that weighted infant sleep products, such as Dreamland's weighted sleep bags and blankets, are unsafe for infant sleep.

7. Weighted infant sleep bags have been on the market for over a decade and millions of such products have been sold. Dreamland's weighted sleep bags and swaddles feature a quilted fabric design which allows weight to be evenly distributed throughout the product. The gentle pressure provided by the weighted sleep bag is comparable to placing a slice of bread or American cheese on an infant's chest.

8. Even though the Commission admitted that it lacked the data necessary to pursue a mandatory safety standard regarding these products, it adopted CDC's and NIH's unsubstantiated product safety determinations anyway. As a result, CPSC abdicated its congressionally delegated

power to make consumer product safety determinations to agencies that are neither empowered to make nor experienced with such determinations.

9. Making matters worse, one CPSC Commissioner took it upon himself to further exceed his authority and write to retailers who sold Dreamland's weighted sleep bags and blankets, telling them that the products were unsafe.

10. It comes as little surprise, then, that those retailers stopped selling Dreamland's products, as the Commissioner undoubtedly intended.

11. While Dreamland may never fully recover from these lawless actions, this lawsuit seeks to repair some of these wrongs.

PARTIES

12. Plaintiff Dreamland Baby Co. is a California Corporation headquartered in Newport Beach, California. Dreamland develops, designs, produces, and sells products for infants and children, including weighted sleep bags and swaddles.

13. Defendant Consumer Product Safety Commission is an independent regulatory commission and agency under 5 U.S.C. § 551(1). It is headquartered in Bethesda, Maryland.

14. Defendant Richard Trumka, Jr. is named in his official capacity as a Commissioner of the CPSC.

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

16. Defendant Centers for Disease Control and Prevention 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.

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

JURISDICTION

18. This Court has jurisdiction under 5 U.S.C. §§ 701–06 and 28 U.S.C. §§ 1331, 2201, 2202.

19. This matter is timely filed. *See* 28 U.S.C. § 2401(a).

VENUE

20. Venue in this district is proper under 28 U.S.C. § 1391(e).

STATUTORY AND REGULATORY BACKGROUND

The Consumer Product Safety Act (Pub. L. No. 92-573, as amended)

21. In 1972, Congress enacted the CPSA in response to concerns that "consumer products which present unreasonable risks of injury" were available to consumers and that then-existing regulatory frameworks were either "inadequate" or potentially "burdensome to manufacturers[.]" 15 U.S.C. § 2051(a)(1), (4), (5).

22. Under the CPSA, the Commission is charged with (1) "protect[ing] the public against unreasonable risks of injury associated with consumer products;" (2) "assist[ing] consumers in evaluating the comparative safety of consumer products;" (3) "develop[ing] uniform safety standards for consumer products[;]" and (4) promot[ing] research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries." 15 U.S.C. § 2051(b).

23. The Act provides a general regulatory framework for many consumer products and authorizes the Commission to fulfill its mission in several ways, including: collecting, maintaining,

and analyzing incident data; assisting with the development of voluntary product safety standards; conducting product safety research, investigations, and product testing; promulgating consumer product safety standards; addressing imminently hazardous products; and banning hazardous products. *See generally* 15 U.S.C. §§ 2054, 2056, 2058, 2061, 2064.

24. "The Commission is authorized to 'promulgate consumer product safety standards' establishing performance or warning requirements for consumer products[.]" *In the Matter of Leachco*, CPSC Docket No. 22-1, Slip op. at 37 (July 3, 2024) (Dkt. 148) (quoting 15 U.S.C. § 2056(a)), *notice of appeal filed* July 10, 2024.

25. In making product safety determinations and promulgating standards, the Commission must follow the procedures set forth by both the CPSA and the Administrative Procedure Act ("APA"). The information upon which the Commission relies and which it may disclose is further subject to the Information Quality Act ("IQA"), Pub. L. 106–554, § 515, and information quality guidelines issued by the Commission and the Office of Management and Budget. *See generally*, CPSC, *Information Quality Guidelines* (undated) (last visited Nov. 19, 2024), https://www.cpsc.gov/Research--Statistics/Information-Quality-Guidelines (noting that CPSC is a "data-driven agency").

26. Under the CPSA, product safety standard requirements "shall be reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product." 15 U.S.C. § 2056(a).

27. Before it is permitted to promulgate a rule, and chooses to do so, the Commission must make several determinations—all backed by evidence and data. For example, 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).

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

29. In addition to governing how CPSC regulates consumer products, the CPSA also limits how the Commission, individual Commissioners, and staff may discuss consumer products. *See* 15 U.S.C. § 2055.

30. Pursuant to Section 6(b), 15 U.S.C. § 2055(b), before the Commission publicly discloses information that identifies a manufacturer or private labeler, or readily allows the public to find out their identity, it must "take reasonable steps to assure" that the information "is accurate, and that such disclosure is fair in the circumstances and reasonably related to effectuating the purposes of [the CPSA]." *See* 15 U.S.C. § 2055(b)(1); *see also* 15 U.S.C. § 2055(b)(6) (requiring the Commission to establish procedures to ensure disclosed information is accurate and not misleading). Moreover, CPSA requires notice *before* such statements are made and an opportunity for a company to respond *before* the information is made public. 15 U.S.C. § 2055(b)(1).

31. The Commission has determined that Section 6(b)(1)'s "notice and analysis provisions" apply if (1) the information "pertain[s] to a specific product which is either designated or described in a manner which permits its identity to be ascertained readily by the public[;]" (2) the information is "obtained, generated or received by the Commission as an entity or by individual members, employees, agents, contractors or representatives of the Commission acting in their official capacities;" (3) "[t]he Commission or its members, employees, agents or representatives" proposes to publicly release the information; and, (4) "[t]he manner in which the product is

designated or described in the information … permit[s] the public to ascertain readily the identity of the manufacturer or private labeler." 16 C.F.R. § 1101.11.

32. The public is able to readily ascertain the identity of a manufacturer or private labeler "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.

33. The Commission considers certain actions sufficiently reasonable to assure the accuracy of information, including when "Commission staff or a qualified person or entity outside the Commission … conducts an investigation or an inspection" or "Commission staff conducts a technical, scientific, or other evaluation" corroborating the information being disclosed. 16 C.F.R. § 1101.32.

34. CPSC has also determined that certain steps are reasonable to provide fairness, including providing the "manufacturer's or private labeler's comments" along with the public disclosure or "accompany[ing] the disclosure of information with an explanatory statement … [and] to disclose any other relevant information [in] its possession" or "limit[ing] the form of disclosure" or "delay[ing] disclosure[.]" 16 C.F.R. § 1101.33.

35. Under the CPSA, 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).

The Public Health Service Act (42 U.S.C. § 241 et seq., as amended)

36. The Secretary of HHS is generally permitted 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).

37. These programs and activities include: supporting CDC registries collecting certain data, 42 U.S.C. § 300c-11(a)(1); "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).

38. The Public Health Service Act ("PHSA") also requires that the Secretary of HHS make sure that there are adequate funds available for research to "make maximum feasible progress toward identification of infants at risk of sudden infant death syndrome and prevention of sudden infant death syndrome." 42 U.S.C. § 300c-12.

39. The PHSA requires the Secretary of HHS to conduct certain activities, including data collection and educating the public about "sudden unexpected infant death and sudden unexplained death in childhood." 42 U.S.C. § 300c-13.

40. The PHSA also requires the Secretary of HHS to make regular reports to Congress about certain information and activities conducted during the applicable reporting period. 42 U.S.C. § 300c-14.

FACTUAL ALLEGATIONS

Dreamland Develops, Designs, Produces, and Sells Weighted Infant Sleep Products

41. Dreamland's weighted sleep bag and swaddle was born out of a common problem facing new parents: being sleep deprived during the newborn phase.

42. In 2019, the company's founder and CEO, Tara Williams, developed the product for her youngest son, who had difficulty falling and remaining asleep. By trial and error, Ms. Williams had discovered that her son was soothed by the feeling of light pressure placed on him.

43. After realizing that she could not find such a product on the market, Ms. Williams designed a weighted sleep bag and worked with her mother-in-law, a trained seamstress, to manufacture a prototype.

44. She tested the prototype on her son and was surprised by how quickly he settled, and the length and quality of his sleep.

45. She then shared prototypes with friends and family and asked them to complete surveys of their experience with the product.

46. After receiving positive feedback, Ms. Williams launched a Kickstarter campaign.

47. Following the successful Kickstarter campaign, the product was featured on ABC's Shark Tank.

48. Since then, Dreamland has sold over 1 million of its products to families.

49. Currently, Dreamland sells three wearable weighted sleep products: a swaddle, a sleep bag, and a transition swaddle. All three products feature a quilted fabric design which allows weight to be evenly distributed throughout the product. The product is filled with non-toxic, hypoallergenic, smooth, non-porous poly beads.

50. The gentle pressure provided by the weighted sleep bag is comparable to placing a slice of bread or American cheese on an infant's chest.

CDC's and NIH's Determinations Regarding Weighted Infant Sleep Products

51. Since 1994, HHS and several of its subagencies, including NIH and CDC, have participated in the Safe to Sleep® campaign and its precursor, the Back to Sleep® campaign. *See* NIH, *Campaign History* (undated) (last visited Nov. 19, 2024), https://safetosleep.nichd.nih.gov/campaign/history.

52. Since their inception, the campaigns have focused on reducing the risk of Sudden Infant Death Syndrome ("SIDS") by promoting back sleep only for young babies. *Id.* The Back to Sleep® campaign's focus was expanded in 2012 "to address not only SIDS, but also other sleep-related infant deaths" and it was renamed the Safe to Sleep® campaign. *Id.*

53. The Eunice Kennedy Shriver National Institute of Child Health and Human Development ("NICHD") "leads the Safe to Sleep® campaign with support from" certain collaborators including the CPSC, CDC, and the American Academy of Pediatrics ("AAP"). NIH, *Collaborators & Partners* (undated) (last visited Nov. 19, 2024), https://safetosleep.nichd.nih.gov/campaign/partners.

54. On June 21, 2022, AAP updated its safe sleep guidelines. *See* Rachel Y. Moon, M.D., FAAP, Rebecca F. Carlin, M.D., FAAP, Ivan Hand, M.D., FAAP, Policy Statement, *Sleep-Related Infant Deaths: Updated 2022 Recommendations for Reducing Infant Deaths in the Sleep Environment*, American Academy of Pediatrics (June 21, 2022), https://doi.org/10.1542/peds.2022-057990.

55. Updating guidelines from 2016, the revised guidelines included a new recommendation regarding the "Soft Bedding" topic stating that: "It is recommended that weighted blankets, weighted sleepers, weighted swaddles, or other weighted objects not be placed on or near the sleeping infant." *Id.*

56. The revised guidelines included a second new recommendation under the "Swaddling" topic stating that: "Weighted swaddle clothing or weighted objects within swaddles are not safe and therefore not recommended." *Id.*

57. The AAP swaddling recommendation notes that "[a] single crossover randomized nonblinded trial of 16 infants with neonatal abstinence syndrome found no adverse events when a 1-pound weighted blanket was placed on each infant for 30 minute observed episodes." *Id.* Rachel Y. Moon, MD, FAAP; Rebecca F. Carlin, MD, FAAP; Ivan Hand, MD, FAAP, *Evidence Base for 2022 Updated Recommendations for a Safe Infant Sleeping Environment to Reduce the Risk of Sleep-Related Infant Deaths* (June 21, 2022) (last visited Nov. 19, 2024)

https://doi.org/10.1542/peds.2022-057991 (citing Virginia Summe, Rachel B. Baker, & Margaret M. Eichel, *Safety, Feasibility, and Effectiveness of Weighted Blankets in the Care of Infants With Neonatal Abstinence Syndrome: A Crossover Randomized Controlled Trial*, ADVANCES IN NEONATAL CARE vol. 20, issue 5, 384–391 (Oct. 2020), https://pubmed.ncbi.nlm.nih.gov/32868588/).

58. AAP concluded however, that "no studies have documented the safety of weights for infants in an unobserved, nonclinical sleep environment." *Id.*

59. As economist Emily Oster observed at the time the revised guidelines were released, the paper AAP cites "is evidence of *safety*" and "[t]here is no data cited suggesting danger." Emily Oster, *New AAP Guidelines on Breastfeeding and Safe Sleep: A case study in bad use of data*, ParentData (July 5, 2022), https://parentdata.org/new-aap-guidelines-on-breastfeeding-and-safe-sleep/ (emphasis in original). She continued that "[her] sense, reading between the lines, is that the AAP is reacting to a lack of wide-scale direct evidence that these products are safe, combined with a theoretical concern that heavy blankets could imperil breathing. It chose to discuss these issues at this time because the products are becoming more popular." *Id.*

60. Sometime thereafter, the Safe to Sleep® campaign "revise[d] its messages to reflect the 2022 American Academy of Pediatrics updated safe infant sleep recommendations." NIH, *Campaign History*.

61. On information and belief, those revised messages include certain product safety determinations made by NIH and CDC regarding weighted infant sleep products.

62. NIH updated its safe sleep guidance to note that "[t]hings in the sleep area can pose dangers for baby, especially if they are: … Weighted (e.g., weighted blankets, weighted

swaddles)." NIH, *Safe Sleep Environment for Baby* (undated) (last visited Nov. 19, 2024), https://safetosleep.nichd.nih.gov/reduce-risk/safe-sleep-environment.

63. CDC updated its safe sleep guidance to state that "[p]roducts labeled as weighted—including weighted sleepers, swaddles, sleep sacks, and blankets—are **not safe** for infants." CDC, *Helping Babies Sleep Safely* (undated) (last visited Nov. 19, 2024), https://www.cdc.gov/reproductive-health/features/babies-sleep.html?CDC_AAref_Val=https://www.cdc.gov/reproductivehealth/features/baby-safe-sleep/index.html (emphasis in original).

64. It is not clear when either of these statements were first made by the respective agencies.

65. Neither agency provides the basis for its respective determination. And on information and belief, neither agency has conducted research regarding the use of weighted infant sleep products, nor have they independently verified the recommendation made by AAP.

CPSC's Determination Regarding Weighted Infant Sleep Products

CPSC Rejects Commissioner Trumka's Attempt to Regulate Weighted Infant Sleep Products

66. On November 8, 2023, the Commission convened a meeting to consider its Fiscal Year 2024 Operating Plan to discuss, among other things, proposed amendments to the Plan.

67. Commissioner Richard Trumka, Jr. proposed Trumka Amendment 3, which would have required CPSC staff to "pursue a mandatory standard to address foreseeable risks posed by [weighted sleep products for infants]." CPSC, *Minutes of Commission Mtg.* at 13 (Nov. 8, 2023), https://www.cpsc.gov/s3fs-public/Comm-Mtg-Min-FY-2024-Operating-Plan-Decisional.pdf?VersionId=GDwWSUy29P7SN9MpqVVWdX5Nn9xe36Vm.

68. The amendment would also have required CPSC to "update all safe sleep messaging and guidance to incorporate recent advice on weighted infant products from the Centers for Disease Control and Prevention and from the National Institutes of Health." *Id.*

69. The Commission rejected Commissioner Trumka's proposal by a 3 to 1 vote. *See id*. at 13 (One seat was vacant at the time of the vote. It has since been filled by Commissioner Douglas Dziak).

70. As Chair Alexander Hoehn-Saric observed, it was "[his] understanding that [CPSC] staff has 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." CPSC, Commission Meeting FY24 Operating Plan Decisional, YouTube at 20:28−20:55 (Nov. 9, 2023), https://www.youtube.com/watch?v=LHemQpZZBN0&list=PLPbI8bR243fHmCYA1a7pZ4l4wzhYjla_V&index=6. He continued by noting that "the staff is very aware of the issue and working diligently to assess and quantify the safety risks associated with weighted blankets." *Id.*at 20:55−21:04.

71. In her remarks, Commissioner Mary T. Boyle noted that a rulemaking was "at this time premature." *Id.* at 21:52−22:05.

72. After his amendment failed, Commissioner Trumka released a statement calling weighted infant blankets "glaring," "concerning," and "alarming" hazards and noting that such products were "deemed dangerous by NIH, CDC, and the American Academy of Pediatrics[.]" Comm'r Richard Trumka Statement, *CPSC Operating Plan Fails to Address Glaring Safety Concerns: Commissioner Trumka Forced to Vote "No"*, CPSC (Nov. 8, 2023),

https://www.cpsc.gov/About-CPSC/Commissioner/Richard-Trumka/Statement/CPSC-Operating-Plan-Fails-to-Address-Glaring-Safety-Concerns-Commissioner-Trumka-Forced-to-Vote-%E2%80%9CNo%E2%80%9D. His statement also attacked his fellow Commissioners for not supporting his amendment. *Id.*

73. On information and belief, Commissioner Trumka may propose the same or a substantially similar amendment again before his term as Commissioner expires in October of 2028.

In the Absence of Data and Evidence, CPSC Amends its Safe Sleep Guidance

74. In his November 8, 2023, remarks, Chair Hoehn-Saric noted that CPSC staff had not "conducted the research necessary to draft a notice of proposed rulemaking in 2024," and that they were working to "assess and quantify the safety risks associated with weighted blankets[.]" CPSC, *Commission Meeting FY24 Operating Plan Decisional* at 20:28−21:04.

75. That is likely because instituting a rulemaking under the CPSA requires data and evidence establishing that a consumer product safety standard regarding weighted infant sleep products was "reasonably necessary to prevent or reduce an unreasonable risk of injury associated with [a] product." 15 U.S.C. § 2056(a).

76. Despite this admission—that the Commission did not have data or evidence to support a rulemaking—Chair Hoehn-Saric noted that "staff is already working on how to modify safe sleep guidance to account for the fact that both NIH and CDC is [*sic*] warning against the use of … weighted wearables for infants," and that CPSC would be updating its guidance. CPSC, *Commission Meeting FY24 Operating Plan Decisional* at 20:01−20:25.

77. Sometime after November 8, 2023, the CPSC's Safe Sleep Guidance was updated to add: "**Don't** use weighted blankets or weighted swaddles*. … *NIH.gov and CDC.gov[.]" CPSC, *Safe Sleep - Cribs and Infant Products* (undated) (last visited July 12, 2024),

https://www.cpsc.gov/SafeSleep (emphasis in original). Sometime after July 23, 2024, *see, infra,* ¶ 124 (discussing retraction request to CPSC), the "*" footnote was edited to say "*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.* (last visited Nov. 19, 2024).

78. The linked NIH webpage states: "Things in the sleep area can pose dangers for baby, especially if they are: … Weighted (e.g., weighted blankets, weighted swaddles)[.]" NIH, *Safe Sleep Environment for Baby* (last visited Nov. 19, 2024), https://safetosleep.nichd.nih.gov/reduce-risk/safe-sleep-environment.

79. The linked CDC webpage states: "Products labeled as weighted—including weighted sleepers, swaddles, sleep sacks, and blankets—are **not safe** for infants." CDC, *Helping Babies Sleep Safely* (last visited Nov. 19, 2024), https://www.cdc.gov/reproductive-health/features/babies-sleep.html?CDC_AAref_Val=https://www.cdc.gov/reproductivehealth/features/baby-safe-sleep/index.html (emphasis in original).

80. Neither webpage cites any specific safety data, evidence, or studies regarding weighted infant sleep products.

81. On information and belief, CPSC likewise lacks safety data, evidence, or studies regarding weighted infant sleep products.

82. On information and belief, the Commission did not take a vote regarding the updated guidance statement before it was published online.

83. Since the November 2023 hearing, the Commission has worked to identify potential product hazards associated with both weighted and non-weighted wearable blankets and swaddles. On July 1, 2024, CPSC staff submitted updated incident data to the ASTM International ("ASTM")

subcommittee overseeing the voluntary standard for wearable blankets and swaddles, the ASTM F15.19 subcommittee. The data was provided to aid the ASTM subcommittee considering the potential hazards associated with such wearable blankets and swaddles. *See* Letter from Khalisa Phillips, CPSC, to Michelle Barry & Tara Williams, Subcommittee Co-Chairs for ASTM F15.19 (July 1, 2024), https://www.cpsc.gov/content/Infant-Blanket-Spring-2024-ASTM-Cover-Letter-and-Spreadsheet?language=th.

84. CPSC staff attempted "[t]o provide the most comprehensive data possible" by including additional product codes, a wider range of search terms, and specific brands, product names, and models in its search. *Id.* Staff then reviewed the dataset and removed certain incidents that did not "identify a wearable infant blanket product." *Id.* The data was then categorized by product type and whether the product was weighted. *Id.* The dataset provided by CPSC staff identified 167 incidents for all such products, weighted and non-weighted, between January 1, 2011 and April 10, 2024. *Id.*

85. The CPSC incident data was reviewed by Dr. Carol Pollack-Nelson and Don Mays, as part of the ASTM F15.19 Wearable Infant Blankets Data Analysis and Performance Requirements Task Group, using the "ASTM Scientific Integrity Guidelines to identify hazard patterns." *See* CPSC, ASTM F15.19 Wearable Infant Blankets Data Analysis and Performance Requirements Task Group Meeting Logs (filed Sept. 12, 2024), https://www.cpsc.gov/s3fs-public/08-26-2024-ASTM-F15-19-Wearable-Infant-Blankets-Data-Analysis-and-Performance-Requirements-Task-Group-Meeting-Log.pdf?VersionId=oeAGyPq1PytG.AICZXfHv0n16VFCFVvr.

86. Dr. Pollack-Nelson and Mr. Mays "noted that multiple unsafe (or unintended) sleep practices were present for at least three (3) of the five (5) fatalities associated with weighted infant

sleep sacks and swaddles. Furthermore, they found no pattern among the 13 incidents (deaths + injuries) involving weighted sleep products." *Id.*

Commissioner Trumka Takes Matters into His Own Hands

87. Despite the Chair's November 2023 admission that CPSC lacked the data to pursue a mandatory standard in FY 2024, the vote rejecting Trumka's proposed amendment to pursue a mandatory standard, and the Commission's ongoing work to determine the safety of weighted infant sleep products like Dreamland's, Commissioner Trumka, using the authority of his position, issued a series of misleading and highly damaging statements, letters, videos, and posts on X (formerly Twitter) and Instagram maligning weighted swaddles and blankets.

88. For example, on January 26, 2024, Commissioner Trumka posted from his X account (@TrumkaCPSC) that CPSC, along with other government agencies and the AAP, were "all in agreement when it comes to weighted infant sleep products: they pose serious threats to the lives of babies. Do NOT use them for sleep." @TrumkaCPSC, X.com (Jan. 26, 2024, at 12:00 PM), https://x.com/TrumkaCPSC/status/1750926680267333669. That post included a link to an article that specifically identified Dreamland and its products. *See* Lauren Kirchner, *Consumer Reports, Weighted blankets are dangerous for babies, doctors warn*, WASH. POST (Jan. 22, 2024, 2:00 PM), https://www.washingtonpost.com/wellness/2024/01/22/weighted-baby-blankets-unsafe.

89. On April 15, 2024, Commissioner Trumka posted a statement on the CPSC website, an accompanying statement on CPSC letterhead, and a video statement on his official X and Instagram accounts alerting the public that weighted infant sleep products were "unsafe" and encouraging retailers to stop selling such products. *See* Comm'r Trumka, Statement, *Beware: Weighted Infant Swaddles and Blankets Are Unsafe for Sleep; Retailers Should Consider Stopping Sales*, CPSC (Apr. 15, 2024), 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; @TrumkaCPSC, X.com (Apr. 15, 2024, 3:16 PM), https://x.com/TrumkaCPSC/status/1779951952559751190; @trumkacpsc, Instagram.com (Apr. 15, 2024), https://www.instagram.com/trumkacpsc/reel/C5y1uX_RNso/.

90. In these public statements he makes several inaccurate, misleading, and/or unsubstantiated claims including that using weighted infant sleep products leads to "a risk of death" for infants. *See*, *e.g.*, @TrumkaCPSC, X.com (Apr. 15, 2024, 3:16 PM), https://x.com/TrumkaCPSC/status/1779951952559751190.

91. The videos include an image of a swaddled infant with two dumbbells crisscrossed over the child's chest, superimposed with a general prohibition sign over the image. In small, barely legible writing, the image states: "Weights and baby not shown to scale. For illustrative purposes only." *See*, *e.g.*, @TrumkaCPSC, X.com (Apr. 15, 2024, 3:16 PM), https://x.com/TrumkaCPSC/status/1779951952559751190.

92. Just days later, on April 26, 2024, Commissioner Trumka posted a statement on the CPSC website, an accompanying statement on CPSC letterhead, and a video statement on his official X and Instagram accounts. *See* Comm'r Trumka, Statement, *Target, Walmart, Nordstrom, and Babylist Commit to Stop Selling Weighted Infant Products*, CPSC (Apr. 26, 2024), https://www.cpsc.gov/About-CPSC/Commissioner/Richard-Trumka/Statement/Target-Walmart-Nordstrom-and-Babylist-Commit-to-Stop-Selling-Weighted-Infant-Products; @TrumkaCPSC, X.com (Apr. 26, 2024, 10:26 AM), https://x.com/TrumkaCPSC/status/1783865218226852073; @trumkacpsc, Instagram.com (Apr. 26, 2024), https://www.instagram.com/reel/C6Ol9phuVEa/?utm_source=ig_web_copy_link.

93. In those statements, he disclosed—for the first time—that he had sent letters to Dreamland's retailers including Target, Walmart, Nordstrom, and Babylist, urging them to stop selling weighted infant sleep products. *See* Letters from Commissioner Trumka to Target, Walmart, Nordstrom, and Babylist (dated Apr. 15, 2024), https://www.cpsc.gov/s3fs-public/Trumka_Statement_Weighted_Infant_Products_4_26_24_with_attachments.pdf?VersionId=iK5EDmatuGu9_z2jKt8t8BaWndFKwWCh.

94. Commissioner Trumka sent similar letters to other retailers. *See* Office of Comm'r Trumka, Log of Meeting with Mercari (dated Apr. 30, 2024), https://www.cpsc.gov/s3fs-public/Telephone%20CallwithMercariMeetingLog.pdf?VersionId=8UB4pmcti05HGsQikZd2WhlE3agW_1zh (noting that Commissioner Trumka's staff held a call with online retailer Mercari in which they "discussed [his] letter to Mercari regarding weighted infant sleep products").

95. Commissioner Trumka's April 26 statement applauding his unlawful actions, and the attached April 15 letters to retailers, repeat the same misleading and inaccurate statements included in his April 15 statements. He again suggests that weighted infant sleep products pose risks to babies, misleadingly recounts CPSC's purported product safety determination of such products, and highlights unsubstantiated third-party statements suggesting that weighted infant sleep products increase the risk of SIDS and harm infants' brain development.

96. Commissioner Trumka and/or his staff also communicated with retailers regarding his letters. For example, Commissioner Trumka and/or his staff spoke with Target's Government Affairs Representative at least three times between April 22 and 25. *See* Office of Comm'r Trumka, Log of Meeting with Target (dated Apr. 22, 2024), https://www.cpsc.gov/s3fs-public/MeetingLogTarget42224.pdf?VersionId=qO4w2wcpN91kbaAXVCXKs6nmw5KfKOj8 (noting that Commissioner Trumka and staff spoke with a representative of Target to discuss the

timeline in which Target can officially respond to Commissioner Trumka's letter regarding weighted infant products"); *See* Office of Comm'r Trumka, Log of Meeting with Target (dated Apr. 23, 2024), https://www.cpsc.gov/s3fs-public/PhonecallwithTargetMeetingLog.pdf?VersionId=EcVh52ZLPxnLtYEkYg8B6QbrLICpBdlS; Office of Comm'r Trumka, Log of Meeting with Target (dated Apr. 25, 2024), https://www.cpsc.gov/s3fs-public/PhonecallwithTargetMeetingLog42524.pdf?VersionId=FzmxF1SjeUuSjsFJFYvMXGAscAKMwlQ_.

97. Dreamland was provided no notice of any of Commissioner Trumka's statements before they were made, even though the statements allow the public to readily ascertain Dreamland'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, Dreamland suffered substantial reputational and economic harm, including retailers stopping sale of its products.

Dreamland Petitions CPSC to Retract CPSC's and Commissioner Trumka's Statements

100. Pursuant to CPSA, 15 U.S.C. § 2055(b)(7), and its implementing regulations, 16 C.F.R. § 1101.52, Dreamland sent a formal retraction request to CPSC on July 23, 2024. *See* Letter from Dreamland Baby to CPSC Secretary Mills (July 23, 2024) (attached as Exhibit 1) ("Retraction Request").

101. The Retraction Request asked the Commission to "retract certain 'inaccurate or misleading information which reflects adversely upon the safety of' Dreamland's weighted sleep

swaddles and blankets and the class of infant weighted sleep swaddles and blankets in general[,]" provided reasons in support of its request, and specified the method of retraction sought. *Id.* at 1, 6–15.

102. The Retraction Request first asked the Commission to withdraw its guidance telling the public not to use weighted blankets and weighted swaddles because the statement is misleading and inaccurate. *Id.* at 7–8. The request noted that while CPSC is supposed to be an evidence- and data-driven administrative agency, it had improperly relied on the statements of other agencies—specifically CDC and NIH—who are not congressionally empowered to make product safety determinations and who also had no basis for their determinations. *Id.* at 7.

103. The Retraction Request explained that CPSC's statement was misleading under CPSA. *See* 15 U.S.C. § 2055(b)(6). The statement gave consumers and parents the false impression that the Commission had "investigated or evaluated the recommendation and that it has a sufficient basis for making that recommendation" because that is what the law requires. *Id.* But CPSC had not complied with the law in this instance.

104. The request also highlighted the inaccuracies contained in the statement according to the regulations governing the Commission, *see* 16 C.F.R. § 1101.32. The inaccuracies arose because CPSC had effectively outsourced a product safety determination to agencies that did not base their assessments and public recommendations on "any data or evidence specific to weighted swaddles or blankets but relied only on a perceived lack of safety data." *Id.* at 7–8.

105. The Retraction Request further sought withdrawal of Commissioner Trumka's statements to retailers, as well as related social media posts, because the communications were inaccurate and misleading. *Id.* at 8–14.

106. As discussed in the request, several of Commissioner Trumka's unfounded adverse statements or posts permitted the public to readily ascertain Dreamland's identity, in violation of CPSA and its implementing regulations, *see* 15 U.S.C. § 2055(b)(1); 16 C.F.R. § 1101.11.

107. For example, Commissioner Trumka posted a Consumer Reports article entitled "Weighted blankets are dangerous for babies, doctors warn" on his X account (@TrumkaCPSC). The article specifically identified Dreamland and its products. Trumka's tweet claimed that CPSC, along with other government agencies and the American Academy of Pediatrics ("AAP"), were "all in agreement when it comes to weighted infant sleep products: they pose serious threats to the lives of babies. Do NOT use them for sleep." @TrumkaCPSC, X.com (Jan. 26, 2024, 12:00 PM), https://x.com/TrumkaCPSC/status/1750926680267333669 (citing Lauren Kirchner, Consumer Reports, *Weighted blankets are dangerous for babies, doctors warn*, WASH. POST (Jan. 22, 2024, 2:00 PM), https://www.washingtonpost.com/wellness/2024/01/22/weighted-baby-blankets-unsafe).

108. Commissioner Trumka cited the same article in subsequent statements and in his letters to retailers. *See* Retraction Request at 9, 10, 14.

109. The letters to retailers also included a hyperlink to a product search for weighted infant sleep products, which necessarily identified Dreamland's products, as they were for sale and searchable on retailers' websites at the time. *Id.* at 13.

110. However, Dreamland was never provided with advance notice of these statements, nor the opportunity to respond. Retraction Request at 6.

111. On August 30, 2024, CPSC's Secretary informed Dreamland that "the Commission voted 3-0-2 on August 29, 2024 to take other action and deny retraction of the CPSC statement and approve" a letter explaining its reasons for denying the Retraction Request. Email from Alberta

E. Mills, CPSC Secretary, to Kara Rollins and Jenin Younes (Aug. 30, 2024) (attached as Exhibit 2). "Chair Hoehn-Saric, Commissioner Trumka and Commissioner Boyle voted to take other action and approved" the letter and "Commissioner Feldman and Commissioner Dziak abstained from the vote and issued a joint statement regarding this matter." *Id.*

112. The Commission's response to the Retraction Request states that the retractions sought by Dreamland were not warranted. Letter from Alberta E. Mills, CPSC Secretary, to Kara Rollins and Jenin Younes (Aug. 30, 2024) ("Retraction Response") (attached as Exhibit 3).

113. The Commission found that its Safe Sleep Guidance "is not barred by section 6(b)(7) of the CPSA" and noted that CPSC may "reference complementary information on other federal websites as long as such information is accurate and not misleading." *Id.* at 2. It indicated that "Commission staff cleared [the Safe Sleep Guidance] for public disclosure pursuant to its internal agency clearance process, found in Directive 1450.2." *Id.*

114. Directive 1450.2 is the CPSC's "Clearance Procedures for Providing Information to the Public." CPSC, Order No. 1450.2, *Clearance Procedures for Providing Information to the Public* (Jan. 16, 2003), (attached as Exhibit 4). The clearance process requires that "each Commission disclosure" receive "careful review and written approval of the information to be disclosed" by certain CPSC staff "in order to eliminate inaccurate or misleading statements." *Id.* at 2. For technical and scientific information, the clearance process requires that the statement, consistent with the Commission's Information Quality Guidelines, is supported by:

> (a) data in Commission files or in currently applicable literature;
>
> (b) articulated technical judgment that is both reduced to writing and based on consideration of all relevant factors; or
>
> (c) a report prepared by a contractor to the Commission and that has been subject to a review process by Commission staff.

Id.

115. But Defendants apparently met none of these requirements. At the time its Safe Sleep Guidance was updated, CPSC admitted that it lacked the data to pursue a mandatory standard in FY 2024 for weighted infant sleep products. It does not appear that HHS, CDC, or NIH conducted *any* independent study or review of *any* data regarding the safety of weighted infant sleep products prior to updating their safe sleep guidance. None of the statements articulated by any of the Defendants is a "technical judgment" "based on consideration of all relevant factors."

116. In fact, the opposite appears to be true: the statements appear at best to be based on no data whatsoever. Nor is there an iota of evidence that any of the Defendants has commissioned research from their staff or independent contractors supporting the safe sleep guidance warning against the use of weighted infant sleep products.

117. Moreover, CPSC's clearance process requires statements made in "Joint Projects," which are "any project where an outside group, with some degree of CPSC involvement, produces any audio, visual, internet, written or other material or program for the public." Exhibit 4 at 9. "An outside group may be non-profit, a company, a trade association, another government agency, or any other entity." *Id.*

118. Under Directive 1450.2, the Safe to Sleep® campaign is a Joint Project because CPSC is a "Collaborator" for the campaign. Thus, any statements made by that campaign would be subject to CPSC's clearance processes.

119. The NIH statement at issue is published on the Safe to Sleep® campaign website. *See*, *supra*, ¶¶ 62, 78. On information and belief its statement was not cleared under CPSC's clearance procedures but should have been.

120. On information and belief, none of the Defendants undertook any efforts to verify or corroborate the AAP's recommendations.

121. Misunderstanding the basis for Dreamland's requested retractions, CPSC "disagree[d] with Dreamland's assertion … that the references to the NIH and CDC guidance are *per se* inaccurate or misleading unless CPSC independently corroborates them." Retraction Response at 2.

122. But Dreamland never made a "*per se*" argument. Instead, it based its Retraction Request on the fact that CPSC is charged by Congress with determining the safety of consumer products and regulating such products—powers not granted to HHS, CDC, or NIH. *See* Retraction Request at 2–3, 4, 5. Given CPSC's role, it is incumbent upon the Commission to verify that the statements it puts forth regarding the safety of a consumer product or class of consumer products are accurate and not misleading, and based on evidence, not hunches. That was not done here as "neither CDC nor NIH based their statements on any data or evidence specific to weighted swaddles or blankets but relied only on a perceived lack of safety data." *Id.* at 8.

123. The CPSC's Retraction Response also argued that its Safe Sleep Guidance was consistent with its "Linking Out Policy" which permits the CPSC to "crosslink to content on federal and state government websites and Social Media Sites, provided that the content complements safety information issued by the agency and is related to the agency's mission." Retraction Response at 2–3 (quoting CPSC, *Commission Policy on Linking to Nongovernment Websites* at 2 (undated) (attached as Exhibit 5))

124. The Retraction Response indicated that "[t]o provide further context for the crosslinks to content from NIH and CDC in the CPSC Statement, the Commission has made a slight modification to the references in the asterisk." Retraction Response at 3; *see also*, *supra*,

¶ 77 (noting modifications to the CPSC's Safe Sleep Guidance after Dreamland submitted its Retraction Request).

125. Finally, CPSC admits that its statement is not based on the NIH's or CDC's independent determinations, but merely their adoption of the AAP's safe sleep recommendations. Retraction Response at 3. While CPSC states that fact is "clear," this information can only be gleaned by combing through NIH's Safe to Sleep® website, *i.e.*, you must know where to look for the information to find it. The basis for the recommendation is nowhere to be found on CDC's linked to website. Nor does CPSC's website ever indicate that its determination is solely the result of blindly adopting AAP's recommendation. Instead, it misleadingly suggests that it is only following the recommendations made by NIH and CDC.

126. In making this statement, the Commission has effectively admitted that it has outsourced its power and authority to make consumer product safety determinations to the AAP, a nongovernmental organization. Just as CPSC cannot abdicate its power to another federal agency, it cannot outsource it power to the AAP.

127. For these reasons, the determination was not based upon CPSA's rigorous research requirements.

128. No action was taken in regard to Dreamland's Retraction Request challenging Commissioner Trumka's statements because "the Commission voted 2-0-2[.]" *See* Exhibit 2 at 1. "Chair Hoehn-Saric and Commissioner Boyle voted to take other action … Commissioner Feldman and Commissioner Dziak abstained from the vote … [and] Commissioner Trumka voluntarily recused himself from this decision and did not participate." *Id.*

129. Chair Hoehn-Saric and Commissioner Boyle voted to deny Dreamland's Retraction Request regarding Commissioner Trumka's statements, finding that the relief sought

"unwarranted." *See* OS# 0319 – Request by Dreamland Baby Co. for Information Retraction Pursuant to Section 6(b)(7) of the Consumer Product Safety Act – Statements by Commissioner Trumka (undated) (attached as Exhibit 6).

130. They determined that the statements Dreamland identified did not "contain the name of Dreamland or any other manufacturer or private labeler" and therefore the company's identity was not "'readily ascertained' within the meaning of the CPSA and Commission regulations, and the advance notice and comment requirements of CPSA section 6(b)(1) do not apply." *Id.*

131. Their determination borders on the incredible, as the article Commissioner Trumka cited in his communications on social media and to retailers specifically named Dreamland and its products. *See*, *e.g.*, Retraction Request at 9, 10, 13, Attachment 4 at 1; *see also* 16 C.F.R. § 1101.13 (the public is able to readily ascertain the identity of a manufacturer or private labeler "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").

132. The truth of this was evidenced by the fact that multiple news outlets contacted Dreamland shortly after Commissioner Trumka's statements and actions were made public. *See*, *e.g.*, Joe Hernandez, *Amazon, Target and other retailers pull weighted infant sleepwear over safety fears*, NPR (May 7, 2024 2:07 PM ET), https://www.npr.org/2024/05/02/1248194639/weighted-infant-sleepwear-amazon-target-safety; Jeremey Tanner, *Amazon, Walmart and others no longer sell weighted infant sleepwear over safety concerns*, NEXSTAR (May 3, 2024 08:23 PM EDT), https://fox8.com/news/amazon-walmart-and-others-no-longer-sell-weighted-infant-sleepwear-over-safety-concerns/.

133. The Commission's determination repeats the same errors regarding Commissioner Trumka's statements and posts as the Commission's Retraction Response regarding the CPSC's safe sleep guidance.

134. Their determination, for the first time, officially confirmed that Commissioner Trumka "acted in his own capacity[.]" Exhibit 6.

135. Commissioners Peter A. Feldman and Douglas Dziak abstained from both votes and issued an independent statement regarding Dreamland's request. *See Statement of Commissioners Peter A. Feldman and Douglas Dziak on the Retraction of Infant Sleep Products Statements* (Aug. 30, 2024) (attached as Exhibit 7).

136. In their statement they noted that "the process in this matter was inadequate to develop the necessary factual record" because it provided no "opportunity for parties to rebut assertions" or "for commissioners to ask questions, weigh evidence, or deliberate as a body." *Id.*

137. They also expressed concern that, absent a developed factual record, the relief sought by Dreamland—full public retractions of the violative statements "'in a manner' equivalent to the original method of dissemination" as contemplated under 16 C.F.R. § 1101.52(c)(4)—could create bad "precedent" within the agency. *Id.*

138. They closed by noting that Dreamland "is not without additional recourse." *Id.* They expressed their view that "the publication of the statements constitutes final agency action" and "that the relief sought is best obtained through an Article III court." *Id.*

139. On information and belief, Commissioner Trumka's statements and social media posts were not reviewed under the Commission's clearance process. *See* Exhibit 4 at 8 ("Section 6(d)(2) of the CPSA provides that the provisions of Section 6(b) (which include section 6(b)(6)) shall apply whenever information is to be disclosed by the Commission or any member of the

Commission. Therefore, Commissioners are urged to refer statements they and their staffs make to appropriate Offices/Directorates for technical, program and legal review.").

140. None of Commissioner Trumka's statements included a disclaimer indicating that the statements and communications were solely his views, and that they are not necessarily representative of the Commission's perspective.

141. In response to media inquiries about Commissioner Trumka's actions regarding weighted infant sleep products, the CPSC has recently said, "Commissioner Trumka's activities in this matter were conducted in his individual capacity as a member of the Commission, and not on behalf of the Commission itself." Andrew Mark Miller, *Immigrant business owner blasts 'anti-science' Biden admin push that crippled her sales: 'Devastating'*, FoxNews.com (Oct. 22, 2024, 5:42 PM), https://www.foxnews.com/politics/immigrant-business-owner-blasts-anti-science-biden-admin-push-that-crippled-her-sales-devastating.

142. This statement is consistent with recent modifications to Commissioner Trumka's signature, that appear to have been made *after* Dreamland sent its retraction letter. For example, statements from Commissioner Trumka that were published before July 23, 2024, ended with the self-appointed title of "Your consumer advocate at the Consumer Product Safety Commission." *See*, *supra*, Comm'r Trumka, Statement, *Beware: Weighted Infant Swaddles and Blankets Are Unsafe for Sleep; Retailers Should Consider Stopping Sales*.

143. His public statements since Dreamland's July 23 retraction request have dropped the title and included a disclaimer stating that: "The views expressed in this statement are solely the views of Commissioner Trumka and do not necessarily reflect the views of the Commission." *See*, *e.g.*, Comm'r Trumka, Statement, *Commissioner Trumka Praises CPSC's Approval of Proposed Aerosol Dusters Rule to Prevent Over 100 Deaths Per Year*, CPSC (Aug. 13, 2024),

https://www.cpsc.gov/About-CPSC/Commissioner/Richard-Trumka/Statement/Commissioner-Trumka-Praises-CPSCs-Approval-of-Proposed-Aerosol-Dusters-Rule-to-Prevent-Over-100-Deaths-Per-Year.

144. On information and belief, no such clarification was made to the retailers to whom Commissioner Trumka sent his letters and the statements continue to exist in their original form on CPSC's website.

CLAIMS FOR RELIEF

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

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

146. The APA provides for review of "final" agency actions, 5 U.S.C. § 704, and requires courts to "hold unlawful and set aside agency action … found to be ... in excess of statutory jurisdiction, authority, or limitations, or short of statutory right[.]" 5 U.S.C. § 706(2)(C).

147. Section 6(b) of the CPSA, 15 U.S.C. § 2055(b)(6), 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." Those procedures are included in Directive 1450.2, *see* Exhibit 4.

148. The decision to publish the Safe Sleep Guidance regarding weighted infant sleep products is a final agency action under the APA. *See Doe v. Tenenbaum*, 127 F. Supp. 3d 426, 465 (D. Md. 2012) ("the [CPSC's] decision to publish the report of harm constitutes final agency action under the APA"), *rev'd on other grounds sub nom. Co. Doe v. Pub. Citizen*, 749 F.3d 246 (4th Cir. 2014).

149. "Administrative agencies are creatures of statue" and "[t]hey accordingly possess only the authority that Congress has provided." *NFIB v. OSHA*, 595 U.S. 109, 117 (2022).

150. The CPSA provides the framework for determining whether consumer products are safe. CPSC is not free to promulgate mandatory safety standards or ban products at will. Rather, it must undertake rigorous data- and evidence-driven processes.

151. For example, before promulgating 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). 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)).

152. 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).

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

154. 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.

155. 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.

156. Accordingly, CPSC's Safe Sleep Guidance is a product safety determination that was made in "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.

157. Likewise, CPSC's 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)

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

159. An agency's published statements may constitute agency actions subject to judicial review. *Apter v. Dep't of Health & Hum. Servs.*, 80 F.4th 579, 590 (5th Cir. 2023) (noting that the APA broadly construes the term "rule" and includes statements made by agencies).

160. A plaintiff may "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).

161. 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*, 80 F.4th at 589–90.

162. Although the PHSA empowers HHS to develop, support, and maintain programs addressing sudden unexpected infant death and sudden unexpected death in childhood, HHS's statements, including those made by its subagencies, NIH and the CDC, regarding weighted sleep products were unauthorized by statute because the PHSA does not authorize HHS or its subagencies to determine the safety of consumer products, that power was granted to CPSC.

163. Accordingly, CDC's and NIH's actions determining the safety of weighted infant sleep products and directing parents and caregivers not to use weighted infant sleep products were *ultra vires*.

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

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

165. Common law *ultra vires* claims are available when the agency or its officials have "plainly and openly crossed a congressionally drawn line in the sand." *Fed. Express Corp. v. United States Dep't of Com.*, 39 F.4th 756, 765 (D.C. Cir. 2022).

166. Such claims are only available when a party is "unable to bring a traditional [APA] challenge." *Id.* at 763.

167. Here, Dreamland cannot bring a traditional APA challenge against Commissioner Trumka because, as the Commission recently clarified, he actions in regard to weighted infant

sleep products were conducted in his individual capacity as a member of the Commission, and not on behalf of the Commission itself. Thus, his actions do not constitute "agency action" and review is unavailable under the APA.

168. Through the CPSA, Congress plainly granted CPSC the power and authority to determine which consumer products are safe, and may be available for sale, so long as the Commission follows the statutorily delineated process. But CPSC took none of those steps 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.

169. Commissioner Trumka likewise exceeded his statutory authority under the CPSA through his statements, social media posts, and letters to retailers which repeated the same statutorily insufficient statements. *See Apter*, 80 F.4th at 595 (finding that "tweet-sized doses" of information beyond an agency's statutory authority permit a party to assert *ultra vires* claims against agencies and their officials).

170. Commissioner Trumka exceeded his authority under Section 6(b) of the CPSA, 15 U.S.C. § 2055(b), and its implementing regulations by publishing adverse statements about Dreamland's weighted infant sleep products, from which the public was readily able to ascertain Dreamland's identity without providing advance notice and the opportunity for the company to respond.

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

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

172. The APA provides for review of "final" agency actions, 5 U.S.C. § 704, and requires courts to "hold unlawful and set aside agency action, findings, and conclusions found to be ... arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 5 U.S.C. § 706(2)(A).

173. Just as agencies are bound by the congressionally-delegated authority provided to them by statute, they are also bound by the regulations that they choose to promulgate. *See Nat'l Ass'n of Home Builders v. Norton*, 340 F.3d 835, 852 (9th Cir. 2003) (agencies must follow their own promulgated policies); *Steenholdt v. FAA*, 314 F.3d 633, 639 (D.C. Cir. 2003) (noting that federal agencies must follow their own rules); *see also United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260 (1954).

174. 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).

175. 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).

176. CPSC did not follow any of the required procedures or conduct any analysis before publishing its Safe Sleep Guidance regarding weighted infant sleep products.

177. On August 29, 2024, "the Commission voted 3-0-2 … to take other action and deny retraction of the CPSC statement and approve [a letter]" providing reasons for denying Dreamland's request. Exhibit 2 at 1.

178. As to Dreamland's request regarding Commissioner Trumka's statements "the Commission voted 2-0-2" and did not reach a majority. *Id.* As a result, no action was taken regarding those statements. *Id.*

179. Both votes also constitute final agency action.

180. CPSC justified its determination that weighted blankets and swaddles are unsafe for infant sleep by relying on the recommendations put forth by CDC and NIH. Exhibit 3 at 2, 3.

181. But as discussed, those agencies were not congressionally empowered to make such determinations, and in fact reached their own conclusions based solely on the determination of the AAP, a non-governmental organization that does not purport to follow any of the processes that the CPSA requires and explicitly relied on a lack of evidence rather than evidence that the products are unsafe.

182. CDC's and NIH's actions warning against the use of weighted infant sleep products are not the product of agency expertise. Rather, they reflect the blind adoption of the AAP's unsubstantiated and statutorily unconstrained recommendations.

183. CPSC has provided no data or evidence to substantiate its determination. In fact, its explanation runs counter to the evidence it has in its possession, directly undermining any reliance on CDC's and NIH's recommendations.

184. Nor is its explanation saved by the fact that the CDC and NIH statements were made as part of the Safe to Sleep® campaign. *Id.* at 3. Nothing in the PHSA authorizes CDC or NIH to make determinations about the safety of a consumer product.

185. CPSC's decision to publish and its refusal to retract its Safe Sleep Guidance regarding weighted infant sleep products were unreasonable, arbitrary, capricious, and not in accordance with law.

186. Moreover, the Commission completely failed to consider the fact that neither CDC nor NIH are empowered to make consumer product safety determinations as they did here.

187. Likewise, its refusal to act with respect to Commissioner Trumka's statements—which are still posted on the CPSC's website—is similarly unreasonable, unjustified and therefore arbitrary and capricious, as well as not in accordance with law.

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

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

189. The APA provides for review of "final" agency actions, 5 U.S.C. § 704, and requires courts to "hold unlawful and set aside agency action, findings, and conclusions found to be ... without observance of procedure required by law[.]" 5 U.S.C. § 706(2)(D).

190. CPSC violated the APA because it did not follow the CPSA or its own regulations and internal procedures when it approved and published its Safe Sleep Guidance regarding weighted infant sleep products.

191. Moreover, CPSC's clearance processes for "Joint Projects" like the Safe to Sleep® Campaign required it to review NIH's statements before NIH made them. But there is nothing in the public record suggesting that NIH's statement was cleared by CPSC.

192. CPSC also violated the APA because it did not follow the CPSA or its own regulations and internal procedures when it rejected Dreamland's request to remove its Safe Sleep Guidance regarding weighted infant sleep products.

193. Additionally, CPSC violated the APA because it did not follow the CPSA or its own regulations and internal procedures when it rejected Dreamland's request to remove Commissioner Trumka's challenged statements.

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

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

195. 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.

196. The Fifth Amendment to the Constitution provides that "[n]o person shall … be deprived of life, liberty, or property, without due process of law[.]" U.S. CONST. AMEND. V.

197. The Fifth Amendment guarantees "[a] fair trial in a fair tribunal" which is a "basic requirement of due process." *In re Murchison*, 349 U.S. 133, 136 (1955).

198. "Fairness" requires the "absence of actual bias." *Id.*

199. The necessity of a fair tribunal "applies to administrative agencies which adjudicate as well as to courts." *Withrow v. Larkin*, 421 U.S. 35, 46 (1975); *see also Masterpiece Cakeshop, v. Colo. Civil Rights Comm'n*, 584 U.S. 617, 634 (2018) (holding that agency adjudication proceedings must provide "neutral and respectful consideration" of a litigant's views free from hostility or bias); *id.* at 643 (Kagan, J., concurring) (agreeing that the Constitution forbids agency or judicial proceedings that are "infected by … bias").

200. Bias can take many forms, including "prejudgment," or the appearance of such by, agency commissioners. *Zen Magnets, LLC v. CPSC*, 968 F.3d 1156, 1168 (10th Cir. 2020).

201. But even statements within "the course of an authorized proceeding … may reflect prejudgment or its appearance." *Id.* at 1171.

202. As a leading administrative law treatise has observed, "[i]t is conceivable that a decisionmaker can form an opinion of a party so extreme that it renders the decisionmaker impermissibly biased." Kristin E. Hickman & Richard J. Pierce, Jr., *Administrative Law Treatise* § 7.7, at 868 (6th ed. 2019); *see Zen Magnets*, 968 F.3d at 1171 (quoting same).

203. It is obvious that Commissioner Trumka has formed an opinion of Dreamland's weighted infant sleep products that renders him impermissibly biased. Commissioner Trumka's statements and letters to retailers make clear that he has already decided that these products are unsafe and should not be available for sale. That decision runs counter to the CPSC's own data.

204. The evidence available also suggests that, because his amendment was rejected, Commissioner Trumka took an end run around the CPSA, and writing to retailers and causing them to stop the sale of Dreamland's weighted infant sleep products.

205. The test for impermissible bias, that violates a regulated party's constitutional right to due process of law, is a question of both "context" and "content." *Zen Magnets*, 968 F.3d at 1171.

206. That test is easily satisfied here. Commissioner Trumka has consistently and repeatedly made inaccurate and misleading statements about weighted infant sleep products. He also abused his position as CPSC Commissioner to write to retailers about weighted infant sleep products, and misleadingly and inaccurately suggested that the products were dangerous when the Commission's evidence does not support that conclusion. It is obvious from his statements and actions that he has clearly formed a strong negative impression of this class of products and is incapable of an unbiased consideration of actions affecting these products in the future.

Count Seven
Violation of Separation of Powers
(Against CPSC)

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

208. The operative questions for determining the constitutionality of removal protections for "Officers of the United States" are (1) whether the officer is a principal, as opposed to inferior; and (2) whether the agency "wields significant executive power." *Seila Law LLC v. CFPB*, 591 U.S. 197, 204 (2020). If the answers to both of those questions are "yes," the President must be able to fire the agency heads at will.

209. The CPSC's Commissioners are principal officers of the United States.

210. The CPSC plainly "wields significant executive power." Indeed, the CPSC has an arsenal of executive powers, many of which closely resemble the classic examples of executive power detailed in the Supreme Court's *Seila Law* decision. For example:

a. The CPSC can unilaterally conduct administrative hearings, 15 U.S.C. § 2064(f), *see also Seila Law*, 591 U.S. at 200, 207;

b. The CPSC can issue rules interpreting its enabling statues, 15 U.S.C. § 2051, *see also Seila Law* LLC, 591 U.S. at 200, 218; and

c. The CPSC can seek to impose significant monetary penalties against regulated parties, 15 U.S.C. § 2069, *see also Seila Law*, 591 U.S. at 219.

211. Because CPSC's Commissioners are "principal" officers who serve as the head of an agency that "wields significant executive power," Congress cannot constitutionally provide for-cause removal protections for the Commission's members. But that is exactly what Congress did in 15 U.S.C. § 2053(a), which provides that the President may only remove a Commissioner for "neglect of duty or malfeasance in office but for no other cause."

RELIEF REQUESTED

WHEREFORE, Plaintiff respectfully requests the following relief:

a. A declaration finding unlawful and setting aside the CPSC's product safety determination regarding weighted infant sleep products because it was made in excess of its statutory authority, was arbitrary and capricious, and was made without observance of the procedures required by law.

b. A declaration finding unlawful and setting aside the CPSC's refusal to retract its product safety determination regarding weighted infant sleep products because it was made in excess of its statutory authority, was arbitrary and capricious, and was made without observance of the procedures required by law.

c. A declaration finding unlawful and setting aside the CPSC's decision to take no action regarding Commissioner Trumka's statements because that determination was made in excess of its statutory authority, was arbitrary and capricious, and was made without observance of the procedures required by law.

d. A declaration finding that HHS, CDC, and NIH acted beyond their statutory powers or authority when they took the actions described above actions determining the safety of weighted infant sleep products and directing parents and caregivers not to use weighted infant sleep products.

e. A declaration finding that Commissioner Trumka acted beyond his statutory power or authority when he made statements regarding the safety of weighted infant sleep products and wrote to retailers and urged them to stop selling weighted infant sleep products.

f. A permanent injunction enjoining Defendants actions determining the safety of weighted infant sleep products and directing parents and caregivers not to use weighted infant sleep products without following the processes set forth by the CPSA.

g. A declaration that Commissioner Trumka's actions have established that he is impermissibly biased against the class of weighted infant sleep products, including Dreamland's products, in violation of the Fifth Amendment's Due Process Clause.

h. A permanent injunction enjoining Commissioner Trumka from participating in any future CPSC actions, including votes, regarding Dreamland's weighted infant sleep products and the class of weighted infant sleep products generally.

i. A declaration that the Commissioners' statutory removal protections violate Article II of the Constitution.

j. An award for all reasonable attorneys' fees and costs incurred herein and that Plaintiff may be entitled to under law.

k. Such other relief as this Court deems just and proper.

Dated this 19th day of November 2024.

Respectfully submitted,

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