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. 1:25-cv-00389-RGA **PLAINTIFF'S MEMORANDUM IN SUPPORT OF RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS**

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NATURE AND STAGE OF THE PROCEEDINGS

In March 2025, Nested Bean commenced this lawsuit, then Defendants moved to dismiss. On October 20, 2025, Nested Bean filed a verified First Amended Complaint asserting (a) three Administrative Procedure Act ("APA") claims and a direct claim under the Consumer Product Safety Act ("CPSA") against the Consumer Product Safety Commission ("CPSC" or "Commission"); (b) an *ultra vires* claim, a due process claim, and a direct claim under the CPSA against former CPSC Commissioner Richard Trumka; (c) a constitutional challenge to the CPSA; and (d) two APA claims and an *ultra vires* claim against the U.S. Department of Health and Human Services ("HHS"), the Centers for Disease Control and Prevention ("CDC"), and the National Institutes of Health ("NIH"). The Amended Complaint also names as Defendants eight individuals who serve or served at CPSC, HHS, CDC, or NIH. On December 19, 2025, Defendants moved to dismiss the Amended Complaint under Federal Rules of Civil Procedure 12(b)(1) and (b)(6).

SUMMARY OF THE ARGUMENT

1. Defendants' Motion to Dismiss Counts I, IV, V, VIII, and IX fails as Plaintiff has plausibly alleged that the Safe to Sleep®[1] guidance published by the CPSC, CDC, and NIH, advising the public to not use weighted infant sleep products, is a final agency action subject to APA review as either a rule or agency action as defined under 5 U.S.C. § 551(4) and (13).

2. Defendants' Motion to Dismiss Counts I and VIII fails as Plaintiff has plausibly alleged that the CPSC's decision to not grant Nested Bean's retraction request was a final agency action subject to APA review as agency action because it was the consummation of the agency's decision-making process.

3. Defendants' Motion to Dismiss Counts I and IX fails as Plaintiff has plausibly

[1] *See* https://safetosleep.nichd.nih.gov/campaign (last visited Jan. 29, 2026).

alleged that the CPSC exceeded its authority and ignored required procedures when it decided to (a) publish the Safe to Sleep® advising against "weighted" infant sleep products, (b) decided to not retract the same guidance, and (c) decided to not retract Trumka's statements.

4. Defendants' Motion to Dismiss Counts V and VIII fails as Plaintiff has plausibly alleged that the CPSC, NIH, and CDC acted arbitrarily and capriciously when it adopted the Safe to Sleep® advising against "weighted" infant sleep products because they failed to engage in reasoned decision making, consider relevant data, cite evidence supporting the conclusions, and explain inconsistent positions.

5. Defendants' Motion to Dismiss Count IV fails as Plaintiff has plausibly pled that HHS, CDC, and NIH exceeded their statutory authority under the Public Health Service Act ("PHSA") because that statute does not authorize them to declare consumer products unsafe or issue warnings of the type published in Safe to Sleep®.

6. Defendants' Motion to Dismiss Count III fails as Plaintiff has plausibly alleged that HHS, CDC, and NIH acted *ultra vires* when they published the Safe to Sleep® advising the public to not use "weighted" infant sleep products.

7. Defendants' Motion to Dismiss Count VI fails as Plaintiff has plausibly alleged that Trumka acted *ultra vires* when he issued statements to the public and letters to retailers advising against the use and sale of "weighted" infant sleep products because the CPSA does not authorize individual commissioners to publicly opine on the safety of consumer products without full commission action and adherence to the required procedures.

8. Defendants' Motion to Dismiss Counts II and VII fails as Plaintiff has plausibly alleged legally cognizable claims for Section 6(b) violations against the CPSC and Trumka.

9. Defendants' Motion to Dismiss Count X fails as Plaintiff has plausibly alleged that

this Court has subject matter jurisdiction over the due process violation.

10. Defendants' Motion to Dismiss Count XI fails as Plaintiff has plausibly alleged that CPSA's removal protections have harmed Nested Bean.

STATEMENT OF FACTS

I. Statutory/Regulatory Background

A. CPSA and The Consumer Product Safety Commission

Congress enacted the CPSA to establish a regulatory framework for addressing concerns about product safety. D.I. 30 ¶ 34. The CPSA tasks the CPSC with protecting the public from unsafe consumer products and streamlining related regulations. *Id.* ¶ 35. The Act authorizes the Commission to fulfill its mission in a variety of ways, including by promulgating safety standards. *See id.* ¶ 34; 15 U.S.C. §§ 2054, 2056, 2061, 2064. These standards "shall be reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product." 15 U.S.C. § 2056(a); D.I. 30 ¶ 38. And the Commission must follow the procedures set forth in the CPSA and the APA. D.I. 30 ¶ 37; *see generally Window Covering Mfrs. Ass'n v. CPSC*, 82 F.4th 1273, 1286 (D.C. Cir. 2023). Specifically, before it can promulgate a binding rule, the CPSC must make several determinations, all backed by evidence and data. For example, it 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); D.I. 30 ¶ 39.

In addition to governing the Commission's regulatory authority, the CPSA limits how the Commission, individual Commissioners, and staff may publicly discuss consumer products. *See* 15 U.S.C. § 2055; D.I. 30 ¶ 45. Under Section 6(b)(1) of the CPSA, 15 U.S.C. § 2055(b)(1), which pertains to product information from which the manufacturer's or private labeler's identity may be ascertained, the Commission 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].” Notice to the relevant business and an opportunity to comment before such disclosures are made public are also required. 15 U.S.C. § 2055(b)(1); D.I. 30 ¶ 48. Even when a disclosure would not allow the public to readily ascertain a manufacturer’s identity, the Commission must establish procedures (known as “Clearance Procedures”) to ensure the information is “accurate and not misleading.” 15 U.S.C. § 2055(b)(6); D.I. 30 ¶ 53. Accordingly, any “inaccurate or misleading” public disclosures that “reflect[] adversely upon the safety of any consumer product or class of consumer products” are subject to retraction “in a manner equivalent to that in which such disclosure[s] w[ere] made[.]” 15 U.S.C. § 2055(b)(7); D.I. 30 ¶ 52. The Commission has promulgated rules to implement the CPSC’s public-disclosure requirements. These regulations specify the information to which § 2055(b)(1)’s “notice and analysis provisions” apply[2]; when information makes a manufacturer’s identity readily ascertainable[3]; which actions are presumptively “reasonable” for purposes of assuring the accuracy of information[4]; and which efforts by the CPSC will presumptively satisfy the CPSA’s requirement that disclosure be “fair”[5].

In addition, a CPSC Directive identifies the Clearance Procedures needed to ensure that publicly disclosed information is accurate, not misleading, and in accordance with the CPSA. *See* CPSC Directive 1450.2.4[6]; D.I. 30 ¶ 53. “No information shall be disclosed until approved as set out in this directive,” which “appl[ies] to any release of information initiated by the Commission, including information disseminated on the agency’s website.” *Id.* at (1)(a), (2). The Directive applies “Commission-wide, to all employees, agents, and representatives” whenever information

[2] 16 C.F.R. § 1101.11; D.I. 30 ¶ 46.
[3] 16 C.F.R. § 1101.13; D.I. 30 ¶ 47.
[4] 16 C.F.R. § 1101.32.
[5] 16 C.F.R. § 1101.33.
[6] Clearance Procedures For Providing Information To The Public Directives, https://www.cpsc.gov/About-CPSC/Policies-Statements-and-Directives/Clearance-Procedures-For-Providing-Information-To-The-Public-Directives (Jan. 16, 2003).

"that reflects on the safety of consumer products" is published. *Id.* The Clearance Procedures also require disclaimers for "all outside publications in which an employee uses his or her official title or states an affiliation with the Commission." *Id.* at (7)(f)(2)(b); D.I. 30 ¶ 59.

B. Advancing Standards Transforming Markets

The Advancing Standards Transforming Markets ("ASTM") is a private organization that develops technical standards for a wide range of products, materials, systems, and services. D.I. 30 ¶ 60. CPSC has long worked with ASTM to create voluntary standards for emerging hazards. *Id*. While ASTM has a subcommittee on Infant Bedding, it has not reached a consensus on a definition or voluntary product standard for "weighted" infant sleep products. D.I. 30 ¶¶ 61, 63.

C. The Public Health Service Act

The PHSA generally permits 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); D.I. 30 ¶ 64. This Act also requires the Secretary to conduct certain activities, including data collection and public education about "sudden unexpected infant death and sudden unexplained death in childhood[.]" 42 U.S.C. § 300c-13; D.I. 30 ¶ 186.

II. Factual Background

A. Safe to Sleep Guidance

Sometime in 2022–23, the NIH and CDC, through the Safe to Sleep® campaign, revised their policies and adopted the American Academy of Pediatrics ("AAP") position that "weighted" infant sleep products are not safe. D.I. 30 ¶ 82–83. They thus discouraged the use of these undefined and uncategorized products. D.I. 30 ¶ 82. The CDC website states: "Products labeled as weighted—including weighted sleepers, swaddles, sleep sacks, and blankets—are **not safe** for infants." *Id.* ¶ 84. It cites no research or scientific studies to support this statement. *Id.* Rather, it cites the AAP webpage which, in turn, cites an AAP 2022 Technical Report. *Id.*; Exhibit 1, AAP

2022 Technical Report. That Report cites only a single 2020 study that **did not recommend against the use of weighted sleepwear**. D.I. 30, Ex. 1 at 20, 27, and n.327. Indeed, that lone study (hereinafter "2020 NICU Study") identified zero adverse events. D.I. 30, Exhibit 2, 2020 NICU Study at 5–6. And its "initial findings [were] that **weighted blankets may be beneficial** …." *Id.* at 7 (emphasis added). Nonetheless, the AAP recommended against using these products due to a lack of data *proving their safety*. D.I. 30 ¶ 85; Ex. 1 at 20. Likewise, the NIH Safe to Sleep® website states that "[t]hings in the sleep area can pose dangers for baby, especially if they are …. [w]eighted (e.g. weighted blankets, weighted swaddles)." D.I. 30 ¶ 86. Again, the only citation is to the AAP's "technical report" misinterpreting the 2020 NICU Study. *Id.* The NIH repeated this negligence in its Frequently Asked Questions section. *Id.* ¶ 87.

B. ASTM and CPSC 2023 Developments

Around March 2022, the ASTM subcommittee on Infant Bedding set out to provide performance standards for wearable sleep products (regardless of weight) to help address a potential suffocation hazard. *Id.* ¶ 95. Then, in early 2023, the compliance branch of the CPSC conducted a review of Nested Bean's products to assess their risk of suffocation. *Id.* ¶ 96. The Office of Compliance found no identifiable hazard patterns related to this risk, similar to the conclusion in the 2020 NICU Study, and, accordingly, sent Nested Bean a closing letter stating no further action was warranted. *Id.* ¶ 96, Ex. 3. In other words, the CPSC's own review of Nested Bean's products showed no identifiable hazard related to suffocation. In May 2023, CPSC staff gave the ASTM subcommittee years of reported incident data so it could draft proposed performance requirements to address the hazard patterns in the incident data. D.I. 30 ¶ 97. That October, the subcommittee submitted a draft voluntary standard that included safety-enhancing performance requirements across all wearable sleep products. *Id.* ¶ 99. CPSC staff provided comments to the ASTM subcommittee on this proposal. *Id.* On October 11, 2023, during a CPSC

meeting to discuss the 2024 fiscal year operating plan, CPSC's Ex-Executive Director Jason K. Levine confirmed that CPSC staff wanted to include a "weighted infant sleep products" category in the broader ASTM voluntary standard being developed for all "wearable infant sleep products." *Id.* ¶ 100. He noted CPSC's interest in crafting a consensus definition for "weighted" products, adding that CPSC staff took no position on AAP's weighted products recommendation since all sleep products have some weight. *Id.* On November 8, 2023, the CPSC convened an internal meeting during which Commissioner Trumka proposed to require CPSC "staff to initiate rulemaking and issue a proposed rule to address risks associated with weighted [sic] infant blankets, sleepers, and swaddles" in order to align the Commission's Safe to Sleep guidance with that of the CDC and NIH. *Id.* ¶ 101. The Commission rejected Commissioner Trumka's proposal in a 3-1 vote. *Id.* ¶ 102. In rejecting the proposal, then-Chairman Hoehn-Saric explained "[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." *Id.* Then-Commissioners Boyle and Feldman (now Chair) agreed that rulemaking "at this time [was] premature." *Id.* On November 16, 2023, CPSC staff reviewed the ASTM subcommittee's Draft Voluntary Standards and provided additional feedback. *Id.* ¶ 103, Ex. 5. The Staff favored keeping "weighted" products within scope of the standard because adopting performance requirements, test methods, and labeling requirements for "weighted" products is an improvement in safety. But they rejected the draft standard without a requirement for specific minimum and maximum amounts of added weight. Staff was concerned that without these limits, "a manufacturer could sell a wearable blanket or swaddle with an extremely heavy weight in it[.]" *Id.* CPSC staff encouraged ASTM members to

conduct and share any research on "weighted" products. *Id.* Also included in this feedback was a CPSC-staff market survey. *Id.* ¶ 104, Ex. 5. Staff noted that due to the "lack of publicly available research" about a maximum allowable weight, weight concentrations across products (whether marketed as weighted or not) differed drastically, with some products distributing the weight throughout the product and others concentrating it in a specific area. *Id.* Staff also observed that many "non-weighted" products weighed as much as, or more than, some products marketed as "weighted." *Id.* While not explicitly stated in the market survey, Nested Bean's products fell in the 25th–55th percentile for total weight among the 108 products considered. *Id.* ¶ 105. Notably, they were (and remain) much lighter than many products that, although not marketed as "weighted," contained filling meant to add warmth, thus adding significantly more mass/weight to the base product. *See id.* ¶ 105, Ex. 5. CPSC staff accordingly voted against the Draft Voluntary Standard. *See id.* ¶ 106, Ex. 5.

C. CPSC Safe to Sleep Guidance

Sometime after the CPSC meeting in which Commissioners rejected as "premature" Commissioner Trumka's proposed rulemaking for "weighted" infant products, the CPSC modified its Safe to Sleep® guidelines to recommend that the public not use "weighted" infant blankets and swaddles. *Id.* ¶ 107. These guidelines, which remain on the CPSC's website, state: "**Don't use weighted blankets or weighted swaddles***." *Id.* The CPSC deflects responsibility by adding the caveat, in a footnote, that "*This guidance is based on information from the [CDC] and the [NIH]." *Id.* In other words, consistent with then-Chair Hoehn-Saric's statement at the Commission's November 8, 2023 meeting, the CPSC admits that it had not (and still has not) conducted its own research or made its own determinations as to the safety of these products.

D. Commissioner Trumka's Vendetta Against Nested Bean

Disregarding the absence of voluntary or mandatory standards, product category

definitions, or product ban, stop sale, or recall, and even though the Commission determined that it lacked the necessary data to propose a mandatory standard for (undefined) "weighted" infant sleepwear, Commissioner Trumka pursued a methodical negative publicity campaign against "weighted" infant sleep products. On January 22, 2024, Commissioner Trumka wrote to Nested Bean and demanded production, within two weeks, of exhaustive information about its product and compliance. *Id.* ¶ 109. He did not inform Nested Bean that he was going to publish statements about the purported category of "weighted" infant sleep products, the safety of these types of products, and Nested Bean itself. *Id*.

1. January 26, 2024 Statements

But before Nested Bean could respond, and only four days after sending the letter, Commissioner Trumka used his official CPSC X account (formerly Twitter)—@TrumkaCPSC—to link to a *Washington Post* article naming Nested Bean in the second sentence. *Id.* ¶ 110, Exhibit 6, *Washington Post* Article. Trumka's post claimed that CPSC is "in agreement" with CDC, NIH, and the AAP that "weighted" infant sleep products "pose serious threats to the lives of babies" and warned the public: "Do NOT use them for sleep." *Id*. Nested Bean quickly responded to Trumka's letter, explaining its unblemished safety record, product-development research and test results, and involvement in the ASTM voluntary standards process. *Id.* ¶ 111. Nested Bean included studies it used for product design and stated its ongoing willingness to share information about its products and meet with Commissioner Trumka. *Id*.

2. April 15, 2024 Statements

Ignoring Nested Bean's offer to meet, Commissioner Trumka sent letters on official CPSC letterhead to seven major retailers. *Id.* ¶ 112, Ex. 7–10. He again cited the *Washington Post* article naming Nested Bean and said "multiple infant deaths" had been linked to "weighted" sleepwear products. *See Id.* ¶ 112, Ex. 6. That same day, Commissioner Trumka posted videos on his official

CPSC X and Instagram accounts, each with a caption stating "Do NOT – I repeat – do NOT put any weighted [sic] swaddles or blankets on your baby. Companies will try to fool you into thinking they're safe, but there's a reason @USCPSC, @CDC, & @NIH have warned you NOT to use them. It's a risk of death to your baby." *Id.* ¶ 113.

CPSC itself posted Trumka's statement (which again cited the *Washington Post* article) on its website. *Id.* ¶ 115, Ex. 6, 11. According to this statement, the "CPSC has a clear warning for safe infant sleep: **Don't** use weighted [sic] blankets or weighted [sic] swaddles for your babies." D.I. 30, Ex. 11. Trumka's statement also alleged, without any citation, 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***" because "[w]e have the power to stop sales" and "take precautions today." *Id.* (emphasis added). This statement—which remains live on CPSC's official website—contains a link to Trumka's April 15, 2024 video on X. Commissioner Trumka signed his statement, "Your consumer advocate at the Consumer Product Safety Commission." *Id.*

Just a few days later, April 19, 2024, representatives from Target emailed Nested Bean in response to "the new CPSC warning that was issued about weighted [sic] swaddles this week," expressly referencing Commissioner Trumka's April 15th statement. *Id.* ¶ 116. They asked Nested Bean for a meeting to discuss the safety of its products "based on" the statement. *Id.* On April 25, 2024, after a Zoom meeting with Nested Bean, Target informed Nested Bean that "after much internal review" it would no longer sell *any* Nested Bean product and would remove the products from its stores and online by the end of the week. *Id.* ¶ 118. In the days immediately leading up to Nested Bean's meeting with Target—April 22, 23, and 25, 2024—Target had been meeting with Commissioner Trumka to discuss its response to his April 15th letter "recommending" Target stop selling "weighted" infant sleep products. *Id.* ¶ 117.

The day after Nested Bean's meeting with Target, Commissioner Trumka published additional official statements gloating about the "good news"—i.e., the harm he inflicted on Nested Bean's business. *Id.* ¶ 120, Ex. 12. It reads, in part, "On April 15, 2024, I wrote to major U.S. retailers informing them of the hazards weighted [sic] infant swaddles and blankets pose to babies, and asking them to consider whether they want to continue selling such products. I am pleased to announce that Target, Walmart, Nordstrom, and Babylist quickly responded by sharing that they will cease sales of weighted [sic] infant products," and "I expect to hear back from additional retailers soon." *Id*.

E. Harm Inflicted on Nested Bean by Defendants

Multiple major retailers stopped selling Nested Bean products in direct response to Defendants' actions and misleading statements; yet most retailers continued to sell brands of "weighted" infant sleep products not mentioned in Trumka's letters. *Id.* ¶¶ 122–123. Nested Bean's harm is significant: Just before Trumka's April 15th letter, Nested Bean had been awarded an expanded footprint across over 1,200 Target stores. *Id.* ¶ 118. It now has no inventory in any Target store. *Id.* By April 23, 2024, Amazon too stopped sales of *all* Nested Bean products and notified Nested Bean customers that CPSC had "warned that these products should not be considered safe for use by children and babies." *Id.* ¶ 119. As a result, Nested Bean's sales have dropped more than 80%, and it was forced to lay off 93% of its workforce. *Id.* ¶ 124. This devastating decline has ruined Nested Bean's relationships in the retail industry, including several independent retailers that have likewise stopped carrying all Nested Bean products in their stores. *Id*.

F. Nested Bean Seeks Retraction of Statements

In November 2024, counsel for Nested Bean sent a letter to the Secretary of the Commission seeking a Section 6(b)(7) retraction of the inaccurate and misleading statements by Commissioner Trumka and by the CPSC itself. *Id.* ¶ 129. The Commission denied Nested Bean's

retraction request in a 0-1-1-2 vote the following month (Commissioner Trumka having recused himself). *Id.* ¶ 131. Zero commissioners voted for the retraction, one and one proposed separate courses of action, and two abstained. *Id.*

III. This Lawsuit

Nested Bean commenced this lawsuit in March 2025 and filed an Amended Complaint on October 20, 2025. D.I. 1, 30. Nested Bean asks this Court to declare the agencies' various statements unlawful, former Commissioner Trumka impermissibly biased, the removal protections unconstitutional; and to order the agencies to retract their statements and refrain from further statements about weighted infant sleep products. *Id.*, Prayer for Relief.

LEGAL STANDARD

Defendants filed a Motion to Dismiss the Amended Complaint for failure to state a claim (Rule 12(b)(6)) and for lack of subject matter jurisdiction (Rule 12(b)(1)). On a motion to dismiss for failure to state a claim, courts "are required to accept as true all allegations in the complaint and all reasonable inferences that can be drawn from them after construing them in the light most favorable to the non-movant." *Jordan v. Fox, Rothschild, O'Brien & Frankel*, 20 F.3d 1250, 1261 (3d Cir. 1994). "Moreover, a case should not be dismissed for failure to state a claim unless it clearly appears that no relief can be granted under any set of facts that could be proved consistently with the plaintiff's allegations." *Id*. "Further, '[t]he issue is not whether a plaintiff will ultimately prevail but whether he or she is entitled to offer evidence to support the claims.'"[7] "A facially plausible claim is one that permits a reasonable inference that the defendant is liable for the misconduct alleged."[8] A motion to dismiss under Rule 12(b)(1) for lack of subject-matter

[7] *Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007) (quoting *Oatway v. Am. Int'l Grp.,* 325 F.3d 184, 187 (3d Cir. 2003)).
[8] *Doe v. Univ. of the Scis.*, 961 F.3d 203, 208 (3d Cir. 2020) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

jurisdiction receives the same treatment as a motion under 12(b)(6) when it is a facial attack filed before Defendants have answered.[9] The alleged facts must be construed in favor of the nonmoving party.[10] Although the plaintiff bears the burden of establishing the elements of standing, "general factual allegations of injury resulting from the defendant's conduct may suffice."[11]

ARGUMENT

I. The Agencies' Actions Are Final Agency Action (Counts I, IV, V, VIII, IX)

Agencies cannot evade review of their actions by engaging in strategic behaviors to game the system. Thus, the Supreme Court recognizes the presumption of judicial review:

> The APA, by its terms, provides a right to judicial review of all "final agency action for which there is no other adequate remedy in a court," § 704, and applies universally "except to the extent that—(1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law," § 701(a).[12]

The publications of Safe to Sleep® by CPSC, NIH, and CDC, as well as the CPSC's refusal to grant Nested Bean's request to retract its statements about "weighted" products are final agency actions subject to review by this Court.

A. The Safe to Sleep® Statements of CPSC, CDC, and NIH Are Final Agency Action for Purposes of the APA

Defendants argue that the agencies' publications of Safe to Sleep® are not "agency action[s]" because they do not fall within the definition of that term in 5 U.S.C. § 551(13) and are

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[9] *See, e.g.*, *Askew v. Church of the Lord Jesus Christ*, 684 F.3d 413, 417 (3d Cir. 2012) ("As the defendants had not answered and the parties had not engaged in discovery, the first motion to dismiss was facial."); *Const. Party of Pa. v. Aichele*, 757 F.3d 347, 358 (3d Cir. 2014) ("The Commonwealth filed the attack before it filed any answer to the Complaint or otherwise presented competing facts. Its motion was therefore, by definition, a facial attack."); *Mortensen v. First Federal Sav. and Loan Ass'n*, 549 F.2d 884, 892 n.17 (3d Cir. 1977) ("A factual jurisdictional proceeding cannot occur until plaintiff's allegations have been controverted.").

[10] *See Const. Party of Pa.*, 757 F.3d at 358; *see also Mortensen,* 549 F.2d at 891 ("The facial attack does offer ... safeguards to the plaintiff: the court must consider the allegations of the complaint as true.").

[11] *Ballentine*, 486 F.3d at 810 (quoting *Lujan v. Defs. of Wildlife,* 504 U.S. 555, 561 (1992)).

[12] *Bennett v. Spear*, 520 U.S. 154, 175 (1997); *see also* 5 U.S.C. § 706.

not "final" because they do not satisfy *Bennett*'s two prongs for assessing the finality of agency action, 520 U.S. at 177–78. None of these arguments should prevail.

First, the agencies' publications of the Safe to Sleep® are "agency actions" under 5 U.S.C. § 551(13)—"the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act"—because they fit comfortably within the APA's broad definition of "rule" in 5 U.S.C. § 551(4). A "rule" under the APA "include[s] nearly every statement an agency may make."[13] And here, the agencies' publications of the Safe to Sleep® make clear statements about the agencies' general policy positions about "weighted" infant products as well as their treatment of them. Specifically, the disclosures emphasize the agencies' conclusions that such products are dangerous and not to be used and that the agencies have a role to play in educating the public about those conclusions. *See* D.I. ¶¶ 82–89, 107. The agencies' statements are consequently subject to judicial review as "rules" under the APA.[14]

Regardless, the agencies' publications of the Safe to Sleep® would still constitute "agency action" even if they were not "rules" because the categories enumerated in § 551(13) "are exemplary, not exhaustive[.]"[15] The government's suggestion to the contrary, *see* D.I. 39 at 9, is thus incorrect, and neither the text of § 551(13) nor this Court's interpretation of it supports such a restrictive view. Rather, courts have found agency actions to fall within the scope of judicial review despite not falling within the possibilities set out in § 551(13).[16] To interpret § 551(13)

[13] *Batterton v. Marshall*, 648 F.2d 694, 700 (D.C. Cir. 1980). *See also, e.g.*, *Dia Nav. Co., Ltd. v. Pomeroy*, 34 F.3d 1255, 1264 (3d Cir. 1994) (referencing the APA's "broad definition" of the term "rule").

[14] *See* 5 U.S.C. § 551(4) (defining "rule" to "mean[] the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe ... policy").

[15] *Gentile v. Sec. & Exch. Comm'n*, 974 F.3d 311, 317 (3d Cir. 2020).

[16] *See Gentile*, 974 F.3d at 317 n.10 (citing cases); *see also Student Loan Mktg. Ass'n v. Riley*, 104 F.3d 397, 405 (D.C. Cir. 1997), *on reh'g,* (Mar. 11, 1997) (letters from agency officials); *Nat. Res.*

narrowly, and contrary to its text, would also contradict the Supreme Court's observation that Congress defined "agency action" broadly so as "to assure the complete coverage of every form of agency power, proceeding, action, or inaction," and accordingly "includes the supporting procedures, findings, conclusions, or statements or reasons or basis for the action or inaction."[17] Defendants' approach also contradicts "the basic presumption of judicial review" for those aggrieved by agency action.[18]

Not only are the Safe to Sleep® publications "agency action[s]," but they are also "final." Generally, agency action must meet two conditions to be "final": (1) "the action must mark the 'consummation' of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature," and (2) "the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow'[.]" *Bennett*, 520 U.S. at 177–78 (internal citations omitted). In analyzing whether an alleged action meets these finality requirements, courts take a "pragmatic approach" over a formalistic one, meaning actions may be "final" given their practical effects, even if they do not themselves trigger enforcement actions[19] and even if they only warn about potential liability.[20] Were it otherwise, agencies could easily insulate substantively final actions from judicial review based on self-serving procedural technicalities.

Applying these finality principles here, the agencies' Safe to Sleep® publications are

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Def. Council, Inc. v. E.P.A., 22 F.3d 1125, 1132–33 (D.C. Cir. 1994) (intra-agency memo and letter); *Appalachian Power Co. v. E.P.A.*, 208 F.3d 1015, 1020–23 (D.C. Cir. 2000) (EPA guidance).

[17] *FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 238 n.7 (1980) (quoting S. Doc. No. 248, 79th Cong., 2d Sess., 255 (1946)).

[18] *Abbott Labs. v. Gardner*, 387 U.S. 136, 140 (1967) (quoting 5 U.S.C. § 702).

[19] *See U.S. Army Corps of Eng'rs v. Hawkes Co.*, 578 U.S. 590 (2016).

[20] *Frozen Food Express v. United States*, 351 U.S. 40, 44 (1956).

"final" actions. Taking the CPSC first, its publication of the Guidance "mark[s] the 'consummation' of the [CPSC's] decisionmaking process" concerning its obligations under the CPSA related to public disclosure of information. *Bennett*, 520 U.S. at 177–78. Specifically, the CPSA requires CPSC to "ensure," or at least "take reasonable steps to assure," that information it discloses to the public about the safety of a product is neither inaccurate nor misleading. 15 U.S.C. § 2055(b)(1), (6). By publicly disclosing product safety information—such as its statements about the safety of "weighted" infant sleep products—the CPSC necessarily represents that it has complied with its clearance procedures and determined the information is accurate and not misleading. There is nothing "tentative" or "interlocutory" about CPSC's decision to publicize the statements at issue because publication was the final result of CPSC's application of the CPSA's requirements to its publication decisions. Thus it meets the first *Bennett* prong.[21]

CPSC's publication also meets the second *Bennett* prong because it is an action "by which 'rights and obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett*, 520 U.S. at 177–78. For one, CPSC clearly determined its own rights and obligations in making the decision to publish in the first place; as discussed above, the CPSA and CPSC regulations oblige the CPSC to follow certain procedures and make a determination that publication will satisfy statutory requirements of accuracy before it may publish information about product safety. And while the government reads *Bennett* narrowly to apply only to the rights and

[21] *See* D.I. 30 at ¶ 131, *available at* https://tinyurl.com/4v2mmtht; *Doe v. Tenenbaum*, 127 F. Supp. 3d 426 (D. Md. 2012) (holding CPSC's publication of a report constitutes final agency action); *id.* at 460 (finding that CPSC's "decision to publish [a] report [of harm] marked the consummation of its decisionmaking process" because "the Commission evaluated the evidence, judged it against the CPSA and its concomitant regulations, and made a factual and legal 'determination' that the report contained no materially inaccurate information").

obligations of parties other than itself, that reading is not supported by the text.[22] Moreover, the consequence of publication was the vesting of Nested Bean's right to seek a retraction of that information under 16 C.F.R. § 1101.52(b) and 15 U.S.C. § 2055—a right of which Nested Bean subsequently took advantage. Were there any remaining doubt about the finality of the publications by CPSC, CDC, and NIH, Nested Bean further reiterates that their impact was "'sufficiently direct and immediate'" so as to have a "'direct effect on ... [Nested Bean's] day-to-day business.'"[23] As a result of the publications, Nested Bean almost immediately lost valuable business relationships with its retailers[24]—a drastic loss that continues to this day—and faced civil liability. [25]

The publication decisions by HHS, NIH, and the CDC are final agency actions for similar reasons. By publicizing consumer product safety information about "weighted" products, these agencies purported to act within their authority under the PHSA to educate the public about the sudden unexpected death of children. These actions are, accordingly, the final culmination of these agencies' determinations that publication about consumer products fell within their power under the PHSA. The same legal consequences set forth above—the mass delisting of Nested Bean's products—apply to these agencies' actions as well. The agencies' publications are final agency

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[22] *See Biden v. Texas*, 597 U.S. 785, 809 n.7 (2022) (assessing final agency action in terms of agency employees' obligations following the agency action at issue); *Doe*, 127 F. Supp. at 461 ("The Commission appears to construe [*Bennett*'s second prong] for the restrictive proposition that the decision must determine Plaintiff's rights or obligations, as opposed to the Commission's, for it to count as final. This self-serving interpretation runs counter to the literal language of *Bennett*.").

[23] *Franklin v. Mass.*, 505 U.S. 788, 796–97 (1992) (quoting *Abbott Labs.,* 387 U.S. at 152).

[24] *See* D.I. 30 ¶ 1. *See also Spirit Airlines, Inc. v. U.S. Dep't of Transp.*, 997 F.3d 1247, 1252 (D.C. Cir. 2021) ("We can see ... that an agency's action need not flatly prohibit a party from acting in order to affect its legal rights; it is enough that the agency action presently and directly limits or defeats a party's ability to enter into an advantageous business arrangement.").

[25] Relying solely on Defendants statements that "weighted" infant sleep products are unsafe, a class action was filed against Nested Bean. This Court can take judicial notice of the public record of the case *In re: Nested Bean, Inc. Weighted Sleep Products Litigation*, No. 1-24-cv-11299-JEK (D. Mass. 2024). *See U.S. ex rel. Travis v. Gilead Scis., Inc.*, 596 F. Supp. 3d 522, 536 (E.D. Pa. 2022) (citing Fed. R. Evid. 201(b)).

action subject to judicial review under the APA.

B. The CPSC's Decision Not to Grant Nested Bean's Retraction Request Is Final Agency Action (Counts I and VIII)

The government says the CPSC's decision not to grant Nested Bean's retraction request is not final agency action because the vote was "deadlocked" and because, even if it wasn't, a denial does not "'impose an obligation, deny a right, or fix some legal relationship.'"[26] These arguments, too, should fail. To start, there simply was no deadlock about whether Nested Bean's request for retraction should be granted; all Commissioners agreed it should not be granted. Moreover, the definition of "agency action" includes a "failure to act." 5 U.S.C. § 551(13). The government's protest that there is no final agency action because the Commission deadlocked on other issues thus misses the point. Its out-of-circuit authorities are similarly inapposite. What's more, this position defies common sense: a decision not to act is a decision. That is why parties can, for example, appeal a court's decision not to hear a matter, even if multiple judges sit on the court. And that is perhaps why courts have not always assumed that agency deadlocks preclude review.[27] In the end, the practical effect of a decision not to decide is often denial.[28] And given the "pragmatic" approach courts take to the finality analysis, *see supra* Section I, the CPSC's vote should not preclude review here even if this Court views it as a deadlocked one.

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[26] D.I. 39 at 13–14 (quoting *Aerosource, Inc. v. Slater*, 142 F.3d 572, 581 (3d Cir. 1998)).

[27] *See, e.g.*, *Democratic Cong. Campaign Comm. v. Fed. Election Comm'n*, 831 F.2d 1131, 1133 (D.C. Cir. 1987) ("Nothing in the text of the FECA's judicial review prescription precludes review of a dismissal due to a deadlock.").

[28] Additional evidence that the vote constituted final agency action as "the consummation of the agency's decisionmaking process," *Bennett*, 520 U.S. at 178, is the fact that the CPSC itself considered it final. *See* D.I. 30 at ¶131, available at https://tinyurl.com/4v2mmtht (stating that "no action will be taken on this matter"). *See also Minard Run Oil Co. v. U.S. Forest Serv.*, 670 F.3d 236, 247 (3d Cir. 2011) ("An agency determination of a particular issue that will not be reconsidered in subsequent agency proceedings may represent the consummation of the agency's decisionmaking process on that issue."). Even were CPSC to revisit its decision, that fact would not preclude finality at this stage because actions are final when they are issued, even if a new final action may be issued later. *See Biden v. Texas*, 597 U.S. at 808–09.

The government's alternative argument, that the CPSC's action would not be final agency action even if it were a denial by the Commission, is also not on point. The government relies on *Aerosource* for this proposition, 142 F.3d 572. But that case is not as applicable here as the government claims. The "actions" in *Aerosource* "concern[ed] nothing more than the issuance of advisory warnings and the FAA's refusal to withdraw the warnings predicated on its conclusion that it properly had issued them." *Id.* at 581. Significantly, *Aerosource* found that the advisory warnings "were not final orders because their conclusions were tentative and indicative of an on-going investigation." *Id.* at 579–80. Here, of course, the Safe to Sleep® concerning the supposed dangers of "weighted" infant products are conclusory on their face, and thus neither tentative nor indicative of any investigation. And unlike the FAA's orders declining to rescind the warnings in *Aerosource* or reconsider that decision, the CPSC's decision not to grant Nested Bean's retraction request was not based on any finding about the information in the Safe to Sleep® at all, much less a finding that any data support it. Regardless, even *Aerosource* noted that a denial of a request could constitute final action subject to review.[29]

The government's contention, that the CPSC's vote does not constitute agency action because it bears no legal consequences, also misses the mark. As discussed, courts have found that definitive agency actions affect legal rights when they impede parties' ability to enter business relationships. *See Spirit Airlines, Inc.*, 997 F.3d at 1252. That consequence has undoubtedly occurred in this case because retailers remain unwilling to carry Nested Bean's products because of CPSC's refusal to grant retraction. Had the CPSC granted Nested Bean's retraction request, Nested Bean would be able to sell its products through the major retailers that pulled the products

[29] *See id.* at 579 n.11 ("We are not implying that in no circumstance could a denial of a request for reconsideration of some action which, in itself, was not a final order not be a final order subject to judicial review.").

in response to the statements. Its denial thus "directly affect[ed]" Nested Bean. *Franklin*, 505 U.S. at 797. The CPSC's decision not to grant Nested Bean's retraction request—whether characterized as a denial or a "failure to act"—constituted a final determination of Nested Bean's right to retraction and the CPSC's obligation to remove the statements, which bore significant legal consequences for Nested Bean. It is therefore reviewable.

II. Nested Bean Has Plausibly Alleged That CPSC Exceeded Its Authority and Ignored Required Procedures (Counts I and IX)

The scope of CPSC's authority is limited to what is delegated by the terms of the CPSA. The CPSA does *not* provide the Commission discretion to adopt consumer product safety determinations made by other agencies without following the CPSA procedures and requirements. The Commission's authority is to protect against unreasonable risks of injury or death. The Safe to Sleep® guidance does not fall within this prescribed authority; CPSC did not take steps to ensure that the information it published was accurate and not misleading (15 U.S.C. § 2055), because if it had done so, it would not have published ill-defined, unfounded, and inaccurate information. Further, agencies are no longer entitled to *Chevron* deference as to their interpretation of their own authority; instead "[c]ourts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the APA requires" and "under the APA [courts] may not defer to an agency interpretation of the law simply because a statute is ambiguous."[30]

The CPSC must have failed to adequately adhere to the prescribed clearance procedures because **there is no scientific basis** for the claims made in Safe to Sleep®. The only research cited as the basis for the warnings is a single study that found weighted products were beneficial, not dangerous. D.I. 30 ¶ 85. To the extent CPSC seeks safe harbor in the presumption of regularity for

[30] *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412–13 (2024) (overruling *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984)).

its decisions, that presumption doesn't shield the CPSC's actions from a "thorough, probing, in-depth review." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971). And that review, which the court should conduct based on the record before the agency at the time it made its decision, *see id.* at 420, does not support Safe to Sleep®. D.I. 30 ¶ 85. For example, the fatalities and injuries cited by Defendants in their Motion to Dismiss[31] are not attributable to Nested Bean; yet Nested Bean's products—not other companies' products—were taken off retailers' shelves. This selective delisting naturally implies that the information published by CPSC and Commissioner Trumka, in tandem, misled retailers to believe inaccurate information about Nested Bean. CPSC has a duty to avoid and correct such errors.[32] CPSC's failure to retract the inaccurate and misleading statements reflects a dereliction of this duty. Therefore, CPSC exceeded its statutory authority by publishing and subsequently refusing to retract inaccurate statements about Nested Bean's products.

III. CPSC, NIH, and CDC Acted Arbitrarily and Capriciously (Counts V and VIII)

To survive arbitrary and capricious review under the APA, courts "insist that an agency 'examine the relevant data and articulate a satisfactory explanation for its action.'"[33] Such

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[31] D.I. 39 at 18. Defendants improperly cite facts from a complaint in a difference lawsuit to support their merits argument. The document cited, a CPSC August 2024 meeting log, is also immaterial because it postdates the Safe to Sleep® publication and Trumka's statements by several months. Plaintiff objects to the incorporation of these facts outside of the pleadings and requests that it be excluded from consideration. Regardless, these factual questions show that discovery is needed and that the Defendants' Motion should be denied. Fed. R. Civ. P. 12(d).

[32] 15 U.S.C. § 2055(b)(6); 16 C.F.R. § 1101.52 ("If the Commission finds that the Commission or any individual member, employee, agent contractor or representative of the Commission has made public disclosure of inaccurate or misleading information that reflects adversely either on the safety of the firm's product or the practices of the firm, the Commission **will publish a retraction of information in a manner equivalent to that in which the disclosure was made**. If the Commission finds that fuller disclosure is necessary, it will publish a retraction in the manner it determines appropriate under the circumstances.") (emphasis added).

[33] *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009) (quoting *Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

explanation must "includ[e] a 'rational connection between the facts found and the choice made.'"[34] "The reviewing court should not attempt itself to make up for such deficiencies: [it] may not supply a reasoned basis for the agency's action that the agency itself has not given."[35] In short, failing to engage in "reasoned decisionmaking" renders an agency action arbitrary and capricious.[36] Nested Bean has plausibly alleged that CPSC, CDC, and NIH failed to engage in the "reasoned decisionmaking" the APA demands. Nested Bean has alleged, for example, that it has been unable to locate any evidence CPSC could have relied upon to meet the requisite clearance requirements for technical and scientific information published on the CPSC website.[37] D.I. 30 ¶ 250. Relatedly, Nested Bean has not been able to locate evidence to support any of the agencies' statements related to Safe to Sleep® and "weighted" infant products. *See, e.g.*, D.I. 30 ¶ 249. The agencies fail to acknowledge that the lack of safety incidents attributed to Nested Bean products (despite selling more than 2.5 million units for over a decade) is in fact data and empirical evidence of their safety. D.I. 30 ¶ 85. Rather, the statements of the agencies here have no rational connection to the facts; they quite literally run counter to the only evidence they cite, the 2020 NICU Study. This is not a mere disagreement; the only study cited by the agencies "in support of" their conclusions objectively comes to the opposite conclusion. The agencies have pointed to no other research and Plaintiff has been unable to locate any research that supports the agencies'

[34] *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)).
[35] *Id.* (citing *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947)).
[36] *Allentown Mack Sales & Serv., Inc. v. N.L.R.B.*, 522 U.S. 359, 374 (1998) (internal quotation omitted).
[37] Defendants seem to imply that a consumer product must be proven safe, by stating that "the absence of a hazard pattern, … does not mean a product…is necessarily safe." D.I. 39 at 20. But the CPSA does not require "pre-market" clearance like, e.g., acts administered by the FDA. Rather, the Commission is authorized to address on-the-market products that present an unreasonable risk of death or injury. *See* 15 U.S.C. §§ 2051, 2053.

conclusions. The agencies' failure to cite any evidence that actually supports their conclusions is significant, as one would expect agencies to refer to the evidence that purportedly underlies and supports their decisionmaking and policies. When, as here, there is "not a 'shred of evidence' supporting the agency's decision," it is arbitrary and capricious.[38]

Further, Nested Bean has alleged that the publication of guidance warning against "weighted" infant sleep products is arbitrary and capricious because it represents an unexplained change in the CPSC's stated course of action.[39] Specifically, CPSC had determined—shortly before the publication of Safe to Sleep®—that there was insufficient research to support a promulgation of a mandatory standard. D.I. 30 ¶ 248. Accordingly, it had planned to continue research efforts to determine whether initiation of rulemaking might be appropriate. To then publish a strong warning against the product, without identifying research or evidence to support that change, is arbitrary and capricious. This abrupt and inexplicable change in course is exactly the type of "'unexplained inconsistency' in agency practice" that justifies an arbitrary and capricious finding under the APA.[40]

IV. HHS, CDC and NIH Exceeded Their Authority (Count IV)

The authority of HHS, CDC, and NIH are derived from the PHSA. That Act does not authorize the HHS, CDC, or NIH to opine on the safety of consumer products. HHS, CDC, and NIH have limited authority to investigate the causes of Sudden Infant Death Syndrome ("SIDS"). But at no point did the SIDS-related research duties of these agencies permit opining on the safety

[38] *Calio v. Pa. Dep't of Transp.*, 101 F. Supp. 2d 325, 331 (E.D. Pa. 2000), *aff'd*, 276 F.3d 576 (3d Cir. 2001) (referencing *Matter of Bell Petroleum Servs., Inc.*, 3 F.3d 889, 905 (5th Cir. 1993)).
[39] D.I. 30 ¶¶ 241–43, 252–56. *See also CBS Corp. v. FCC*, 663 F.3d 122, 145 (3d Cir. 2011) (quoting *Massachusetts v. EPA*, 549 U.S. 497 (2007)) (stating that an agency's actions will be "set aside as 'arbitrary and capricious' if the agency failed to provide a 'reasoned explanation' for its decision to change course.").
[40] *See CBS Corp.*, 663 F.3d at 145 (quoting *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005)).

of purported categories of consumer products, and it certainly is not within their now-narrowed SIDS research participation.[41] A plain reading of the statute shows that the CDC and NIH are not authorized to make consumer product safety determinations. Therefore, HHS, CDC and NIH exceeded the scope of their statutory authority by publishing unfounded statements about "weighted" infant sleep products.

V. HHS, CDC and NIH Acted *Ultra Vires* in Publishing Unfounded Safe to Sleep® Guidance (Count III)

Even if an agency's actions are not final, a nonstatutory *ultra vires* action is available. When an agency's actions fall "on the wrong side of the line between telling *about* and telling *to*," individuals "can use the APA to assert their *ultra vires* claims against the Agencies and the Officials."[42] As explained in *Apter*, "authority to inform, announce and apprise" does not encompass the authority to "endorse, denounce, or advise." *Id.* HHS, CDC, and NIH published guidance telling the public what to do. *See* D.I. 30 ¶¶ 82–89. And they did this without any scientific evidence to support it; the only cited research on "weighted" infant sleepwear reached the opposite conclusion. Surely the PHSA does not delegate the authority to produce guidance that not only lacks supporting scientific evidence, but actually contradicts the guidance, without addressing the contradiction. The broad reading of the PHSA that would be necessary to anoint these actions would raise a nondelegation issue, and therefore it should be read more narrowly under the canon of constitutional avoidance.[43]

VI. Commissioner Trumka Acted *Ultra Vires* (Count VI)

Defendants argue that, because CPSC did not adopt a mandatory product safety standard

[41] In April 2025, the Trump administration cancelled federal participation in the Safe to Sleep® SIDS campaign. D.I. 30 ¶ 198.
[42] *Apter v. Dep't of Health & Hum. Servs.*, 80 F.4th 579, 595 (5th Cir. 2023).
[43] *See Jennings v. Rodriguez*, 583 U.S. 281, 296 (2018).

or ban on "weighted" products for infants, then-Commissioner Trumka could not have "determined" that such products present an unreasonable risk of injury. D.I. 39 at 25. They also contend that then-Commissioner Trumka "merely repeat[ed]" lawful CPSC guidance and therefore did not act beyond the bounds of his authority.[44] *Id.* A review of select statements from then-Commissioner Trumka should quickly disabuse this Court of the idea that he reached no "determination" about product safety and merely parroted CPSC's position. He publicly stated, for example, that the CDC, AAP, and CPSC "are all in agreement when it comes to weighted [sic] infant sleep products: they pose serious threats to the lives of babies. Do NOT use them for sleep." D.I. 30 ¶ 110. And he said "Do NOT – I repeat – do NOT put any weighted [sic] swaddles or blankets on your baby. Companies will try to fool you into thinking they're safe, but there's a reason [CPSC], [CDC], & [NIH] have warned you NOT to use them. It's a risk of death to your baby." *Id.* ¶ 113. At one point, he accompanied his comments with an image of a dumbbell weight on a sleeping infant with a red circle and line drawn through it. Trumka implored retailers to immediately stop selling Nested Bean's products, by posting on social media, on the CPSC website, and sending letters directly to the retailers on CPSC letterhead. Trumka followed up with retailers to ensure they complied, posting again on social media to announce which retailers bent to his will and stating that he "[has] letters out to other retailers as well" and that he would "report" when he heard back, and he "expect[ed] to hear back from additional retailers soon." D.I. 30 ¶¶ 120–21.

Nested Bean asserts an *ultra vires* claim against Trumka based on public statements like these because they "fell on the wrong side of the line between telling *about* and telling *to*."[45] In

[44] Defendants' argument that the statements were "lawful" guidance shows that the guidance is a considered agency position, i.e., final agency action.
[45] *Apter*, 80 F.4th at 595.

fact, the FDA's statements in *Apter* are eerily similar to those of then-Commissioner Trumka. One of FDA's statements there read: "There's a lot of misinformation around, and you may have heard that it's okay to take large doses of ivermectin. It is not okay." *Id.* at 584. Others included images of a horse and said "Hold your horses, y'all. Ivermectin may be trending, but it still isn't authorized or approved to treat COVID-19." *Id.* at 585. There is no meaningful difference between the statements at issue in *Apter* and those here. The effect of Trumka's actions is reminiscent of the strongarming present in *Solar Turbines Inc. v. Seif*, where the challenged order "required the immediate cessation of construction of Solar's gas turbine facility. It further ordered that Solar certify its compliance with the order within 10 days after its receipt." 879 F.2d 1073, 1083 (3d Cir. 1989) (concurrence). The language of EPA's order "has the clear ring of finality to it" and clearly "reflects EPA's definitive position on the question of Solar Turbine's compliance with the requirements of PSD[.]" *Id.* Former Commissioner Trumka's posts, statements, and letters to retailers were intended to give retailers their "marching orders."[46] He met with Target representatives multiple times to discuss Target's response to his April 15th letter recommending Target stop the sale of "weighted" infant sleep products. D.I. 30 ¶ 117. Retailers, including Target, fell in line and did as they were told, removing Nested Bean's products from their storefronts in one fell swoop. D.I. 30 ¶¶ 118–19. Trumka's actions amounted to a de facto ban on Nested Bean products, without following the required procedures for the CPSC to promulgate a stop sale order. Trumka did not even include the disclaimer required by the generic Clearance Procedures prescribed by CPSC Directive 1450.2 (7)(f)(2)(b), and it is exceedingly likely that he failed to adhere to the technical, program, policy, editorial and legal clearance procedures. Constitutional

[46] *See Appalachian Power Co. v. E.P.A.*, 208 F.3d 1015, 1023 (D.C. Cir. 2000) ("Through the Guidance, EPA has given the States their 'marching orders' and EPA expects the States to fall in line, as all have done, save perhaps Florida and Texas.").

avoidance counsels that this Court should reasonably interpret the CPSA to not confer such enormous powers on individual Commissioners.

VII. There May Be a Legally Cognizable Cause of Action Under 15 U.S.C. § 2055(b)(1) and 2055(b)(6) (Counts II and VII)

In Defendants' first Motion to Dismiss they admitted that 15 U.S.C. § 2055(b)(6) "does apply here," and implied that Plaintiff should file a claim against the Commission for violation of 2055(b)(6) specifically. D.I. 26-1 at 17. Accordingly, Plaintiff amended the complaint to directly assert claims against the CPSC and Commissioner Trumka for violating 15 U.S.C. § 2055(b)(1) and 15 U.S.C. § 2055(b)(6), the statutes that require CPSC to ensure its published information is accurate and not misleading, and to provide notice to readily ascertainable manufacturers before disclosing information about their products. Defendants now argue that it is not a legally cognizable claim. D.I. 39 at 27–28. They cannot have it both ways.[47] Some statutes are self-executing.[48] Even if it may be unclear from precedent whether a cause of action arises directly under a constitutional right or statute, the Supreme Court has recognized that the absurd result that an individual is left with no cause of action to vindicate their rights "does not hold." *Id.* at 293. Nested Bean has requested a retraction of the offending statements, but the CPSC did not retract the statements. The only recourse left for Nested Bean is this lawsuit. Commissioners Feldman and Dziak have repeatedly stated that they "believe that the relief sought is best obtained through an Article III court."[49] Even if these are novel claims, that does not preclude finding that there is

[47] Doctrine of judicial estoppel stops parties from playing fast and loose with the court by asserting conflicting positions. *See Ryan Operations G.P. v. Santiam-Midwest Lumber Co.*, 81 F.3d 355, 358 (3rd Cir. 1996).

[48] *See DeVillier v. Texas*, 601 U.S. 285, 291 (2024) (citing *Knick v. Twp. of Scott*, 588 U.S. 180, 192 (2019)).

[49] *See* D.I. 31 at ¶ 131, Statement of Commissioners Peter A. Feldman and Douglas Dziak on the Retraction of Infant Sleep Products Statements (Dec. 20, 2024), https://tinyurl.com/4v2mmtht (citing Statement of Commissioners Peter A. Feldman and Douglas Dziak on the Retraction of Infant Sleep Products Statements (Aug. 30, 2024), https://tinyurl.com/49ny5vb7).

a cause of action under 2055(b)(1) and 2055(b)(6).[50]

VIII. Nested Bean Has Plausibly Alleged an Injury in Fact for Its Asserted Due Process Claim (Count X)

On May 8 and 9, 2025, President Trump fired Commissioners Boyle, Hoehn-Saric, and Trumka.[51] The fired Commissioners challenged their removal, summary judgment was entered in their favor, and they were reinstated to their roles. *Id.* at 605. The case is currently on appeal to the Fourth Circuit and an application for stay was granted by the Supreme Court. *Trump v. Boyle*, 145 S. Ct. 2653 (2025). Although Trumka is not currently serving as Commissioner, his actions thus far suggest he will continue to fight his termination up to and including a decision on the merits by the U.S. Supreme Court—the stay that is currently in place is not a permanent resolution.

Although the plaintiff bears the burden of establishing the elements of standing, "general factual allegations of injury resulting from the defendant's conduct may suffice."[52] "The Due Process Clause was 'intended to secure the individual from the arbitrary exercise of the powers of government.'"[53] "[T]here exists a variety of interests which are difficult of definition but are nevertheless comprehended within the meaning of either 'liberty' or 'property' as meant in the Due Process Clause."[54] For example, "[t]he Supreme Court held in *Wisconsin v. Constantineau*, 400 U.S. 433 (1971) that an individual has a protectable interest in reputation. 'Where a person's good name, reputation, honor, or integrity is at stake because of what the government is doing to him, notice and an opportunity to be heard are essential.'"[55] An attempt to drive a plaintiff out of

[50] *See DeVillier*, 601 U.S. at 292 ("[T]he absence of a case relying on the Takings Clause for a cause of action does not by itself prove there is no cause of action.").
[51] *See Boyle v. Trump*, 791 F. Supp. 3d 585, 588 (D. Md. 2025).
[52] *Ballentine*, 486 F.3d at 810 (quoting *Lujan*, 504 U.S. at 561).
[53] *Holt Cargo Sys., Inc. v. Delaware River Port Auth.*, 20 F. Supp. 2d 803, 829 (E.D. Pa. 1998), *aff'd,* 165 F.3d 242 (3d Cir. 1999) (quoting *Hurtado v. California*, 110 U.S. 516, 527 (1884)).
[54] *Paul v. Davis*, 424 U.S. 693, 710–11 (1976).
[55] *Hill v. Borough of Kutztown*, 455 F.3d 225, 235 (3d Cir. 2006) (citation omitted).

business that results in serious financial damage can establish a constitutional claim.[56] Trumka has deprived and will continue to deprive Nested Bean of a valuable property interest—a formerly thriving business that was built on partnerships with the retailers that Trumka strong-armed into severing ties with Nested Bean through direct letters, meetings, official statements on the CPSC website, and social media posts on his official CPSC account. Nested Bean has suffered serious ongoing economic damage and financial losses. D.I. 30 ¶ 124. Nested Bean's survival is at risk. *Id.* "Ordinarily, due process of law requires an opportunity for 'some kind of hearing' prior to the deprivation of a significant property interest."[57] But Commissioner Trumka took these actions to deprive Nested Bean of its property in an arbitrary and biased manner, without any typical process that attaches to a formal stop sale order, recall, or mandatory standard. Additionally, Trumka's actions towards Nested Bean convey an actual bias and as such he would be impermissibly biased in any future actions towards Nested Bean. There is no guarantee that he will not be involved in future decisions by the CPSC because his case challenging his removal is still pending. *See Boyle v. Trump*, 145 S. Ct. 2653 (2025). The Third Circuit historically has frowned upon district courts granting dismissals as a matter of law in similar cases where a plaintiff has alleged that its property rights have been interfered with by the improper conduct of government defendants motivated by bad faith, bias, economics or politics.[58]

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[56] *See Holt Cargo Sys., Inc.*, 20 F. Supp. 2d at 830 (discussing due process claim that government acted to drive plaintiff out of business, but because plaintiff had increased profits over the past several years the required actual deprivation was not shown).

[57] *Memphis Light, Gas & Water Div. v. Craft*, 436 U.S. 1, 19 (1978) (citing *Boddie v. Connecticut*, 401 U.S. 371, 379 (1971)).

[58] *See, e.g.*, *Blanche Road Corp. v. Bensalem Tp.*, 57 F.3d 253, 257 (3d. Cir. 1995) (reversing trial court's dismissal as a matter of law of substantive due process claim against government defendant alleged to have acted with improper purpose); *DeBlasio v. Zoning Bd. of Adjustment for Twp. Of West Amwell*, 53 F.3d 592, 593–94 (3d. Cir. 1995) (same); *Midnight Sessions, Ltd. v. City of Philadelphia*, 945 F.2d 667, 687 (3d. Cir. 1991) (same); *Parkway Garage, Inc. v. City of*

IX. CPSA's Removal Protections Harmed Nested Bean (Count XI)

Defendants move to dismiss Count XI because the Supreme Court has permitted the removal of CPSC Commissioners and because there is no evidence the removal protection prevented President Trump from removing then-Commissioner Trumka. D.I. 39 at 30. Actually, the Supreme Court has only temporarily stayed the District Court's reinstatement of Commissioners Trumka, Boyle, and Hoehn-Saric; there has been no final decision in that case; and the Commissioners may still be reinstated. In fact, Trumka's case is stayed[59] pending the outcome of *Trump v. Slaughter*, No. 25-332 (U.S.), argued in December 2025, which will likely decide the limits of the President's removal authority and may resolve issues related to *Humphrey's Executor v. United States*, 295 U.S. 602 (1935). In the interest of judicial economy this Court should refrain from dismissing this claim until a decision is issued in *Trump v. Slaughter*.

CONCLUSION

For the foregoing reasons the Court should deny Defendants' motion to dismiss the Amended Complaint.

Respectfully submitted this 30th day of January 2026.

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Philadelphia, 5 F.3d 685, 692 (3d. Cir. 1993) (same); *Bello v. Walker*, 840 F.2d 1124, 1128 (3d. Cir. 1988) (same).

[59] *See* Order, *Boyle v. Trump*, No. 8:25-cv-01628 (D. Md. Oct. 8, 2025), Dkt. No. 41 (Order from the Fourth Circuit placing the case is abeyance until a decision by the U.S. Supreme Court in *Trump v. Slaughter*, No. 25-332).