IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DREAMLAND BABY CO.,

Plaintiff,

v.

CONSUMER PRODUCT SAFETY COMMISSION; RICHARD TRUMKA, JR., in his official capacity as Commissioner of the Consumer Product Safety Commission; DEPARTMENT OF HEALTH AND HUMAN SERVICES; CENTERS FOR DISEASE CONTROL AND PREVENTION; NATIONAL INSTITUTES OF HEALTH,

Defendants.

Case No. 1:24-cv-03277-RC

ORAL HEARING REQUESTED

PLAINTIFF'S MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

Parents and other consumers rely on Defendant Consumer Product Safety Commission ("CPSC") to base its decisions and disclosures on the best evidence and data available to it. They trust that when CPSC makes a determination regarding the safety of a product or class of products there is a basis for that decision, and that it is not based on speculation or a perceived need to "just do something" in the absence of its ability to lawfully regulate a product. Congress had the same expectations for the Commission when it adopted the Consumer Product Safety Act ("CPSA"). The purpose and structure of that Act, and the substantial evidentiary and procedural requirements CPSC must follow to make product safety determinations and regulate, recall, or ban unreasonably risky or hazardous products point in one direction: CPSC must make federal consumer product safety determinations and must do so on a data-driven, informed basis.

But that is not what happened here. Instead, CPSC abdicated its authority and role in determining whether consumer products are safe to agencies that are not tasked with determining consumer product safety. In other words, the Defendants got the order of operations, *i.e.*, who can make determinations and when, wrong. Here Defendants Department of Health and Human Services ("HHS") and its subagencies the Centers for Disease Control and Prevention ("CDC") and the National Institutes for Health ("NIH") made unauthorized and unsubstantiated determinations regarding the safety of weighted infant sleep products. CPSC then adopted those determinations, misleadingly suggesting to the public that it too had made a product safety determination. But it turns out that the CDC's and NIH's determinations were just the parroted recommendations of a non-governmental third-party unconstrained by statute. Those recommendations were not based on data or evidence of harm but the perception that there was not enough data to prove safety. CPSC, however, is only empowered to regulate based on

determinations of the risk of harm and hazard patterns, not a lack of evidence of safety. Importantly, there is no hazard pattern with respect to weighted infant sleep products.

CPSA's statutory guardrails should have stopped unsubstantiated disclosures from being made in the first instance. But they failed. Not only were the challenged disclosures made, Commissioner Richard Trumka, Jr. then took it upon himself to repeat, embellish, and amplify them with devasting effects for Plaintiff Dreamland Baby Co.'s ("Dreamland") business and reputation. It came as little surprise that after Trumka sent letters to retailers that identified Dreamland and were replete with false, misleading, and inaccurate information the retailers stopped selling Dreamland products.

This case seeks review of the Defendants' various misleading, inaccurate, and unauthorized actions that pushed Dreamland's business to the brink of destruction. They are entitled to such review under the Administrative Procedure Act ("APA"), the CPSA, and the Constitution and this Court should deny Defendants' Motion to Dismiss Dreamland's claims.

BACKGROUND

I. STATUTORY AND REGULATORY BACKGROUND

A. The Consumer Product Safety Act

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); Compl. ¶ 21. 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); Compl. ¶ 22. 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* 15 U.S.C. §§ 2054, 2056, 2058, 2061, 2064; Compl. ¶ 23.

The Commission is also "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; Compl. ¶ 24. In making product safety determinations and promulgating standards, the Commission must follow the procedures set forth by both the CPSA and the APA. Compl. ¶ 25; *see generally Window Covering Mfrs. Ass'n v. CPSC*, 82 F.4th 1273, 1286 (D.C. Cir. 2023).

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); Compl. ¶ 26. 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); Compl. ¶ 27. The CPSA also permits the Commission to ban hazardous products which present "an unreasonable risk of injury" but requires an evidence and data-backed determination. 15 U.S.C. § 2057; Compl. ¶ 28.

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; Compl. ¶ 29. 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, the CPSA requires notice before such disclosures are made and an opportunity for a company to respond before the information is made public. 15 U.S.C. § 2055(b)(1); Compl. ¶ 30. Public disclosures that "reflect[] on the safety of a consumer product or class of consumer products" but do not allow the public to "ascertain readily the identity of a manufacturer" are subject to the Commission's Clearance Procedures. 15 U.S.C. § 2055(b)(6); Compl. ¶¶ 30, 114; Doc. 1-4 (Directive 1450.2). [1] Public disclosures of any kind that are "inaccurate or misleading" and "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 was made[.]" 15 U.S.C. § 2055(b)(7); Compl. ¶ 100.

The Commission has determined that § 2055(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,

[1] Pincites to the Exhibits to the Complaint, Docs. 1-1–107 refer to the documents' ECF-assigned pagination.

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; Compl. ¶ 31. Under CPSC's regulations, the public is able to readily ascertain the identity of a manufacturer "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 … of a particular product." 16 C.F.R. § 1101.13; Compl. ¶ 32.

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; Compl. ¶ 33. CPSC has also determined that certain steps are reasonable to provide fairness, including providing the "comments" along with the public disclosure or "accompany[ing] the disclosure of information with an explanatory statement … [and] disclos[ing] any other relevant information [in] its possession" or "limit[ing] the form of disclosure" or "delay[ing] disclosure[.]" 16 C.F.R. § 1101.33; Compl. ¶ 34.

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); Compl. ¶ 35.

B. The Public Health Service Act

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); Compl. ¶ 36. The Public Health Service Act ("PHSA") also

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; Compl. ¶ 39.

II. FACTUAL AND PROCEDURAL BACKGROUND

Dreamland develops, designs, produces, and sells weighted infant sleep products. Compl. ¶¶ 40–50. Its products feature a quilted fabric design that allows weight to be evenly distributed throughout the product, and the gentle pressure provided by Dreamland's weighted sleep bag is comparable to placing a slice of bread or American cheese on an infant's chest. *Id*. Since the company was founded in 2019, Dreamland has sold over 1 million of its products. Compl. ¶ 48.

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

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 alongside the CPSC and outside groups like the American Academy of Pediatrics ("AAP"). Compl. ¶¶ 51–53. The Safe to Sleep® campaign focuses on addressing sleep-related infant deaths, including sudden infant death syndrome ("SIDS"). Compl. ¶ 52. On June 21, 2022, AAP updated its safe sleep guidelines, which for the first time included recommendations that weighted infant sleep products, like swaddles and blankets, should not be used. Compl. ¶¶ 54–56. The revised guideline regarding swaddling notes a single study that "found no adverse events when a 1-pound weighted blanket was placed on each infant for 30 minute observed episodes." Compl. ¶ 57. Despite that study, AAP concluded that "no studies have documented the safety of weights for infants in an unobserved, nonclinical sleep environment." Compl. ¶ 58. As professor and economist Emily Oster observed, the paper AAP cites "is evidence of safety" and "[t]here is no data cited suggesting danger" but the recommendation may be a reaction "to a lack of wide-scale direct evidence" of safety and "theoretical concern[s]" about such products. Compl. ¶ 59–60.

Sometime thereafter the Safe to Sleep® campaign, as well as the CDC and NIH the Safe revised their "messages" to "reflect" the AAP's updated recommendations. Compl. ¶¶ 60, 64. 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)." Compl. ¶ 61. 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." Compl. ¶ 62. Neither agency provided the basis for, or data or evidence in support of, its respective determination. Compl. ¶ 64.

B. CPSC "Adopts" CDC's and NIH's Unsubstantiated Determinations

On November 8, 2023, the Commission convened a meeting to consider its Fiscal Year 2024 Operating Plan and discussed, among other things, Commissioner Trumka's proposed amendment that would have required CPSC staff to "pursue a mandatory standard to address foreseeable risks posed by [weighted sleep products for infants]" and "update all safe sleep messaging and guidance to incorporate recent advice on weighted infant products from the [CDC] and from the [NIH]." Compl. ¶¶ 66–68. His amendment was rejected by a 3 to 1 vote. Compl. ¶ 69. Then-Chair Hoehn-Saric observed that 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." Compl. ¶ 70. Commissioner Boyle indicated that she thought rulemaking was "premature" at the time. Compl. ¶ 71. After his amendment was rejected, Commissioner Trumka released a public statement stating that weighted infant sleep products are "deemed dangerous" and admonishing his fellow commissioners for not adopting his amendment. Compl. ¶ 72.

Despite the admission that the CPSC lacked the data or evidence to support a rulemaking, then-Chair Hoehn-Saric noted that staff was "working on how to modify safe sleep guidance to account for the fact that both NIH and CDC" warned against the use of weighted infant sleep products. Compl. ¶ 76. Sometime after November 8, 2023, the CPSC's safe sleep website was updated to add: "**Don't** use weighted blankets or weighted swaddles*. … *NIH.gov and CDC.gov" and linking to webpages maintained by CDC and NIH. Compl. ¶ 77–79. None of the webpages cite any specific safety data, evidence, or studies regarding weighted infant sleep products.

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. Compl. ¶¶ 83–84. The comprehensive dataset was provided to aid the ASTM subcommittee considering the potential hazards associated with such wearable blankets and swaddles. *Id.* As part of the ASTM process, the data was independently reviewed. Compl. ¶¶ 85–86. That independent review "found no pattern among the 13 incidents (deaths + injuries) involving weighted sleep products." Compl. ¶ 86.

C. Commissioner Trumka Takes Matters into His Own Hands

Despite the then-Chair Hoehn-Saric'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 public statements, letters, videos, and posts on X (formerly Twitter) and Instagram maligning weighted swaddles and blankets. Compl. ¶¶ 87–96; Doc 1-1 at 30–60. For example, on April 15, 2024, he made the post below:

Doc. 1-1 at 39.

The public statements, letters, and at least one social media post linked to *Washington Post* article that specifically named Dreamland. Compl. ¶¶ 88, 107–08; Doc. 1-1 at 36, 49. Likewise, his letters to Dreamland's retailers also identified the company through search links for weighted infant sleep products that either Commissioner Trumka or his staff created and included in the letters. Compl. ¶ 109. After receiving his letters, Dreamland's retailers stopped selling their weighted infant sleep products. Compl. ¶ 10. Dreamland was not provided notice of the statements before they were made, or of the meetings Commissioner Trumka, or his staff, had with retailers. Compl. ¶¶ 96–97, 110. Those public statements, letters, and social media posts were not reviewed

under the CPSC's clearance process and included no disclaimers qualifying that they were made in his own capacity and not on behalf of the Commission. Compl. ¶¶ 139–144.

D. CPSC Denies Dreamland's Retraction Request and Takes No Action Regarding Commissioner Trumka's Disclosures

Pursuant to the 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 ("Retraction Request"). *See* Compl. ¶ 100; Doc. 1-1 (and attachments). The Retraction Request asked CPSC to retract its disclosure and Commissioner Trumka's disclosures because they were inaccurate or misleading and reflected adversely on Dreamland's products. Compl. ¶¶ 101–05; Doc. 1-1 at 2, 7–16. As to Commissioner Trumka's disclosures, Dreamland also requested retraction because they allowed the public to readily ascertain its identity, were misleading or inaccurate, and not fair under the circumstances. Compl. ¶¶ 106–09. Commissioner Trumka did not notify Dreamland of the disclosures before they were made and, on information and belief, failed to clear them through CPSC's clearance processes. Compl. ¶¶ 110, 139–44.

On August 29, 2024, the Commission voted 3-0-2 to take other action and deny retraction of CPSC's disclosure. Compl. ¶ 111. Then-Chair Alexander Hoehn-Saric, Commissioner Mary Boyle, and Commissioner Richard Trumka, Jr. voted to take other action and deny retraction of the CPSC disclosure. *Id.*; Doc. 1-2. CPSC also approved a letter providing the Commission's reasons for denying Dreamland's request. Compl. ¶¶ 111–26; Doc. 1-3, Doc. 1-4; Doc. 1-5. Now-Acting Chair Peter A. Feldman and Commissioner Douglas Dziak abstained from the vote and provided a joint statement. Compl. ¶ 111; Doc. 1-7.

That same day, the Commission took no action regarding Dreamland's Retraction Request challenging Commissioner Trumka's disclosures. Compl. ¶ 128, Doc. 1-2. Commissioners Hoehn-Saric and Boyle voted to deny Dreamland's request. Compl. ¶¶ 128–34; Doc. 1-6. Now-Acting

Chair Feldman and Commissioner Dziak abstained from the vote and provided a joint statement. Compl. ¶¶ 135–38; Doc. 1-7. Commissioner Trumka voluntarily recused himself from the vote and did not participate. Compl. ¶ 128; Doc. 1-2.

Dreamland filed this action on November 19, 2024.

E. President Trump Fires Three CPSC Commissioners

On May 8 and 9, after the Motion to Dismiss was filed, President Donald J. Trump fired Commissioners Boyle, Hoehn-Saric, and Trumka. *See Boyle v. Trump*, No. CV MJM-25-1628, 2025 WL 1677099, at *1, *2 (D. Md. June 13, 2025).[2] The fired Commissioners challenged their removal, summary judgment was entered in their favor, and they were reinstated to their roles. *Id.* at *14. The President filed a motion for temporary administrative stay with the U.S. Court of Appeals for the Fourth Circuit, which was denied. *See* Order, *Boyle v. Trump*, No. 25-1687 (4th Cir. July 1, 2025), Doc. 19. The President's application for a stay was granted by the Supreme Court on July 23, 2025. *Trump v. Boyle*, No. 25A11, 2025 WL 2056889 (U.S. July 23, 2025).

As relevant here, the fired Commissioners all voted against retracting the CPSC's Safe Sleep Guidance. Compl. ¶¶ 111–27. Commissioners Boyle and Hoehn-Saric voted "to take other action" regarding Dreamland's Retraction Request as to Commissioner Trumka's disclosures, and Commissioner Trumka voluntarily recused himself causing a deadlock. Compl. ¶ 128. At some point after Commissioner Trumka was fired, his X.com account, @TrumkaCPSC, where many of the challenged disclosures were made, *see* Compl. ¶¶ 88–92, was deleted. *See* @TrumkaCPSC, X.com (last visited July 23, 2025), https://x.com/TrumkaCPSC (noting that "This account doesn't exist"); *but see* Doc. 1-1 at 30, 39 (screen captures of Commissioner Trumka's X.com posts).

[2] Courts may take judicial notice of facts available in public court filings. *See Heidi Aviation, LLC v. Jetcraft Corp.*, 573 F. Supp. 3d 182, 191 n.4 (D.D.C. 2021).

LEGAL STANDARD

A motion to dismiss under Rule 12(b)(6) "tests the legal sufficiency of a complaint[.]" *Browning v. Clinton*, 292 F.3d 235, 242 (D.C. Cir. 2002). Under that Rule, courts "assume the truth of [a plaintiff's] allegations" and construe a complaint liberally and grant plaintiffs the benefits of inferences derived from the factual allegations. *Zukerman v. U.S. Postal Serv.*, 961 F.3d 431, 441 (D.C. Cir. 2020) (citations omitted). A court should deny a motion to dismiss if the complaint includes "sufficient factual matter" that, if "accepted as true," states a facially plausible claim for relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556, 570 (2007)). "The issue on a motion to dismiss is not whether the plaintiff will ultimately prevail, but whether the plaintiff is entitled to offer evidence to support the claims." *Koch v. Schapiro*, 759 F. Supp. 2d 67, 72 (D.D.C. 2011), *aff'd sub nom. Koch v. White*, No. 14-5101, 2016 WL 1275025 (D.C. Cir. Feb. 8, 2016). In deciding a motion to dismiss, courts "may consider the facts alleged in the complaint, documents attached thereto or incorporated therein, and matters of which it may take judicial notice." *Stewart v. Nat'l Educ. Ass'n*, 471 F.3d 169, 173 (D.C. Cir. 2006) (citing *EEOC v. St. Francis Xavier Parochial Sch.*, 117 F.3d 621, 624–25 (D.C. Cir. 1997)).

Defendants raise a single Rule 12(b)(1) challenge as to Count Six of the Complaint, which alleges a Due Process violation against Commissioner Trumka. *See* Br. at 37–40; Compl. ¶¶ 194–206. When a party raises challenges under both Rule 12(b)(1) and Rule 12(b)(6) of the Federal Rules of Civil Procedure, courts "must first consider whether it has subject-matter jurisdiction." *Hamilton v. United States*, 502 F. Supp. 3d 266, 272 (D.D.C. 2020). Dreamland bears the burden of establishing that this Court has subject-matter jurisdiction over its claims "by a preponderance of the evidence." *Moran v. U.S. Capitol Police Bd.*, 820 F. Supp. 2d 48, 53 (D.D.C. 2011). A facial challenge under Rule 12(b)(1) "asks whether the complaint alleges facts sufficient to establish the

court's jurisdiction." *R-CALF USA v. U.S. Dep't of Agric.*, 573 F. Supp. 3d 324, 332 (D.D.C. 2021) (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992)). "In this posture, the Court must accept the factual allegations of the complaints as true … but also assess the 'plausibility' of the plaintiff's standing allegations in light of the relevant context and the Court's 'judicial experience and common sense[.]'" *R-CALF USA*, 573 F. Supp. 3d at 332–33 (citations omitted). Courts "must construe the complaint in favor of the complaining party[.]" *Warth v. Seldin*, 422 U.S. 490, 501 (1975). A factual challenge under Rule 12(b)(1) "disputes the factual bases on which the plaintiff's jurisdictional allegations rely." *Cherokee Nation v. U.S. Dep't of the Interior*, 643 F. Supp. 3d 90, 104 (D.D.C. 2022). But such evidentiary attacks are not permitted "at the pleading stage in this Circuit[.]" *Id.*

ARGUMENT

Dreamland has pleaded claims upon which relief can be granted for all counts, and this Court has jurisdiction to adjudicate Count Six. Accordingly, the Court should deny Defendants' Motion to Dismiss under Fed. R. Civ. P. 12(b)(1) and (6).

I. DREAMLAND ADEQUATELY ALLEGES THAT CPSC EXCEEDED ITS STATUTORY AUTHORITY

The APA requires courts to "hold unlawful and set aside agency action, findings, and conclusions found to be ... in excess of statutory jurisdiction, authority, or limitations, or short of statutory right[.]" 5 U.S.C. § 706(2)(C). As Dreamland has argued, the entire series of events at issue in this case originates from an order of operations problem where agencies that are not authorized to determine the safety of consumer products did so, without any factual or evidentiary basis. Having done so, CPSC simply repeated those determinations but failed to evaluate those claims according to the standards imposed by the CPSA and CPSC's own regulations and procedures. *See* Compl. ¶¶ 77–79, 154. CPSC's issuance of its determination constitutes final

agency action. In any event, Dreamland is also entitled to relief because CPSC's decision not to retract its disclosure is another final agency action subject to this Court's review—CPSC does not dispute this fact. Likewise, Dreamland is entitled to seek review of Commission Trumka's actions through Count Three, which is available in part because the Commission's vote deadlocked. *See infra* pp. 27–33.

A. CPSC's Decision to Make a Public Disclosure Was Final Agency Action

Under the APA, "agency action" includes an "order" or a "sanction[.]" 5 U.S.C. § 551(13). An "order" is "the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making[.]" 5 U.S.C. § 551(6). Congress, as well as the D.C. Circuit, has recognized that "adverse publicity" could "operate as a sanction" under the APA. *Indus. Safety Equip. Ass'n v. EPA*, 837 F.2d 1115, 1119 (D.C. Cir. 1988); *see also* 5 U.S.C. § 551(10). Contrary to CPSC's assertion, Defs.' Br. at 15–16, Dreamland does not allege that CPSC's disclosure is a "rule," only that is an "agency action."[3] Compl. ¶ 148. CPSC's information disclosure is either an "order" or a "sanction," both of which constitute "agency action" under the APA.

The CPSC's disclosure is agency action. CPSC's information disclosure is an "order" because it represents the "final disposition" of the Commission's review under its clearance process. *See*, *e.g.*, Compl. ¶¶ 113–16. As the Supreme Court has observed, the term "agency action" was meant "to assure the complete coverage of every form of agency power, proceeding, action, or inaction[.]" *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)). Like the issuance of a complaint after the

[3] Dreamland invokes *Apter v. Dep't of Health & Hum. Servs.*, 80 F.4th 579 (5th Cir. 2023) only with regard to its *ultra vires* claims in Counts Two and Three, not its APA claims. *See* Compl. ¶¶ 159, 161, 169.

completion of an agency's investigation, CPSC's public disclosure after completing its clearance process "is 'a part of a final disposition' and therefore is 'agency action.'" *Id.*

CPSC's disclosure is also a sanction and nothing in *Hearst Radio v. FCC*, 167 F.2d 225 (D.C. Cir. 1948) suggests otherwise. As the D.C. Circuit recognized, the APA "does not provide judicial review for everything done by an administrative agency." *Id.* at 227. It only provides for review of those actions defined in 5 U.S.C. § 551. *Id.* In *Hearst Radio*, the court suggested that the only action "approaching" the FCC's challenged publication was a "sanction" but declined to find such. *Id.* Unlike the FCC's publication in *Hearst Radio*, CPSC's disclosures are constrained by the CPSA's statutory guardrails and the regulations and procedures adopted by the Commission, which are specifically designed to avoid unjust adverse publicity. *See*, *e.g.*, 15 U.S.C. § 2055(b)(6), (7); 16 C.F.R. §§ 1101.1(c), 1101.32, 1101.51, 1101.52; Doc. 1-4 (Directive 1450.2); Doc. 1-5 (Linking Policy). *Hearst Radio* did not deal with, nor did it consider a statute like the CPSA that limits an agency's public disclosures based on its determination that the disclosure is not "inaccurate or misleading" and "reflects adversely" on the safety of a product or class of products. 15 U.S.C. § 2055(b)(6), (7). That case did not deal with a statute like the CPSA, that specifically prescribes when an agency can act and what it may say regarding concerns about a product's safety. 15 U.S.C. §§ 2055, 2056, 2058, 2061. Thus, *Hearst Radio v. FCC* is an imperfect fit, if relevant at all, for reviewing this case.

CPSC argues that *Hearst Radio* is controlling here, Br. at 14, but it does not grapple with § 2055(b)'s obligations or its implementing regulations, which the CPSC is bound by, and which distinguish this case from *Hearst Radio*. *See Morton v. Ruiz*, 415 U.S. 199, 235 (1974) (agencies are bound by the regulations they adopt). As the D.C. Circuit noted in *Trudeau v. FTC*, the court has "never had the need either to reconsider *Hearst Radio*, or to consider whether it is

distinguishable." 456 F.3d 178, 189 (D.C. Cir. 2006). But that is precisely what the circumstances demand the Court to do here. Further, the D.C. Circuit has "twice questioned 'the continued validity of the Hearst Radio decision.'" *Id.* (citing *Indus. Safety Equip. Ass'n*, 837 F.2d at 1118 and *Impro Prods., Inc. v. Block*, 722 F.2d 845, 849 (D.C. Cir. 1983)).

The statutory regime and nature of the agencies' authority before the court in *Hearst Radio* or *Trudeau* did not support determination that the challenged publications were "sanctions" or some other form of agency action. *See Trudeau*, 456 F.3d at 189 (citing *Hearst Radio*, 167 F.2d at 227). But the statutory limitations and authority differ here, and, therefore, so do the nature and consequences of the CPSC's disclosure. The D.C. Circuit's analysis in *Impro Products* is helpful on this point. In that case, the court was "disinclined to find that no 'agency action' ha[d] taken place" when the agency released information, subject to a "specific statutory authorization for dissemination of information" and the information disclosed was "concededly false[.]" 722 F.2d at 849. But the court did not go so far as to "reconsider" *Hearst Radio*. *Id.* at 849 (reversal warranted because of statute of limitations). Regardless, *Impro Products* suggests that in cases like this, where there is a statutory authorization regarding dissemination of information and the disclosed information is harmful, agency action may be found.

Indeed, the CPSC's disclosure here is a sanction, as "Congress itself did note that in certain circumstances adverse publicity might operate as a sanction." *Indus. Safety Equip. Ass'n*, 837 F.2d at 1119 (citing H. Rep. No. 79–1980, 79th Cong., 2d Sess. (1946)). Unlike the information published in *Industrial Safety Equipment Association*, the information released by CPSC, which was based on inaccurate or misleading information, "caused 'destruction … of [Dreamland's] property[,]'" *i.e.*, its business. *Id.*; *see also* Compl. ¶ 99. Dreamland's core allegation is that CPSC could not regulate weighted infant sleep products because it lacked data and evidence showing that

the products presented any risk of harm. Compl. ¶¶ 8, 69–71, 74, 80–81, 83–86. Instead of accepting that fact, CPSC acted in the absence of evidence, or in direct contradiction to the evidence in its possession, and publicly adopted CDC's and NIH's determination. Compl. ¶¶ 77–81, 115–26. As the Supreme Court recently noted, we should not be surprised when third parties react in predictable ways to government actions, like retailers pulling products when CPSC makes a public disclosure suggesting that it has determined them "unsafe" (especially not when that message is amplified by a sitting Commissioner). *Diamond Alt. Energy, LLC v. EPA*, 145 S. Ct. 2121, 2134 (2025); *but see* Br. at 14–15. As Dreamland has alleged, Compl. ¶¶ 102–04 and Doc. 1-1, the disclosure at issue here is "false or unauthorized" publicity, which the *Industrial Safety Equipment Association* court suggested "might well merit" the court's review. 837 F.2d at 1119.

CPSC's disclosure is either and "order" a "sanction" under the APA and is therefore "agency action."

The CPSC's disclosure is final agency action. An agency action is final when it "mark[s] the 'consummation' of the agency's decisionmaking process" and "the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow[.]'" *Bennett v. Spear*, 520 U.S. 154, 178 (1997) (citations omitted). The cases CPSC relies on, which involve various agency warning letters, release of investigative reports, and requests for voluntary compliance are inapposite to this case. *See* Br. at 16–18 (citing cases). In those cases, the challenged statement or action was merely a step in a larger process, or there was some future process that must be completed before the agency's action could "bind" a party. *See*, *e.g.*, *Reliable Automatic Sprinkler Co. v. CPSC*, 324 F.3d 726, 732 (D.C. Cir. 2003) (noting that CPSA requires an "on-the-record adjudication before it can make any determination that is legally binding"); *Jake's Fireworks Inc. v. CPSC*, 105 F.4th 627, 632 (4th Cir. 2024) (noting that a notice of

noncompliance "does not trigger" an enforcement action and "the power to make a final determination as to whether a violation has occurred and whether to pursue enforcement rests with the Commission itself"); *see also Doe v. Tenenbaum*, 127 F. Supp. 3d 426, 462–64 (D. Md. 2012), *rev'd on other grounds sub nom. Doe v. Public Citizen*, 749 F.3d 246 (4th Cir. 2014) (rejecting CPSC's reliance on *Invention Submission Corp. v. Rogan*, 357 F.3d 452 (4th Cir. 2004) and *Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA*, 313 F.3d 852 (4th Cir. 2002) and distinguishing from CPSC process requiring preclearance review of publications under 15 U.S.C. § 2055a).

In contrast, the decision to publish CPSC's determination is the consummation of its clearance process, meant to fulfill its statutory and regulatory obligations for deciding whether its public disclosure is in conformity with the law and the disclosure can be made. *See Tenenbaum*, 127 F. Supp. 3d at 461; *see also* Doc. 1-7 (Commissioners Feldman and Dziak indicating that in their view "publication of the statements constitutes final agency action"). Here, the CPSC's clearance process is intended to fulfill its obligations under 15 U.S.C. § 2055(b)(6). *See* Doc. 1-4 at 3 (¶ 5.a.). CPSC defines clearance as "a careful review and written approval of the information to be disclosed … in order to eliminate inaccurate or misleading statements." *Id.* (¶ 7.a.). Directive 1450.2 bars release of any information disclosures until they are approved under the clearance process. *Id.* The last step in the clearance process is "legal review" which determines "that the statement is consistent with applicable laws and regulations" and "that any possibly inaccurate or misleading statements are eliminated." *Id.* at 4 (¶ 7.a.(5)). In other words, the clearance process involves the evaluation of disclosures, and supporting evidence, and "a factual and legal 'determination' that the report contained no materially inaccurate information." *Tenenbaum*, 127 F. Supp. 3d at 460; *see also id.* at 462 (deciding "mixed question of law and fact culminating an adjudicatory process" is "a hallmark of final agency action"). That determination triggers CPSC's

authority to publicly disclose information under 15 U.S.C. § 2055. It is a "definitive statement of position" that the information disclosure does not violate the law. *Standard Oil*, 449 U.S. at 241.

Where, as here, the publication includes a determination that is inaccurate or misleading and reflects adversely on a product's safety, the act of the CPSC publishing the determination triggered Dreamland's right to seek retraction under the CPSA and its implementing regulations. 15 U.S.C. § 2055(b)(7); 16 C.F.R. §§ 1101.51–1101.52. Triggering of that right easily meets *Bennett*'s second prong. Even if that were not the case, legal consequences did flow because of CPSC's disclosure as Dreamland was subject to litigation that was predicated on CPSC's alleged determination that weighted infant sleep products were unsafe. *See generally* Consolidated Class Action Complaint, *In re Dreamland Baby Co. Weighted Sleep Prods. Litig.*, No. 3:24-cv-02996 (N.D. Cal. Aug. 7, 2024), ECF No. 38. That legal consequence was a direct result of CPSC's decision to publish misleading and inaccurate determination that reflected adversely on Dreamland's products.

CPSC attempts to distinguish *Tenenbaum* from the allegations here by trying to limit that case as only relating to 15 U.S.C. § 2055a. But the 15 U.S.C. §§ 2055 and 2055a is the same—to avoid publication of inaccurate information. *See* 15 U.S.C. § 2055a(c)(4). Unlike § 2055(b), which governs almost all public disclosures, § 2055a specifically governs CPSC's consumer product database, which takes in reports from the public and publishes them. *See* SaferProducts.gov (last visited July 23, 2025); *see also* 15 U.S.C. § 2055a(a). Thus, it makes sense that there is some variation between the two provisions, but that does not mean that a case analyzing § 2055a cannot provide a helpful analytical framework for reviewing the § 2055(b). CPSC's disclosure was a final agency action.

B. CPSC Exceeded Its Statutory Authority

CPSC's argument asserting its inherent authority to speak fails. Br. at 21–22. Unlike the City of Boston, CPSC is a "creature[] of statue" and it "accordingly possess[es] only the authority that Congress has provided." *NFIB v. OSHA*, 595 U.S. 109, 117 (2022). Thus, its inherent authority to speak is circumscribed by what powers Congress has given and the limitations it places on CPSC. *Cf. Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81, 86 (D.C. Cir. 2014) ("But we have also recognized that any inherent reconsideration authority does not apply in cases where Congress has spoken."); *Tokyo Kikai Seisakusho, Ltd. v. United States*, 529 F.3d 1352, 1361 (Fed. Cir. 2008) ("An agency cannot, for example, exercise its inherent authority in a manner that is contrary to a statute."). CPSC's claim of inherent authority contradicts the CPSA's clear limitations on its authority to speak.

Congress prescribed how the Commission is to go about making product safety determinations through regulation, recalls, and enforcement actions. *See* 15 U.S.C. §§ 2056, 2058, 2061, 2064. For each type of action, the Commission is required to follow the specific procedures and requirements set out by the CPSA. Compl. ¶¶ 5, 24–30. But it did not undertake any of those procedures with respect to weighted infant sleep products prior to making its statement, which is a product safety determination. Congress limited CPSC's power to act with respect to consumer product safety determinations and limited when it can publicly disclose information that adversely reflects on a product's safety. Those provisions must be read in harmony. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) ("A court must ... interpret [a] statute as a symmetrical and coherent regulatory scheme and fit, if possible, all parts into a[ ] harmonious whole." (cleaned up)). And must be followed. *NFIB v. OSHA*, 595 U.S. at 117 ("Administrative agencies are creatures of statute. They accordingly possess only the authority that Congress has provided."). Otherwise, CPSC could achieve by its statements what it cannot achieve through

regulation—elimination of products from the public marketplace. Such an outcome is antithetical to the CPSA's structure and purpose.

Contrary to CPSC's arguments, Br. at 21, 22–23, Dreamland does not ignore CPSC's general authority to disseminate product safety determinations. Dreamland takes the view that CPSC's general authority must be read in conjunction with and respect to the clear limitations Congress placed on it, including when CPSC may make product safety determinations, and what is required of the Commission in doing so. *But see* Br. at 22–23. Principles of statutory construction support this conclusion. "[T]he ancient interpretive principle that the specific governs the general (*generalia specialibus non derogant*) applies only to conflict between laws of equivalent dignity." *Nitro-Lift Techs., L.L.C. v. Howard*, 568 U.S. 17, 21 (2012). This is true even when the provisions at issue are in different statutes. *See Ginsberg & Sons v. Popkin*, 285 U.S. 204, 208 (1932). Or are enacted at different times. *Morton v. Mancari*, 417 U.S. 535, 550–51 (1974) ("[A] specific statute will not be controlled or nullified by a general one, regardless of the priority of enactment."). This "well-established canon" is premised on the view "that a general provision should not be applied 'when doing so would undermine limitations created by a more specific provision.'" *Coady v. Vaughn*, 251 F.3d 480, 484 (3d Cir. 2001) (quoting *Varity v. Howe*, 516 U.S. 489, 511 (1996)).

Contrary to CPSC's arguments, Dreamland disputes that CPSC's disclosure even falls within its general power to disseminate information. Br. at 21. Based on the text of the CPSA, CPSC can only "disseminate injury data, and information," if it is "relat[ed] to the causes and prevention of death, injury, and illness associated with consumer products[.]" 15 U.S.C. § 2054(a)(1). Undefined words in statutes are given their ordinary meaning. *See Burrage v. United States*, 571 U.S. 204, 210 (2014). A "cause" is "something that brings about an effect or a result[.]" *Cause*, MERRIAM-WEBSTER (last visited July 23, 2025), https://www.merriam-

webster.com/dictionary/cause. But whether a consumer product *causes* death, injury, or illness is a question of fact. Dreamland has alleged that there is no information in the CPSC's possession establishing that weighted infant sleep products cause injuries. Compl. ¶¶ 74–75, 83–86, 115–16. Yet even here, the CPSC misleadingly and inaccurately suggests that weighted infant sleep products "can cause of risk of suffocation[.]" Br. at 22. But there is no evidence supporting a causal relationship between weighted infant sleep products and a risk of suffocation. *See*, *e.g.*, Compl. ¶ 56 (weighted blanket study AAP cited in revised guidelines suggested evidence of safety); Compl. ¶ 86 (no hazard pattern found regarding weighted infant sleep sacks and swaddles). And CPSC exceeded its authority in making its determination in light of the lack of evidence supporting it.

Likewise, CPSC's decision not to retract its unauthorized, misleading, and inaccurate determination exceeded its statutory authority. Faced with clear and unambiguous claims that its disclosure was misleading and inaccurate, running ran afoul of the CPSA and its implementing regulations, *see* Doc. 1-1, CPSC continued its willful blindness to the real-world implications of its disclosure and how it was perceived. It also continued to ignore that it was without any data or evidence supporting its decision. Dreamland's allegations are not conclusory, CPSC's adoption of the determination that weighted infant sleep products should not be used was. In acting in such a manner, it exceeded its statutory authority, and Dreamland adequately pleaded as much.

II. DREAMLAND ADEQUATELY ALLEGES THAT NIH'S AND CDC'S DETERMINATIONS WERE *ULTRA VIRES* (COUNT TWO)

Contrary to the CDC's and NIH's assertions, Dreamland's claim that HHS, CDC, and NIH acted *ultra vires* is not a "gambit," Br. at 24, rather it reflects careful consideration of existing precedent and an understanding of the principles of statutory construction and administrative law. While Defendants lean on their general statutory authority to inform the public about health-related concerns, they ignore Plaintiff's key contention—that CPSC, and only CPSC, is authorized by

statute to make consumer product safety determinations in the first instance. *Compare* Br. at 24–27 *with* Compl. ¶¶ 60–61, 102, 104, 126–27, 153–56, 186. What the CDC and NIH try to recast as providing health information to the public within their general statutory authority or their inherent authority to communicate is, as Dreamland has alleged, an impermissible arrogation of authority to determine the safety of consumer products granted exclusively to CPSC.

Count Two of the Complaint satisfies the three-part test for *ultra vires* agency action articulated in *Federal Express Corp. v. U.S. Dep't of Commerce*, 39 F.4th 756, 763 (D.C. Cir. 2022). *First*, "there is no express statutory preclusion of all judicial review" in either the CPSA or the PHSA, and Defendants do not argue otherwise. *Id. Second*, "there is no alternative procedure for review of the statutory claim" because, as CDC and NIH admit, their determinations are not final agency action, nor does Dreamland allege that they are. *Id.* While Defendants approach this point as some sort of trump card regarding Count Two, it is precisely because CDC's and NIH's determinations are not final agency action under the APA that there is no alternative procedure for challenging them. *See Apter v. Dep't of Health & Hum. Servs.*, 80 F.4th 579, 593 (5th Cir. 2023) (noting that "several other circuit courts have applied the common-law doctrine only when APA review was unavailable" and collecting cases). The primary dispute then is as to the third factor: whether CDC and NIH "plainly act[ed] in excess of [their] delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory." *Fed. Express*, 39 F.4th at 763 (citation and quotation omitted). Contrary to Defendants' assertion, this case is one of the rare and extreme instances of agency error that permits *ultra vires* review, and Dreamland alleged as much.

CDC's and NIH's "overstep [is] 'plain on the record and on the face of the [statute].'" *Id.* at 765 (quoting *Oestereich v. Selective Serv. Sys. Loc. Bd. No. 11*, 393 U.S. 233, 238 n.7 (1968)). Unlike most *ultra vires* challenges, which concern an agency's error regarding its own statutory

authority, this case requires the Court to resolve an *ultra vires* challenge based on agencies arrogating the authority expressly provided to another agency under a different statute. *See, e.g.*, Compl. ¶ 162. Here, CDC and NIH defend their actions under the general provisions of the PHSA providing that HHS and its subagencies may disseminate or make health information available to the public regarding "sudden unexpected infant death." Br. at 25–26 (citing 42 U.S.C. §§ 300c-13(a)(2), 300c-11(a), 300u-3(1)). And they argue that these general provisions "plainly authorize NIH's and CDC's challenged statements." Br. at 25. Likewise, they invoke HHS's general authority to conduct research and make information available regarding "AAP's study of the evidence relating to sleep-related infant deaths and its recommendations based on such study[.]" Br. at 26. But the PHSA's general provisions are not the controlling provisions, the CPSA is. And the CPSA only permits the Commission to make product safety determinations when it is "reasonably necessary to prevent or reduce an unreasonable risk of injury" through regulation or file a district court action to seize "imminently hazardous" products that "present[] imminent and unreasonable risk of death, serious illness, or severe personal injury" or recall products that present a "substantial product hazard[.]" 15 U.S.C. §§ 2056, 2058, 2061, 2064. To the extent that public information is disclosed that reflects on the safety of consumer products, Congress has limited when, how, and on what basis, CPSC may speak. 15 U.S.C. § 2055. Stated another way, the "congressionally drawn line in the sand" that CDC and NIH "plainly and openly crossed" in making their determinations is the CPSA, not the PHSA. As discussed, principles of statutory construction support this conclusion. *See supra* p. 21.

Here, Dreamland alleges that Congress placed specific limitations on when, how, and on what basis CPSC may determine a product's safety, and address product safety concerns. Compl. ¶¶ 5, 24–30. In comparison, the PHSA only generally authorizes dissemination of certain health

information as related to general topics like "sudden unexpected infant death," or "child care," "disease prevention," and "safety and accident prevention." *Compare* Br. at 25 *with supra* pp. 21–22. Thus, PHSA's general statutory provisions "must be construed in a manner that will accommodate" the more specific requirements of the CPSA. *See Nat'l Republican Cong. Comm. v. Legi-Tech Corp.*, 795 F.2d 190, 192 (D.C. Cir. 1986).

For similar reasons, the CDC's and NIH's arguments asserting an inherent authority to speak also fail. Br. at 27 (citing Br. at 21–22); *see also supra* pp. 20–22. Unlike the City of Boston, the CDC and NIH "possess only the authority that Congress has provided." *NFIB v. OSHA*, 595 U.S. at 117. Thus, their inherent authority to speak is circumscribed by what powers Congress has given to them and the limitations it places on them. *Cf. Ivy Sports Med., LLC*, 767 F.3d at 86; *Tokyo Kikai Seisakusho, Ltd.*, 529 F.3d at 1361.

In the present case, construing the PHSA to accommodate the CPSA's more specific requirements simply means that when a statement is a consumer product safety determination, *i.e.*, it reflects on the safety of consumer product or declares whether a product should be used, CPSC should speak first after it fulfills its statutory obligations. Again, what Dreamland has alleged occurred here is an order of operations problem. CDC and NIH—who are not authorized to make product safety determinations—spoke first stating that weighted infant sleep products should not be used and inferring that they are "dangerous" or unsafe products. *See* Compl. ¶¶ 61–64. CPSC—who is charged with making such product safety determinations—then relied on CDC's and NIH's determinations as the basis for its disclosure, despite there being no evidence supporting the determinations. *See* Compl. ¶¶ 74–86. Under this order, CDC's and NIH's determinations regarding the safety of weighted infant sleep products are *ultra vires*.

But such a construction does not mean that CDC or NIH are always restricted from disseminating public health information regarding consumer products, or that the PHSA's general provisions are superfluous. *See FCC v. NextWave Pers. Commc'ns Inc.*, 537 U.S. 293, 304 (2003) ("'[W]hen two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective.'" (citation omitted)). Take for example the Defendants' recommendations regarding inclined sleeping products. *See* CPSC, *Safe Sleep – Cribs and Infant Products* (last visited Jul. 23, 2025), https://www.cpsc.gov/SafeSleep (stating that "[i]nclined products with an angle greater than 10º … *should never be used for infant sleep*" (emphasis in original)); *see also* NIH, *Safe Sleep Environment for Baby*, https://safetosleep.nichd.nih.gov/reduce-risk/safe-sleep-environment (last visited July 23, 2025) (noting that safe sleep environments should not include "an angle or incline").[4] Inclined sleepers are banned hazardous products under 15 U.S.C. § 2057d and 16 C.F.R. part 1310. Therefore, the CPSA places no limits on CDC's or NIH's ability to communicate that such products are unsafe for infant sleep and should not be used.

Moreover, it is questionable that CDC's and NIH's determinations even meet the requirements of the PHSA as they suggest. Br. at 25–26. As the Complaint alleges, there is no evidence or data establishing that weighted infant swaddles pose any danger to babies. *See, e.g.,* Compl. ¶¶ 6, 57–59; 70, 74–75, 78–80, 83–86, 115–16. CDC and NIH did not independently study these products, or review incident data related to them prior to making their determinations. Compl. ¶¶ 65, 115. Nor did they provide any disclaimer indicating that they had done so. Instead, they simply adopted and repeated AAP's recommendation, without clear attribution. *Id.* ¶ 60. That

[4] The Court may take "judicial notice of information posted on official public websites of government agencies." *Pharm. Rsch. & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 33 (D.D.C. 2014).

recommendation relied on AAP's consideration of a single study, which it noted "found no adverse events" related to the use of a 1-pound weighted blanket with NICU infants. *Id.* ¶ 57. While AAP observed that "no studies have documented the safety of weights for infants in an unobserved, nonclinical sleep environment[,]" as the Complaint alleges, the AAP was reacting to a lack of safety evidence and theoretical concerns, even though the study AAP relies on shows some evidence of safety. *Id.* ¶¶ 58–59. It is hard to surmise how, in the absence of data or research, CDC and NIH could have determined that these statements relate to "sudden unexpected infant death," "disease prevention," "safety and accident prevention," or "causes … and prevention of physical and mental diseases." Br. at 25–26 (citing 42 U.S.C. §§ 241(a), 300c-13(a)(2), 300c-11(a), 300u-3(1)). In any event, CDC and NIH cannot overcome the fact that their statements were product safety determinations, which are specifically controlled by the CPSA.

III. DREAMLAND ADEQUATELY ALLEGES THAT COMMISSIONER TRUMKA'S DISCLOSURES WERE *ULTRA VIRES* (COUNT THREE)

CPSC has admitted that Commissioner Trumka's actions were made in his individual capacity and were not done on behalf of the Commission. Compl. ¶¶ 140–43. They have also argued that APA review is unavailable because deadlocked votes do not constitute final agency action. Br. at 20-21, 31, 35. Thus, "there is no alternative procedure for review of the statutory claim" that Commissioner Trumka violated § 2055(b). *Fed. Express*, 39 F.4th at 763. As with Count Two, the primary dispute regarding Count Three is whether Commissioner Trumka "plainly act[ed] in excess of [his] delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory." 39 F.4th at 763.

Contrary to Commissioner Trumka's argument that his liability is predicated on CPSC exceeding its power, Br. at 28, the *ultra vires* action here is based on his own unlawful disclosures and actions in excess of his statutory authority. *See* Compl. ¶¶ 169–70. As Dreamland alleged,

Commissioner Trumka lacked data and evidence to make the product safety determination that he did. *See*, *e.g.*, Compl. ¶¶ 168–69, 203. He was aware that the Commission lacked that information when it rejected his attempt to promulgate mandatory safety standards for weighted infant sleep products. Compl. ¶¶ 74–76, 203. He did not merely step beyond § 2055(b)'s bounds. He acted in clear defiance of § 2055(b), made a mockery of its limitations, and ignored the CPSC's internal processes. Compl. ¶ 139. Unfortunately for Commissioner Trumka, the adage that "it is better to ask for forgiveness than permission" does not apply under § 2055(b).

Commissioner Trumka's argument that he was merely repeating the CPSC's disclosure is demonstrably false. Even if CPSC's disclosure was permissible, Commissioner Trumka did not merely repeat that recommendation, *see* Br. at 28, he expanded and embellished it, with devasting effects for Dreamland's business and reputation. Compl. ¶¶ 1, 99. At the time of Trumka's pronouncements CPSC merely recommended, "**Don't** use weighted blankets or weighted swaddles*. … *NIH.gov and CDC.gov", while linking to certain pages on those agencies' websites. Compl. ¶ 77–79 (emphasis in original); Doc. 1-1 at 7, 20.

But consider for a moment, the series of disclosures that Commissioner Trumka made on April 15, 2024.[5] In his public statement, he cites to the AAP's unsupported claims to suggest that weighted infant sleep products "'can lead to lower oxygen levels, which … may be harmful to the developing infant's brain.'" Doc. 1-1 at 36; Compl. ¶ 89.[6] In his X.com post linking to that same

[5] His other challenged disclosures likewise go well beyond repeating CPSC's disclosure. *See* Doc. 1-1 at 46–60. The Complaint also alleges that Commissioner Trumka made similar disclosures in meetings with retailers and interest groups, but Dreamland was not privy to those. *See* Compl. ¶ 96; Doc. 1-1 at 15 & n.87, 62.

[6] The statement cites that AAP statement to the *Washington Post* article at issue in this case, though the quoted claim is nowhere in that article. *Compare* Doc. 1-1 at 36 n.4 *with* 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-

public statement, he wrote that "Companies will try to fool you into thinking [weighted infant sleep products are] 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." Doc. 1-1 at 39; Compl. ¶¶ 89–90. The X.com post is accompanied by a video that includes an image of a swaddled infant with two dumbbells crisscrossed over the child's chest and superimposed with a general prohibition sign over the image. Doc. 1-1 at 39; Compl. ¶ 91.[7] Commissioner Trumka's Instagram post is nearly identical, but he states, "Read *our* full statement using the link in bio[,]" which implies that his public statement was the Commission's view (the public statement was made on CPSC letterhead and did not disclose that it represented solely his views) Doc. 1-1 at 41 (emphasis added); Compl. ¶¶ 89, 91, 140. Commissioner Trumka's messages insinuate that weighted infant sleep products will crush infants, damage their brains, and potentially kill them; that companies are duping consumers into buying these products; and, that CPSC, CDC, and NIH share those views. But none of that is true, and his statements clearly convey new information beyond what CPSC had previously disclosed. Compl. ¶ 90. By comparison, the CPSC's disclosure, though still unlawful, is prosaic.

Commissioner Trumka's second argument—that 15 U.S.C. § 2055(b)(1) does not apply to his disclosures—is incorrect. *See* Br. at 28–31. As discussed, his disclosures contained new information. His footnote argument that violation of § 2055(b)(1)'s implementing regulations cannot support an *ultra vires* claim should not be credited. *See CTS Corp. v. EPA*, 759 F.3d 52, 64 (D.C. Cir. 2014) (noting that "[a] footnote is no place to make a substantive legal argument"). Even

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blanketsunsafe. Curiously, an AAP statement supporting Commissioner Trumka's actions cites this claim to Trumka himself. *See* Steve Scherling, AAP News, *AAP leaders call decision to pull harmful weighted sleep products a 'strong first step'* (Apr. 29, 2024), https://publications.aap.org/aapnews/news/28768/AAP-leaders-call-decision-to-pull-harmful-weighted.

[7] Commissioner Trumka did include a (barely legible) disclaimer stating "[w]eights and baby not shown to scale. For illustrative purposes only." Doc. 1-1 at 39; Compl. ¶ 91.

if this Court were to consider that argument, it defies the basic principle of administrative law that federal agencies, including agency commissioners, must follow their own rules. *See Steenholdt v. FAA*, 314 F.3d 633, 639 (D.C. Cir. 2003). Commissioner Trumka is bound both by § 2055(b)(1) and its implementing regulations, which impose the same requirement that a manufacturer be notified and provided a summary of the information *before* a disclosure is made that "will permit the public to ascertain readily" its identity. *Compare* 15 U.S.C. § 2055(b)(1) *with* 16 C.F.R. §§ 1101.1(b)(1), 1101.13. This is true even if, as he has publicly admitted, he disagrees with the statute and its implementing regulations. *See, e.g.*, Comm'r Trumka, Statement, *CPSC Must Fix Gag Rule Regulations so Consumers Can Protect Their Families* (Feb. 8, 2023), https://www.cpsc.gov/About-CPSC/Commissioner/Richard-Trumka/Statement/CPSC-Must-Fix-Gag-Rule-Regulations-so-Consumers-Can-Protect-Their-Families. His actions in violation of either the statute or the regulations are *ultra vires*.

Commissioner Trumka's argument that § 2055(b)(1) does not apply because he did not specifically say "Dreamland" within the four-corners of his disclosures also fails. *See* Br. at 29–31. Section 2055(b)(1) requires the Commission, or a Commissioner, to "notify and provide a summary of the information" to the manufacturer that the information "pertains" to "if the manner in which such consumer product is to be designated or described in such information will permit the public to ascertain readily the identity of such manufacturer or private labeler[.]" 15 U.S.C. § 2055(b)(1).Such notice must be given "not less than 15 days prior to [the information's] public disclosure[.]" *Id.* And "shall provide such manufacturer … with a reasonable opportunity to submit comments to the Commission in regard to such information." *Id.* The Commission "shall take reasonable steps to assure, prior to its public disclosure thereof, that information from which the identity of such manufacturer or private labeler may be readily ascertained is accurate, and that

such disclosure is fair in the circumstances and reasonably related to effectuating the purposes of [the CPSA]." *Id.*

As Dreamland alleges, and Commissioner Trumka does not dispute, he completed none of the statutorily required actions before he made the challenged disclosures. *See* Compl. ¶ 139. Moreover, the Commission's clearance process would have required that Commissioner Trumka's public statements, letters, and social media posts to be reviewed by the "appropriate Offices/Directorates for technical, program and legal review." *Id.* (quoting Doc. 1-4 at 9). Stated another way, CPSC's own internal processes required a second impartial set of eyes beyond the self-serving consideration of these disclosures by Commissioner Trumka or his staff. His failure to seek out that review is telling.

Commissioner Trumka's public statements, letters, and social media posts publicly disclosed information, *i.e.*, his specific unsubstantiated claims that weighted infant sleep products are dangerous (or deadly), in a manner that allowed the public to readily ascertain its identity because the statements included citations to a news article that specifically identified Dreamland and searches that included its products on its retailers' websites. Compl. ¶¶ 88, 107–109; *see also* Doc. 1-1 at 30, 36, 48–55. Moreover, the public did ascertain Dreamland's identity because retailers stopped selling its products after he wrote to them. Also, multiple news outlets reached out to Dreamland shortly after Commissioner Trumka's statements were made public. Compl. ¶¶ 9–10, 132, 99. Dreamland was provided no notice of the public statements, letters, or social media posts before they were made as required by the statute. These factual allegations are sufficient at this preliminary stage to state a claim for relief. *See Iqbal*, 556 U.S. at 678.

Commissioner Trumka's strained reading of § 2055(b)(1) and his reliance on CPSC's interpretation of 16 C.F.R. § 1101.13 does not support dismissal of Count Three. Br. at 29–31. This

argument is premature. And, even if it is not, it still fails. He attempts to argue that "the contents of third-party documents that are *referenced* in a Commissioner's statements are not relevant in determining whether 15 U.S.C. § 2055(b)(1) applies[,]" Br. at 29. But that "reference" limitation is not found anywhere in the text of the statute, which controls, and the CPSC's interpretation is entitled no deference. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 403, 413 (2024). Commissioner Trumka's invocation of the regulation's preamble to suggest that he was not required to "look beyond the face of the document to determine whether the identity of a manufacturer can be ascertained[,]" Br. at 30, is "unavailing" because it "is not controlling over the language of the regulation itself[.]" *Wyo. Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 53 (D.C. Cir. 1999) (citation omitted). At best "the preamble to a regulation is evidence of an agency's contemporaneous understanding of its proposed rules[.] *Id.* (citation omitted). But there is little work for the preamble or the implementing regulations to do here. The statute controls and Dreamland has alleged a violation of § 2055(b).

Commissioner Trumka's argument also makes no sense and is counter to how people regularly and routinely interact with information, citations, and hyperlinks. For example, someone (likely Commissioner Trumka or his staff) chose to include both the *Washington Post* article and the search hyperlinks that name Dreamland in his communications.[8] As to the latter, and contrary to Commission Trumka's arguments, searches for products do not just exist, they must be created. Here, the searches that were created, either by Commissioner Trumka or his staff, identified Dreamland's products. Compl. ¶ 109. He then provided those searches to the retailers in his letters,

[8] Commissioner Trumka's public statements and letters to retailers quote directly from the *Washington Post* article, so it is not plausible that he, or his staff, were unaware that the article specifically names Dreamland as a manufacturer of weighted infant sleep products. *See, e.g.,* Compl. ¶¶ 88, 107; Doc. 1-1 at 36, 49. Nor does he argue that he was unaware the article named Dreamland.

alongside his unsupported allegations that the products included in that created search may seriously harm or kill an infant. *See*, *e.g.*, Doc. 1-1 at 54–55. By combining his statements with the information he cited, he created a new public disclosure. That is a clear and direct violation of § 2055(b)(1) because the information he disclosed identified Dreamland's products. Dreamland alleged as much for these and the other challenged statements.

IV. DREAMLAND ADEQUATELY ALLEGES THAT CPSC ACTED ARBITRARILY OR CAPRICIOUSLY (COUNT FOUR)

The APA 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). Agency actions are arbitrary and capricious when, as here, the agency has:

> relied on factors which Congress has not intended it to consider, 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). The CPSC's statement is final agency action. *See supra* pp. 14–19. Even if CPSC's statement is not final agency action, Dreamland is entitled to relief because CPSC's decision not to retract its disclosure is final agency action subject to this Court's review and Commissioner Trumka's disclosures are subject to review under Count Three.

Dreamland alleged that CPSC did not adhere to its internal clearance process. Br. at 32. That process requires CPSC to clear disclosures by a "careful review" of the information to be disclosed. Doc. 1-4 at 7.a. The Clearance Procedures also require the cleared statements to be supported by "data in Commission files[.]" Doc. 1-4 at 7.a.(1)(a). Which Dreamland has adequately alleged CPSC did not do. *See*, *e.g.*, Compl. ¶¶ 6, 8, 81, 85–86, 150, 168. CPSC's disclosure was arbitrary and capricious because the data they had in their possession was an

important aspect that they failed to consider. Arguably, CPSC's reliance on CDC, NIH, AAP "relied on factors which Congress had not intended it to consider" which is also arbitrary. *State Farm*, 463 U.S. at 43.

CPSC's arguments regarding its reliance on CDC's and NIH's determinations, Br. at 33–34, fails because CDC and NIH are not authorized to make product safety determinations in the first instance. *See supra* pp. 22–27. As CPSC argues, it is permitted to outsource its core power—determining whether consumer products are safe—because CDC and NIH have statutory authority to educate the public and the information is complementary to CPSC's information and mission. *See* Br. at 33–34. But if that is so, then there is no need for the CPSC and no purpose for dictating its procedures. If CDC and NIH can freely make product safety determinations and warn the public about consumer products in the name of public health, then most of the CPSA's purposes can be achieved by other agencies through their public statements. *See*, *e.g.*, 15 U.S.C. §§ 2051, 2054. But that is not the system Congress carefully proscribed. Congress determined that CPSC would oversee determinations about whether consumer products are safe by empowering them to address unreasonable risks of injury or "imminent and unreasonable risk of death, serious illness, or severe personal injury" or product defects that create "substantial risk of injury to the public" for such products *and* limiting statements made without adequate procedures. *See*, *e.g.*, 15 U.S.C. §§ 2055, 2056(a), 2058, 2061(a), 2064. That is not what happened here. Here, CPSC said not to use weighted infant sleep products, inferring that they are unsafe, because CDC and NIH said they are unsafe. Compl. ¶¶ 121–25; Doc. 1-5 at 2–3. Those agencies in turn merely parroted AAP's unsubstantiated recommendation. Compl. ¶¶ 54–65, 125–26.

CPSC also seems to argue that because it went through its clearance process and "it was reasonable for CPSC to cite and rely on" CDC and NIH, its decision to publish its statement was

not arbitrary or capricious. Br. at 33–34. But Dreamland has alleged that CPSC's decision was not reasonable because those agencies are not charged with determining product safety and did not study the safety of weighted infant sleep products before making their recommendation. Compl. ¶¶ 64–65, 118–20. CPSC's blind reliance on CDC and NIH (and ultimately the AAP) is the definition of arbitrary and capricious decisionmaking, especially when, as here, CPSC is the agency charged with determining whether consumer products are safe. CPSC's argument that its reliance on CDC and NIH is reasonable because the Commission says its reasonable is not sufficient to defeat Dreamland's well-plead allegations to the contrary.

CPSC also attempts to argue that the Commission did not act contrary to the information in its possession because the standard for federal regulation and "that needed to make a non-binding public statement are different." Br. at 34. But that argument runs directly counter to its own clearance process which requires statements to be supported by "data in Commission files[.]" Doc. 1-4 at 3 (¶ 7.a.(1)(a)). CPSC's general dissemination powers are also limited to "causes" or prevention of certain incidents, which requires at least some fact-bound or data-driven consideration to be made. 15 U.S.C. § 2054(a)(1); *see also supra* pp. 21–22. CPSC also misunderstands or mischaracterizes the data at issue in this case. *See* Br. at 34–35. As Dreamland alleged, there is no data or evidence supporting an across-the-board determination against using weighted infant sleep products. Compl. ¶¶ 74–75, 83–86, 115–16. The data referred to in Paragraphs 83–86 of the Complaint was an attempt by CPSC "[t]o provide the most comprehensive data possible" related to wearable infant blanket products, which includes weighted and non-weighted products. Compl. ¶ 84.[9] That dataset—for *all* wearable infant blankets—includes a total

[9] Full data-set *available at* https://www.cpsc.gov/content/Infant-Blanket-Spring-2024-ASTM-Cover-Letter-and-Spreadsheet. *Infant Blanket Spring 2024 ASTM Cover Letter and Spreadsheet*, CPSC (July 2, 2024).

of 167 incidents (including deaths and injuries). *Id.* CPSC seems to suggest that those incidents were all for weighted products, *see* Br. at 34–35, but that is not so. As the Complaint noted, CPSC's data was independently reviewed and only "13 incidents (deaths + injuries) involve[ed] weighted sleep products." Compl. ¶ 86. That independent review stated that there was no hazard pattern[10] found among the incidents with weighted sleep products. This data, showing *no* hazard pattern as to weighted wearable blankets, was available to CPSC in December 2023 when it made its statement. Dreamland's allegations are not conclusory because CPSC's determination, which weighted infant sleep products should not be used (inferring that they are dangerous), was counter to the evidence in its possession. That is sufficient to plead a claim under § 706(2)(A).

V. DREAMLAND ADEQUATELY ALLEGES THAT CPSC FAILED TO OBSERVE PROCEDURES REQUIRED BY LAW (COUNT FIVE)

The APA 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). A court's "review of an agency's procedural compliance with statutory norms is an exacting one." *Nat. Res. Def. Council, Inc. v. SEC*, 606 F.2d 1031, 1048 (D.C. Cir. 1979). Agencies "must adhere firmly to self-adopted rules by which the interests of others are to be regulated." *Mass. Fair Share v. Law Enf't Assistance Admin.*, 758 F.2d 708, 711 (D.C. Cir. 1985). And where, as here, "the rights of individuals are affected, it is incumbent upon agencies to follow their own procedures." *Ruiz*, 415 U.S. at 235. "This is so even where the internal procedures are possibly more rigorous than otherwise would be required." *Id.* Even if the CPSC's statement is not final agency action, Dreamland is entitled to relief because CPSC's decision not to retract its statement is final agency action subject to this Court's review and Commissioner Trumka's statements are

[10] A hazard pattern is how an injury usually happens with a particular product.

subject to review under Count Three. CPSC does not contest that it did not clear NIH's disclosure *before* it was made, as it was required to do.

CPSC's arguments that it was not required to clear NIH's Safe to Sleep® Campaign statement are wrong. Contrary to CPSC's argument, Br. at 36, NIH's statements were not "NIH-initiated," they were made as part of the Safe to Sleep® Campaign in which CPSC collaborates. *See* Br. at 26–27, 33; *see also* Compl. ¶ 53. As Dreamland alleged, and CPSC does not contest, the Safe to Sleep® Campaign is a "Joint Project" and is governed by paragraph h. of CPSC's Clearance Procedures. *See* Compl. ¶¶ 117–18, 191; *see also* Doc. 1-4 at 10–11 (¶ h). Those procedures require that "[a]ny material, in any form, to be disseminated to the public must be 6(b) cleared in accordance with paragraph 7." Doc. 1-4 at 10 (¶ h.(2)). It does not matter, as CPSC contends, Br. 35–36, that these requirements are not explicitly included in § 2055(b) or its implementing regulations. Having adopted a more rigorous procedure that applies to *any* material in *any* form that is publicly disseminated by Joint Projects, like the Safe to Sleep® Campaign, the Commission was bound to clear the disclosures on NIH's website through the process outlined in paragraph 7 of Directive 1450.2. *See Ruiz*, 415 U.S. at 235. But as Dreamland alleges, CPSC did not clear NIH's statement made as part of the Safe to Sleep® Campaign, and at issue here. That is a clear failure to follow required procedures in violation of the APA.

CPSC argues that despite its procedural failing, Dreamland is not entitled to any relief because "there is no CPSC action that this Court could compel or set aside that would afford Dreamland any meaningful relief." Br. at 36. But that is incorrect, the economic and reputational harm that Dreamland has suffered are a direct result of the uncleared disclosure. The meaning, and gravitas, of this statement turns in part on whether it has been reviewed and vetted. A determination

and declaration[11] from this Court that the Commission failed to follow its procedural obligations by reviewing NIH's Safe to Sleep® Campaign statement *before* it was made public would help remediate Dreamland's harm because it could show that the disclosure was not properly vetted by the agency charged with determining whether products are safe in the first instance.

Finally, CPSC's invocation of the harmless-error doctrine is premature, Br. at 36–37, as it asks this Court to weigh the evidence and narrowly construe the Complaint in its favor, rather than the liberal construction to which Dreamland is entitled. *Zukerman*, 961 F.3d at 441; *see also St. Francis Xavier Parochial Sch.*, 117 F.3d at 624–25 (courts "may consider only the facts alleged in the complaint, any documents either attached to or incorporated in the complaint and matters of which [it] may take judicial notice"). As the Supreme Court has cautioned, "determining whether an error is harmless" requires "case-specific application of judgment, based upon examination of the record." *Shinseki v. Sanders*, 556 U.S. 396, 407 (2009). But the full administrative record in this case has not been yet produced, and a "record" that is only CPSC's self-serving analysis, Br. at 37, does not count. Moreover, harmless error "is an affirmative defense to liability" not a basis for dismissal before a factual record can be developed. *See Christensen v. United States*, 60 Fed. Cl. 19, 26 (2004) (collecting cases). The procedural violation alleged here is binary, the CPSC either followed its procedures or it did not. Dreamland has alleged that it did not; that is sufficient at this stage to defeat a motion to dismiss.

VI. THIS COURT HAS SUBJECT-MATTER JURISDICTION OF DREAMLAND'S DUE PROCESS CLAIMS AND ITS ALLEGATIONS ARE NOT SPECULATIVE (COUNT SIX)

Commissioner Trumka tries to suggest Dreamland's claims are speculative, to defeat this Court's jurisdiction over Dreamland's due process. But his argument ignores the many ways that

[11] Dreamland has sought injunctive and declaratory relief pursuant to both the APA and the Declaratory Judgment Act. *See* Compl. ¶ 18 and Relief Requested.

his biased views infect ongoing processes before the Commission related to Dreamland or weighted infant sleep products. "Just exactly how the concept of 'due process' is to be applied will vary with the type of proceeding involved[.]" *Amos Treat & Co. v. SEC*, 306 F.2d 260, 263 (D.C. Cir. 1962). As alleged, Dreamland's injuries—financial harm, reputational damage, and deprivation of statutory process—have either occurred or are ongoing. There can be little doubt that Commissioner Trumka's actions, which caused significant ongoing financial harm, interfere with Dreamland's "property." *See* Compl. ¶ 99. His actions also impact Dreamland's "liberty" and "property" interests to engage in its chosen lawful occupation, developing and selling infant weighted sleep products, "free from unreasonable governmental interference[.]" *Cf. Greene v. McElroy*, 360 U.S. 474, 492 (1959). As long as Commissioner Trumka is a member of the Commission, he still wields power that can continue to harm those protected interests.

Commissioner Trumka narrowly reads Dreamland's due process claim as being based on "future agency rulemaking" or "possible future claims," Br. at 38, but that is not what Dreamland alleges. The allegations made and the remedies sought relate to the many ways CPSC Commissioners impact agency decision-making, or, as here, act on their own accord and in defiance of procedural protections, to the detriment of Dreamland's protected interests. Those actions are not strictly limited to rulemaking processes. For example, here Commissioner Trumka attempted to have a mandatory standard promulgated by adding it to the CPSC's annual operating plan. Compl. ¶¶ 66–68. And he spoke in violation of § 2055(b) without following CPSC's clearance process. Compl. ¶ 139. Commissioner Trumka's failure to follow the processes required by § 2055(b) deprived Dreamland of the procedural and judicial protections to which it was entitled. *See*, *e.g.*, 15 U.S.C. § 2055(b)(3)(A) (providing right to seek judicial review *before* statements are made). There can be little doubt that his bias towards these products played a role

in his decisions to conceal his actions from scrutiny by the Commission and Dreamland. Compl. ¶¶ 93–94, 96–97, 139. And there is nothing stopping him from doing the same in the future. These harms are not speculative, Br. at 38, they are real, concrete deprivation of rights driven by Commissioner Trumka's bias that will continue so long as he is a member of the Commission or until this Court intervenes.

Commissioner Trumka's reliance on the D.C. Circuit's *Jarkesy v. SEC* decision, Br. at 39, is misplaced. 803 F.3d 9 (D.C. Cir. 2015). The prejudgment issue in that case arose in the context of an agency adjudication and was based on the agency's acceptance of settlements with other individuals. *See Id.* at 22–23. Here, the challenged bias is Commissioner Trumka's clear belief that weighted infant sleep products are dangerous and that they should not be available for sale, despite an absence of evidence or data supporting that belief. *See supra* pp. 8–10, 27–29 (discussing Commissioner Trumka's statements). Unlike the conduct in *Jarkesy*, prejudicial statements made by Commissioner Trumka on his own accord and "outside an authorized proceeding" are likely to signal a due process violation. *Zen Magnets, LLC v. CPSC*, 968 F.3d 1156, 1171 (10th Cir. 2020). As the Tenth Circuit noted, recusal before an action is taken is a permissible method to address impermissible bias based on prior conduct. *See id.* at 1168. And in any event, the D.C. Circuit's *Jarkesy* decision may no longer be good law. *See Axon Enter., Inc. v. FTC* and *Cochran v. SEC*, 598 U.S. 175, 185 (2023) (noting "that the review schemes set out in the Exchange Act … do not displace district court jurisdiction over [plaintiff's] far-reaching constitutional claims"). As the Supreme Court has recognized, agencies, or their officers, have no special expertise in constitutional interpretation. *Id.* at 195. Whether Commissioner Trumka is unconstitutionally biased falls outside of the CPSA's judicial review provision for rulemakings. *See* 15 U.S.C. § 2060; *cf. Amos Treat & Co.*, 306 F.2d at 265 ("We are confronted by a situation where the asserted

infirmity is fundamental."). And Dreamland is not required to wait for a rulemaking process to challenge his deprivation of its due process rights.

Commissioner Trumka's arguments against the existence of bias are also premature. *First*, a bias determination requires a factual inquiry into both the "context and content" of the statements. *Zen Magnets*, 968 F.3d at 1168–69. But the evidence here is only preliminary and only includes publicly available information. Even with that limitation, Dreamland has included sufficient factual matter, which it is entitled to have accepted as true, as to Commissioner Trumka's biased actions. *Iqbal*, 556 U.S. at 678. It has also sufficiently pleaded that his violative actions are not limited to only those that are publicly known. Compl. ¶¶ 94, 96; Doc. 1-1 at 15 & n.87, 62. The question at this stage is not whether Dreamland will ultimately prevail, "but whether [it] is entitled to offer evidence to support [its] claims." *Koch*, 759 F. Supp. 2d at 72.

Second, Commissioner Trumka's reliance on the "presumption of regularity" cannot defeat Dreamland's well-pleaded allegations. That presumption may be "rebutted through clear or specific evidence." *Riggs Nat. Corp. & Subsidiaries v. Comm'r of Int. Rev.*, 295 F.3d 16, 21 (D.C. Cir. 2002). Dreamland has pleaded clear and specific evidence of Commissioner Trumka's bias. He only took his actions after his attempt to regulate these products failed. Compl. ¶ 69. He also criticized his fellow Commissioners for not adopting his amendment. Compl. ¶ 72. Undeterred, he formulated and executed a plan to write to retailers to achieve through a pressure campaign, what he could not achieve through more complete agency action. Compl. ¶¶ 87–99. In those letters and public statements, he made unsubstantiated and harmful claims about weighted infant sleep products and named Dreamland in the process of doing so. *Id.* All in direct violation of § 2055(b). *See supra* pp. 27–33. In the year since he took his actions, he has never bothered to correct the record or remove the public statements, letters, or social media posts. *But see* Compl. ¶ 143

(Commissioner Trumka has added disclaimers to his public statements made after Dreamland's Retraction Request). It is hard to see, given the positions he took, how he could ever walk those public statements back or take an alternative position. *See Cinderella Career & Finishing Sch., Inc. v. FTC*, 425 F.2d 583, 590 (D.C. Cir. 1970) ("Conduct such as [making statement to third parties that they can act more swiftly than the agency to remediate perceived harms] may have the effect of entrenching a Commissioner in a position which he has publicly stated, making it difficult, if not impossible, for him to reach a different conclusion in the event he deems it necessary to do so after consideration of the record."); *see also* Compl. ¶¶ 142–44 (noting that Commissioner Trumka added disclaimers to public statements he made after Dreamland submitted its retraction request but has never clarified the challenged public statements). At this preliminary stage, which is enough to adequately allege that Commissioner Trumka is impermissibly biased.

There is also no way for Dreamland to fully understand the full scope of the actions Commissioner Trumka has or may take that implicate Dreamland's due process rights because Commissioner Trumka's actions have never been fully disclosed publicly. Compl. ¶ 94 (noting meeting with Mercari about Commissioner Trumka's letter to Mercari, which was never publicly disclosed); Compl. ¶ 96 (late-disclosed meeting with Target); Doc. 1-1 at 15 & n.87, 62 (late-disclosed meetings with stakeholders). Or how his actions have influenced his fellow Commissioners. *See Cinderella*, 425 F.2d at 592 ("Litigants are entitled to an impartial tribunal whether it consists of one man or twenty and there is no way which we know of whereby the influence of one upon the others can be quantitatively measured."). And the CPSC shields its Decision-Making Procedures ("DMPs") from public view. *See* Defendant's Motion to Seal, *Boyle v. Trump*, No. 8:25-cv-1628-MJM (D. Md. filed June 18, 2025), ECF No. 35. Putting aside whether it is appropriate for an agency to shield a document governing how it conducts its official business,

Dreamland faces an information asymmetry at this preliminary stage and cannot fully identify all the ways that Commissioner Trumka may interfere with its protected interests in violation of the Fifth Amendment. While Dreamland has met the requirements of standing to satisfy Rule 12(b)(1), jurisdictional discovery is a permissible avenue that would permit it to "present new facts to bolster [its] theory" to the extent that there are lingering concerns. *GTE New Media Servs. Inc. v. BellSouth Corp.*, 199 F.3d 1343, 1352 (D.C. Cir. 2000).

VII. THE COMMISSIONERS' REMOVAL PROTECTIONS VIOLATE THE SEPARATION OF POWERS AND DREAMLAND HAS BEEN HARMED BY THOSE PROTECTIONS (COUNT SEVEN)

While the Motion to Dismiss was pending, CPSC notified the Court that the Department of Justice determined that § 2053(a)'s for-cause removal protections were unconstitutional and that it would no longer defend those protections. ECF No. 10. Despite this, the Defendants maintain that Count Seven of the Complaint should still be dismissed "for failure to state a claim for relief because Dreamland has failed to allege the required harm from the removal protection." *Id.* (citing ECF No. 8-1 at 41–42). But intervening events establish otherwise.

On May 8 and 9, 2025, President Trump fired Commissioners Boyle, Hoehn-Saric, and Trumka. *See Boyle*, 2025 WL 1677099, at *1, *2. The fired Commissioners challenged their removal, summary judgment was entered in their favor, and they were reinstated to their roles. *Id.* at *14–15. The case is currently on appeal to the Fourth Circuit and an application for stay was granted by the Supreme Court. *Trump v. Boyle*, 2025 WL 2056889.

The fired Commissioners all voted against retracting the CPSC's disclosure and provided a letter explaining their reasons for doing so. Compl. ¶¶ 111–27. Commissioners Boyle and Hoehn-Saric voted "to take other action" regarding Dreamland's retraction request as to Commissioner Trumka's disclosures, and Commissioner Trumka voluntarily recused himself from the decision causing a deadlock. Compl. ¶ 128. The remaining Commissioners, Acting Chair Peter A. Feldman

and Commissioner Douglas Dziak, abstained from both votes. Compl. ¶ 135; Doc. 1-7. In a statement, they expressed concern that "the process in this matter was inadequate" and did not provide an opportunity for the Commissioners to "deliberate as a body." Compl. ¶ 136 Doc.1-7. Had the fired Commissioners not been reinstated, the remaining two Commissioners would have constituted a quorum and could have conducted official CPSC business for up to six months. *See* 15 U.S.C. § 2053(d).

This case presents the "compensable harm" scenario contemplated in *Collins v. Yellen*, as President Trump did fire Commissioners Boyle, Hoehn-Saric, and Trumka "but was prevented from doing so by a lower court decision holding that he did not have 'cause' for removal." 594 U.S. 220, 259 (2021); *see also Boyle*, 2025 WL 1677099, at *13 (finding that "removal from their roles as CPSC Commissioners without cause is unlawful"). As the Tenth Circuit noted, establishing harm under *Collins* requires a plaintiff "to make a showing that the challenged removal provisions actually impacted, or will impact, the actions taken by the CPSC against it." *Leachco, Inc. v. CPSC*, 103 F.4th 748, 757 (10th Cir. 2024), *cert. denied*, 145 S. Ct. 1047 (2025); *see also* Br. at 41 (citing same).

The challenged removal provisions impacted or will impact Dreamland. *First*, as a matter of basic math, the retraction request votes would have come out different had the fired Commissioners not participated. For example, the vote to retract Commissioner Trumka's disclosures would not have deadlocked and would unquestionably constitute final and reviewable agency action. *Second,* the remaining Commissioners' statement suggests that if they held the majority, the retraction process would have allowed for a more developed factual record and "opportunity for parties to rebut assertions[.]" Compl. ¶¶ 135–37; Doc. 1-7. Such a process may have obviated the need for this Court's intervention. *Third*, to the extent that the remaining

Commissioners' votes were in part based on their view that review of the disclosures "is best obtained through an Article III court" the CPSC's litigation position in this case directly conflicts with that view. *Compare* Compl. ¶ 138 and Doc. 1-7 *with* Br. at 12–21. A change in the composition of the Commission has real implications for how this matter progresses. If the remaining Commissioners held the majority, it seems unlikely, given their past position that review is available, that they would have challenged, or maintained their challenge, to the Complaint on the same grounds that the Commission has here. *Finally*, Commissioner Trumka's removal from the Commission would obviate the ongoing harm he poses to Dreamland because of his clear bias against it and weighted infant sleep products. Thus, under current circumstances, *Collins* does not stand as a barrier to relief here and Dreamland has adequately alleged that it was harmed by § 2053(a)'s removal restrictions.

CONCLUSION

For the foregoing reasons, the Court should deny the Motion to Dismiss.

REQUEST FOR ORAL HEARING

Pursuant to LCvrR 7(f), Plaintiff respectfully requests an oral hearing on this motion.

Dated this 23rd day of July 2025.

Respectfully submitted,

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