UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

DREAMLAND BABY CO., :

:

Plaintiff.

Civil Action No.: 24-3277 (RC)

v. :

Re Document No.: 6

CONSUMER PRODUCT SAFETY

COMMISSION, et al.,

:

Defendants. :

MEMORANDUM OPINION

GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS

I. INTRODUCTION

Dreamland Baby Co. ("Dreamland") makes and sells weighted sleep blankets, bags, and swaddles for infants and children. Dreamland filed this suit in November 2024 against the Consumer Product Safety Commission ("CPSC" or "Commission"), former CPSC Commissioner Richard Trumka, Jr., in his official capacity, the Department of Health and Human Services ("HHS"), and two of its sub-agencies, the Centers for Disease Control and Prevention ("CDC") and the National Institutes of Health ("NIH") (collectively, "Defendants"). The Complaint seeks declaratory and injunctive relief for (1) violations of the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2), related to CPSC's Safe Sleep guidance advising against the use of weighted blankets and swaddles for infants; (2) *ultra vires* actions based on statements made by HHS, CDC, NIH, and Trumka; and (3) constitutional violations of the Fifth Amendment's due process clause and separation of powers principles. Defendants moved to dismiss the Complaint for lack of subject-matter jurisdiction and failure to state a claim under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). For the reasons stated below, the Court

denies Defendants' motion in part as to Dreamland's arbitrary and capricious claim under the APA, and grants the motion as to the other claims.

II. BACKGROUND

A. Statutory and Regulatory Background

In 1972, Congress passed the Consumer Product Safety Act ("CPSA") in response to growing concerns that "consumer products which present unreasonable risks of injury" were readily accessible to the public, and that existing regulatory frameworks were "inadequate" and potentially "burdensome to manufacturers." 15 U.S.C. § 2051(a)(1), (4), (5); Compl. ¶ 21, ECF No. 1. Through the CPSA, Congress established the CPSC, an independent agency aimed to protect the public against unreasonable risks of injury from consumer products. *See* 15 U.S.C. §§ 2051(b), 2053. The CPSC is comprised of "five Commissioners who shall be appointed by the President, by and with the advice and consent of the Senate," and who "may be removed by the President for neglect of duty or malfeasance in office but for no other cause." *Id.* § 2053(a).

The CPSA requires the CPSC to follow certain procedures when making public disclosures relating to consumer product safety. *Id.* § 2055. Pursuant to Section 6(b) of the CPSA, before the CPSC may publicly disclose information that "will permit the public to ascertain readily the identity of [a] manufacturer or private labeler," the CPSC must typically "notify and provide a summary of the information to" the manufacturer, and provide the manufacturer "a reasonable opportunity to submit comments to the Commission in regard to such information." *Id.* § 2055(b)(1); 16 C.F.R. § 1101.13. The CPSC must also "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

Case 1:24-cv-03277-RC

such disclosure is fair in the circumstances and reasonably related to effectuating the purposes" of the CPSA. 15 U.S.C. § 2055(b)(1); see Compl. ¶ 30.

In addition, the CPSA requires the CPSC to "establish procedures designed to ensure" that the "public disclosure of information that reflects on the safety of a consumer product or class of consumer products . . . is accurate and not misleading," regardless of whether a manufacturer's identity is readily ascertainable. 15 U.S.C. § 2055(b)(6); see Compl. ¶¶ 30, 114. The CPSC has implemented this requirement through its internal clearance process outlined in Directive 1450.2, titled "Clearance Procedures for Providing Information to the Public." U.S. Consumer Prod. Safety Comm'n, Directive Sys. Order No. 1450.2, Clearance Procedures for Providing Information to the Public (Jan. 16, 2003), https://www.cpsc.gov/About-CPSC/Policies-Statements-and-Directives/Clearance-Procedures-For-Providing-Information-To-The-Public-Directives ("Directive 1450.2"), Ex. 4, ECF No. 1-4; see 16 C.F.R. § 1101.1(c); Compl. ¶ 147.1

Directive 1450.2 "describe[s] the clearance procedures to be used when initiating the public disclosure of information that reflects on the safety of consumer products" when the "release of information [is] initiated by the Commission, including information disseminated on the agency's web site, regardless of whether the information disclosed would enable the public to ascertain readily the identity of a manufacturer or private labeler." Directive 1450.2 § 1.a. Appendix B to this Directive establishes the Commission's "Linking Out Policy," which permits the CPSC to "crosslink to content on federal and state government websites and Social Media

¹ For pincites to Exhibits attached to the Complaint, ECF Nos. 1-1 through 1-7, the Court refers to the pagination assigned by the ECF system unless otherwise indicated.

Sites, provided that the content complements safety information issued by the agency and is related to the agency's mission." Directive 1450.2, App. B ¶ 4, Ex. 5 at 3, ECF No. 1-5.

The CPSA also provides a mechanism for retraction of inaccurate or misleading disclosures: "If the Commission finds that . . . it has made public disclosure of inaccurate or misleading information which reflects adversely upon the safety of any consumer product or class of consumer products, or the practices of any manufacturer . . . of consumer products, it shall, in a manner equivalent to that in which such disclosure was made, take reasonable steps to publish a retraction of such inaccurate or misleading information." 15 U.S.C. § 2055(b)(7); see 16 C.F.R. §§ 1101.51–1101.52. Written retraction requests may be submitted by manufacturers to the CPSC, in accordance with 16 C.F.R. § 1101.52(a)–(c). The Commission must act "expeditiously" on such requests, and "promptly notify the requester in writing of its decision on request for retraction" with its reasons for the decision. 16 C.F.R. § 1101.52(d)–(e).

B. Factual and Procedural Background

Dreamland designs, manufactures, and sells weighted sleep products for infants. Compl. ¶¶ 41–50. These products use a "quilted fabric design which allows weight to be evenly distributed throughout the product." *Id.* ¶ 49. Dreamland compares the "gentle pressure provided" by its weighted sleep bag to "placing a slice of bread or American cheese on an infant's chest." *Id.* ¶ 50. Dreamland has sold over one million of these products in the past six years. *Id.* ¶¶ 42, 48.

"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." *Id.* ¶ 51. The campaign aims to reduce sleep-related infant deaths, including those caused by sudden infant death syndrome ("SIDS"). *Id.* ¶ 52. The Eunice Kennedy Shriver National

Institute of Child Health and Human Development, an NIH institute, leads the initiative in collaboration with the CPSC, CDC, and organizations including the American Academy of Pediatrics ("AAP"). Id. ¶ 53.

On June 21, 2022, the AAP updated its safe sleep guidelines, for the first time advising against the use of weighted infant sleep products, such as swaddles and blankets. *Id.* ¶ 54–56. Though the AAP noted a "single crossover randomized nonblinded trial of 16 infants" that "found no adverse events when a 1-pound weighted blanket was placed on each infant for 30 minute observed episodes," the AAP based its recommendation on the fact that "no studies have documented the safety of weights for infants in an unobserved, nonclinical sleep environment." Id. ¶¶ 57–58 (quoting Rachel Y. Moon, MD, FAAP; Rebecca F. Carlin, MD, FAAP; Ivan Hand, MD, FAAP, Evidence Base for 2022 Updated Recommendations for a Safe Infant Sleeping *Environment to Reduce the Risk of Sleep-Related Infant Deaths* (June 21, 2022), https://doi.org/10.1542/peds.2022-057991).²

Subsequently, the Safe to Sleep campaign, as well as the CDC and NIH, updated their messaging to reflect the AAP's revised guidance. *Id.* ¶¶ 60, 62–63. NIH amended its safe sleep materials to state that "[t]hings in the sleep area can pose dangers for baby, especially if they are: . . . Weighted (e.g., weighted blankets, weighted swaddles)." Id. ¶ 62. Similarly, the CDC revised its guidance to assert that "[p]roducts labeled as weighted—including weighted sleepers, swaddles, sleep sacks, and blankets—are **not safe** for infants." *Id.* ¶ 63. "Neither agency provides the basis for its respective determination." $Id. \ 965$.

² In deciding this motion to dismiss, the Court considers "the facts alleged in the complaint, documents attached thereto or incorporated therein, and matters of which it may take judicial notice," including the various webpages linked in the Complaint. See 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)).

At a November 8, 2023 CPSC meeting, Commissioner Trumka proposed an amendment to the Commission's Fiscal Year 2024 Operating Plan that would have required CPSC staff to pursue a mandatory standard for weighted sleep products for infants. *Id.* ¶¶ 66–68. The Commission voted 3–1 to reject the amendment. *Id.* ¶ 69. Then-Chair Alexander Hoehn-Saric explained that although CPSC staff was aware of the issue and working to assess the safety risks associated with weighted blankets, the CPSC had not yet "conducted the research necessary to draft a notice of proposed rulemaking in 2024." *Id.* ¶ 70. He also explained that the CPSC would be updating its guidance to account for the NIH and CDC's warnings. *Id.* ¶ 76. Commissioner Mary T. Boyle similarly remarked that a rulemaking was "premature." *Id.* ¶ 71.

Despite the Commission's decision, Trumka released a public statement the same day asserting that weighted infant sleep products are "concerning" hazards and chastising his fellow Commissioners for failing to adopt his amendment. *Id.* ¶ 72. Thereafter, Trumka continued to make public statements on the CPSC website and his social media channels warning against such products, including a January 26, 2024 post on X.com that linked to a *Washington Post* article that specifically named Dreamland and its line of weighted infant sleep products. *Id.* ¶¶ 87–91; Ex. 1 at 30, ECF No. 1-1. Additionally, Trumka sent letters to, and met with, various retailers and urged them to stop selling these products. Compl. ¶¶ 92–96. "The letters to retailers also included a hyperlink to a product search for weighted infant sleep products, which necessarily identified Dreamland's products, as they were for sale and searchable on retailers' websites at the time." *Id.* ¶ 109. Dreamland was provided no advanced notice of Trumka's statements, and alleges that his statements caused retailers to stop selling Dreamland's products. *Id.* ¶ 97, 99.

Sometime after the November 8, 2023 meeting, CPSC updated the "Safe Sleep – Cribs and Infant Products" page within the "Safety Education" portion of its website to include the

following: "Follow these simple tips to make every sleep a safe sleep: . . . Don't use weighted blankets or weighted swaddles*." *Id.* ¶ 77; Ex. 1 at 18–19. The text at the asterisk simply stated: "*NIH.gov and CDC.gov" with hyperlinks to corresponding NIH and CDC webpages. Compl. ¶¶ 77–79; Ex. 1 at 19. Neither of the linked webpages "cite[d] any specific safety data, evidence, or studies regarding weighted infant sleep products." Compl. ¶ 80. Sometime after July 23, 2024, the text at the asterisk was edited to explain: "This guidance is based on information from the Centers for Disease Control and the National Institutes for Health. Please go to CDC.gov and NIH.gov for more information." *Id.* ¶ 77.

"On July 1, 2024, CPSC staff submitted updated incident data to the ASTM International ("ASTM") subcommittee overseeing the voluntary standard for wearable blankets and swaddles, the ASTM F15.19 subcommittee. The data was provided to aid the ASTM subcommittee considering the potential hazards associated with such wearable blankets and swaddles." *Id.* ¶ 83. The data identifies 167 incidents related to wearable infant blanket products, weighted and non-weighted, between January 1, 2011 and April 10, 2024. *Id.* ¶ 84. The dataset included five fatalities associated with weighted infant sleep sacks and swaddles, but the task group members who reviewed the data "found no pattern among the 13 incidents (deaths + injuries) involving weighted sleep products." *Id.* ¶ 86.

In response to CPSC's website update and Commissioner Trumka's public campaign,
Dreamland submitted a formal retraction request to the Commission on July 23, 2024. *Id.* ¶ 100;
Ex. 1. The request sought the removal of the CPSC website's Safe Sleep guidance and
Commissioner Trumka's individual statements, arguing that both were "inaccurate or misleading" and cast Dreamland's products in an unfairly negative light. Compl. ¶¶ 100–05.

Dreamland also emphasized that it was not notified in advance of the disclosures or of meetings Trumka or his staff conducted with retailers. Id. ¶ 110.

On August 30, 2024, the CPSC formally responded. *Id.* ¶ 111; Ex. 2, ECF No. 1-2. Regarding the statement on CPSC's website, the Commission voted 3-0-2 to deny retraction, with two Commissioners abstaining. Ex. 2 at 2. The accompanying letter explained that the CPSC Safe Sleep statement was permitted under the CPSA and had been cleared "for public disclosure pursuant to [CPSC's] internal agency clearance process, found in Directive 1450.2." Ex. 3 at 3, ECF No. 1-3. The CPSC further clarified that cross-references to CDC and NIH materials were permissible and complied with Appendix B of Directive 1450.2, and explained that the citations to those agencies' websites had been updated to better identify their source. *Id.* at 3-4. Lastly, the Commission explained that the challenged guidance was derived from the Safe to Sleep campaign—a longstanding public health initiative involving the CPSC, NIH, CDC, and partners such as the AAP. *Id.* at 4. The CPSC noted that the campaign has consistently incorporated AAP's recommendations since 2000, and that the NIH has clearly described this collaboration on its website. *Id.*

With respect to Commissioner Trumka's public disclosures, the Commission's vote deadlocked at 2-0-2, lacking a majority needed to take action. Compl. ¶ 128. The two Commissioners who voted against retraction explained that (1) none of the statements contained Dreamland's name, (2) the challenged statements were neither inaccurate nor misleading, and (3) Trumka was not prohibited from requesting, in his own capacity, voluntary actions that retailers could disagree with or ignore. Ex. 6 at 2, ECF No. 1-6. Commissioner Trumka had recused himself, and Commissioners Feldman and Dziak had again abstained. Ex. 2 at 2. The abstaining Commissioners expressed their view that the process in the matter had been

"inadequate to develop the necessary factual record," and that the "relief sought is best obtained through an Article III court" based on their view that the "publication of the statements constitutes final agency action." Ex. 7 at 2, ECF No. 1-7.

In November 2024, Dreamland filed its Complaint seeking declaratory and injunctive relief. Compl. Counts 1, 4, and 5 allege that the CPSC violated the APA, 5 U.S.C. § 706(2), by making a "product safety determination" when it updated its Safe Sleep guidance and when it failed to retract its statement or Trumka's statements, all of which constituted agency action taken in excess of statutory authority, arbitrarily and capriciously, and without required procedures. Compl. ¶¶ 145–57, 171–93. Counts 2 and 3 allege that HHS, NIH, CDC, and Trumka took *ultra vires* actions by making statements that were unauthorized by statute. *Id.* ¶¶ 158–70. Count 6 alleges that Trumka "has clearly formed a strong negative impression of this class of products and is incapable of an unbiased consideration of actions affecting these products in the future," in violation of the Fifth Amendment's due process clause. *Id.* ¶¶ 194–206. And Count 7 alleges that the for-cause removal protection for CPSC Commissioners in 15 U.S.C. § 2053(a) violates the Constitution's separation of powers principles. *Id.* ¶¶ 207–11.

In January 2025, Defendants moved to dismiss the Complaint under Rules 12(b)(1) and 12(b)(6). Mot. to Dismiss, ECF No. 6; Defs.' Corrected Mem. in Supp. Mot. to Dismiss ("MTD"), ECF No. 8-1. In their motion, Defendants argue that the CPSC statement on its website and deadlocked vote on retracting Commissioner Trumka's statements were not final agency actions, and that Dreamland fails to state an APA claim related to CPSC's decision not to retract its Safe Sleep guidance. MTD at 1–2. Defendants further argue that Counts 2 and 3 fail to state an *ultra vires* claim because the Complaint does not plausibly allege that the challenged statements by Trumka, NIH, or CDC violated any clear statutory authority. *Id.* at 2. Defendants

also argue that this Court lacks subject-matter jurisdiction over Count 6 because Dreamland lacks standing for the prospective relief it seeks, and that Dreamland fails to state a claim because its due process allegations are purely speculative. *Id.* Finally, Defendants argued that Count 7 fails to state a claim because the removal protection for CPSC commissioners does not violate the separation of powers, and Dreamland failed to show it was harmed by the removal protection. *Id.* In March 2025, Defendants filed a Notice of Change in Position, explaining that they no longer intend to argue that the CPSA's for-cause removal provision is constitutional, but maintain that "Dreamland has failed to allege the required harm from the removal protection." ECF No. 10.

In May 2025, while the parties were briefing this motion, President Trump fired Commissioners Boyle, Hoehn-Saric, and Trumka without cause. *Boyle v. Trump*, No. 25-cv-1628, 2025 WL 1677099, at *1 (D. Md. June 13, 2025). Though a United States District Court granted those Commissioners a permanent injunction that reinstated them to their positions, *see id.* at *14–15, in July 2025, the Supreme Court stayed that order pending disposition of the appeal, *Trump v. Boyle*, 145 S. Ct. 2653, 2654 (2025). As a result, those Commissioners are no longer serving on the CPSC. *See* Reply in Supp. of Defs.' Mot. to Dismiss ("Defs.' Reply") at 19, ECF No. 16. Defendants' motion is now fully briefed, and ready for this Court's consideration. *See* Pl.'s Mem. in Opp'n ("Pl.'s Opp'n"), ECF No. 15; Defs.' Reply.

III. LEGAL STANDARDS

"Federal courts are courts of limited jurisdiction," and courts "presume[] that a cause lies outside this limited jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). When deciding a motion to dismiss for lack of subject-matter jurisdiction under Rule 12(b)(1), courts "assume the truth of all material factual allegations in the complaint and

'construe the complaint liberally, granting plaintiff[s] the benefit of all inferences that can be derived from the facts alleged,' and upon such facts determine jurisdictional questions." *Abuzeid v. Mayorkas*, 62 F.4th 578, 583 (D.C. Cir. 2023) (alteration in original) (quoting *Am. Nat'l Ins. Co. v. FDIC*, 642 F.3d 1137, 1139 (D.C. Cir. 2011)). Courts "may consider materials outside the pleadings to determine [their] jurisdiction," including whether a plaintiff has standing. *Jibril v. Mayorkas*, 101 F.4th 857, 866 (D.C. Cir.), *cert. denied*, 145 S. Ct. 550 (2024) (quoting *Kareem v. Haspel*, 986 F.3d 859, 866 n.7 (D.C. Cir. 2021)). A plaintiff "need only make a plausible allegation of facts establishing each element of standing" at the pleading stage. *Cutler v. U.S. Dep't of Health & Hum. Servs.*, 797 F.3d 1173, 1179 (D.C. Cir. 2015).

To survive a motion to dismiss for failure to state a claim under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* But courts need not "accept as true the complaint's factual allegations insofar as they contradict exhibits to the complaint or matters subject to judicial notice." *Owens v. BNP Paribas, S.A.*, 897 F.3d 266, 272–73 (D.C. Cir. 2018) (superseded by statute on other grounds) (quoting *Kaempe v. Myers*, 367 F.3d 958, 963 (D.C. Cir. 2004)).

Further, courts need not accept as true conclusory allegations or legal conclusions. *Iqbal*, 556 U.S. at 678, 681. Instead, courts must draw upon their "judicial experience and common sense" to determine whether the "well-pleaded facts" support a reasonable inference rising above just the "mere possibility of misconduct" to establish a plausible claim. *Id.* at 679.

IV. ANALYSIS

The Court first analyzes Dreamland's APA claims against the CPSC (Counts 1, 4, and 5), followed by Dreamland's *ultra vires* claims against the HHS, NIH, CDC, and Trumka (Counts 2 and 3), and lastly Dreamland's constitutional claims against Trumka and the CPSC (Counts 6 and 7). Ultimately, the Court concludes that only one of Dreamland's claims survive Defendants' motion to dismiss—Dreamland's arbitrary and capricious claim brought under the APA. Dreamland fails to state a claim that CPSC exceeded its statutory authority or failed to follow required procedures. The Court is unable to say the same, however, for Dreamland's arbitrary and capricious claim, which will require review of the Administrative Record in this case that has not yet been filed. The Court further concludes that Dreamland fails to meet the high bar required to state an *ultra vires* claim based on any clear statutory violation, and that it lacks standing to pursue constitutional claims that are no longer viable after three CPSC Commissioners have been removed. For the reasons discussed below, the Court grants Defendants' motion as to all claims but Dreamland's arbitrary and capricious claim.

A. APA Claims

The parties raise the preliminary issue of whether there has been a final agency action ripe for judicial review. Under the APA, courts may review "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. Consistent with this rule, a "preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action." *Id.* Though "the requirement of finality is not jurisdictional," *Soundboard Ass'n v. FTC*, 888 F.3d 1261, 1267 (D.C. Cir. 2018), absent final agency action or a statute specifically authorizing judicial review, there is no cause of action under the APA, *Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n*,

324 F.3d 726, 731 (D.C. Cir. 2003). The Supreme Court has articulated a two-prong test to determine whether an agency action is "final": "First, the action must mark the 'consummation' of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. And second, 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, 177–78 (1997) (citations omitted) (first quoting *Chicago & S. Air Lines, Inc. v. Waterman S.S. Corp.*, 333 U.S. 103, 113 (1948), then quoting *Port of Boston Marine Terminal Assn. v. Rederiaktiebolaget Transatl.*, 400 U.S. 62, 71 (1970)).

Here, Dreamland's APA claims challenge the CPSC's publishing of its Safe Sleep guidance advising against the use of weighted blankets or swaddles, its decisions not to retract that statement, and its deadlocked vote on retracting Trumka's individual statements. See Compl. ¶¶ 148, 157, 176–79, 185, 187, 190–93. Defendants argue that the CPSC statement and deadlocked vote on Trumka's statements were neither "agency action" nor "final" within the meaning of the APA. MTD at 13–21. Plaintiffs appear to concede in their opposition brief that the deadlocked vote was not final agency action. See Pl.'s Opp'n at 14, 27. And Defendants do not contest whether CPSC's denial of Dreamland's retraction request was a reviewable final agency action. See Defs.' Reply at 2. Thus, the parties dispute only whether CPSC's Safe Sleep statement on its website advising against the use of weighted blankets and swaddles was a final agency action. See id.; Pl.'s Opp'n at 14–19. But the Court need not decide this issue to resolve the present motion—as Plaintiffs explain, "[e]ven if CPSC's statement is not final agency action, Dreamland is entitled to [review] because CPSC's decision not to retract its disclosure is final agency action subject to this Court's review." See Pl.'s Opp'n at 14, 33, 36. On this point, the parties appear to agree, so the Court proceeds to analyze Dreamland's various APA claims

regarding this final agency action, which encompasses the Commission's initial decision to make the Safe Sleep statement. *See* 5 U.S.C. § 704.

1. Excess of Statutory Authority

The APA provides courts with authority to "hold unlawful and set aside agency action . . . found to be . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C). Under the CPSA, the "Commission's powers include the authority to collect and disseminate product safety information, 15 U.S.C. § 2054(a)(1), to conduct research and tests on consumer products, 15 U.S.C. §§ 2054(b)(1) and (2), to promulgate safety standards, 15 U.S.C. § 2056, and to ban hazardous products, 15 U.S.C. § 2057." *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 104 (1980). "Section 6 of the CPSA, 86 Stat. 1212, 15 U.S.C. § 2055, regulates the 'public disclosure' of information by the Commission." *Id.* at 105.

Here, Defendants argue that the "CPSC statement plainly falls within the agency's broad authority to disseminate product safety information." MTD at 22. Dreamland responds that the CPSC failed to take required procedures—based in part on "an order of operations problem" where it relied on other agencies—before making its statement on weighted infant sleep products, and thus acted beyond its statutory authority. Pl.'s Opp'n at 13. But Dreamland fails to identify which procedures the CPSC was statutorily required, but failed, to take.

The Complaint cites provisions related to promulgating product safety standards under 15 U.S.C. § 2056(a), Commission rulemaking under § 2058(e), and banning hazardous products under § 2057, but does not allege that the Commission took any of those actions. *See* Compl. ¶¶ 26–28. And Dreamland does not argue that the general statement regarding weighted blankets "permit[ted] the public to ascertain readily [its] identity," 15 U.S.C. § 2055(a)(3), (b)(1), so the

only potentially relevant provisions of the CPSA appear to be § 2055(b)(6) and (7). Subsection (6) requires the Commission to "establish procedures designed to ensure that [the public disclosure of] information is accurate and not misleading," which it has done through Directive 1450.2. 15 U.S.C. § 2055(b)(6); *see* 16 C.F.R. § 1101.1(c). Subsection (7) requires the Commission to "take reasonable steps to publish a retraction of . . . inaccurate or misleading information." 15 U.S.C. ¶ 2055(b)(7).

As Defendants explained to Dreamland in the August 30, 2024 retraction denial letter, "Commission staff cleared [the statement] for public disclosure pursuant to [CPSC's] internal agency clearance process, found in Directive 1450.2." Ex. 3 at 3. That Directive specifically allows for crosslinking to other agencies' guidance "provided that the content complements safety information issued by the agency and is related to the agency's mission." Directive 1450.2, App. B, Ex. 5 at 3. Though Dreamland alleges that CPSC's "statement was not cleared under CPSC's clearance procedures," Dreamland provides no basis for this allegation and, regardless, it is unclear what procedure in Directive 1450.2 Dreamland believes the Commission was required, but failed, to take. *See* Compl. ¶ 119. To the extent Dreamland argues that "[t]he Clearance Procedures also require the cleared statements to be supported by 'data in Commission files," Pl.'s Opp'n at 33, 35, Dreamland omits that the procedures also allow for statements to be supported by "data... in currently applicable literature," that is, outside the Commission's files. Directive 1450.2 § 7.a.(1)(a).

Dreamland also faults CPSC for "ignor[ing] that it was without any data or evidence supporting its" statement. Pl.'s Opp'n at 22; see also Compl. ¶ 81. But that allegation is contradicted by Dreamland's own allegations, including data documenting five fatalities and eight injuries involving weighted sleep products. Compl. ¶¶ 84–86. Accepting those allegations

as true, Dreamland is wrong to state that the CPSC lacked any data or evidence of safety risks involving weighted sleep products for infants. *See* Pl.'s Opp'n at 22. Dreamland also repeatedly emphasizes that an "independent review stated that there was no hazard pattern found among the incidents with weighted sleep products." *See id.* at 36 (footnote omitted). It explains that a "hazard pattern is how an injury usually happens with a particular product." *Id.* at 36 n.10. But the absence of a hazard pattern, especially within a limited data set, does not mean a product involved in multiple infant fatalities is necessarily safe. Though there may not have been a discernible hazard pattern as of that review, that does not mean the Commission had no data of safety risks associated with weighted infant sleep products. *But see id.* at 22. Dreamland has accordingly failed to plead a plausible claim that CPSC exceeded its statutory authority, and Count 1 must be dismissed.

2. Arbitrary and Capricious

Under the APA, courts have authority to "hold unlawful and set aside agency action . . . found to be arbitrary" or "capricious." 5 U.S.C. § 706(2)(A). Agency action is arbitrary and capricious "if 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 of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). Arbitrary and capricious review is "highly deferential" and "presumes agency action to be valid." Am.

Wildlands v. Kempthorne, 530 F.3d 991, 997 (D.C. Cir. 2008) (quoting Ethyl Corp. v. EPA, 541 F.2d 1, 34 (D.C. Cir. 1976)). The agency action need only be "reasonable and reasonably explained." FCC v. Prometheus Radio Project, 592 U.S. 414, 417 (2021).

Dreamland reasserts its "order of operations" theory, arguing that Congress intended for CPSC to make product safety determinations independently of the CDC, NIH, or AAP. *See* Pl.'s Opp'n at 34. Specifically, Dreamland argues that "[i]f 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." *Id.* But Dreamland fails to contemplate that Congress could give multiple agencies concurrent jurisdiction to speak on issues that implicate both consumer protection and public safety, and fails to identify any statutory text to the contrary. Thus, Dreamland fails to provide a persuasive legal basis for its "order of operations" arguments.

Dreamland further argues that CPSC blindly relied on CDC and NIH guidance, which was in turn based on "AAP's unsubstantiated recommendation." *See id.* at 34–35. As mentioned above, Dreamland alleges that the AAP lacked any data or studies on the safety risks of weighted infant sleep products when it promulgated its revised guidance, on which the Safe to Sleep campaign relied. *See* Compl. ¶¶ 54–60. If there were no evidence of safety risks associated with weighted infant sleep products, then Dreamland's position would be logical, as consensus amongst health agencies based on nothing more than a data-less echo chamber and blind cross-linking would seemingly be arbitrary. But the face of Dreamland's Complaint refutes the absence of evidence—particularly the CPSC data involving multiple infant fatalities associated with weighted sleep products. *See* Compl. ¶¶ 84–86. As Defendants note, Dreamland "acknowledges that the data set revealed double-figure incidents—defined as 'deaths + injuries'—involving weighted sleep products." Defs.' Reply at 17 (quoting Pl.'s Opp'n at 36). And Dreamland argues the CPSC had access to this data at least as early as December 2023. *See* Pl.'s Opp'n at 36.

But in the absence of an Administrative Record, it is unclear whether the CPSC based its decision to publish and not retract the statement on this data, or on blind reliance on the CDC and NIH. Though the August 30, 2024 retraction denial letter implies that CPSC determined that the statement was "accurate and not misleading," the letter is ambiguous as to whether this determination was based on the CPSC data or solely the "accurate" republishing of CDC and NIH guidance. See Ex. 3 at 3–4. The combination of the CPSC data with consensus amongst other Safe to Sleep collaborators would seemingly make the CPSC's decision to publish, and not retract, its guidance both "reasonable and reasonably explained." See Prometheus Radio Project, 592 U.S. at 417. But without the Administrative Record, or any indication in the letter as to what evidence the CPSC considered, the Court cannot "assess whether the [CPSC] 'examined the relevant data and articulated a satisfactory explanation for its action including a rational connection between the facts found and the choice made." See Swedish Am. Hosp. v. Sebelius, 691 F. Supp. 2d 80, 88 (D.D.C. 2010) (quoting MD Pharm., Inc. v. Drug Enf't Admin., 133 F.3d 8, 16 (D.C. Cir. 1998)). Review of the Administrative Record will also enable to Court to assess Dreamland's arguments that the CPSC either failed to consider data it possessed, or reached a conclusion counter to its assessment of that data. See Pl.'s Opp'n at 33–34, 36.

Dreamland challenges not just the conclusion CPSC reached, but whether it acted arbitrarily and capriciously in reaching that decision. Without the Administrative Record, the Court is unable to make that determination at this juncture. *See Swedish Am. Hosp.*, 691 F. Supp. 2d at 89 ("[T]he plaintiff is challenging not only the administrative decision, but also the process that led to that decision. The court is unable to assess the merits of these arguments without considering the administrative record."); *Dist. Hosp. Partners, L.P. v. Sebelius*, 794 F. Supp. 2d 162, 173 (D.D.C. 2011) (denying motion to dismiss arbitrary and capricious APA claim

without first reviewing the administrative record). Accordingly, the Court denies Defendants' motion to dismiss Count 4.

3. Without Required Procedures

Judicial review under the APA also provides courts with authority to "hold unlawful and set aside agency action . . . found to be . . . without observance of procedure required by law." 5 U.S.C. § 706(2)(D). Dreamland bases this claim on its argument that CPSC was required to clear NIH's disclosure before it was made because NIH's Safe to Sleep Campaign was part of a "Joint Project" governed by paragraph (h) of CPSC's clearance procedures. Pl.'s Opp'n at 37. Defendants respond that NIH's statement falls outside the scope of Directive 1450.2's definition of "Joint Projects." Defs.' Reply at 17. Defendants have the better argument.

Directive 1450.2 § 7.h(1) defines a joint project as "any project where an outside group, with some degree of CPSC involvement, produces any audio, visual, internet, written or other material or program for the public." Directive 1450.2 § 7.h(1), Ex. 4 at 9 (emphasis added). But Dreamland's entire case is built around its view that CPSC "adopted" the NIH's determination and merely "inferr[ed] that [weighted infant sleep products] are unsafe" without making its own product safety determination. See Pl.'s Opp'n at 1, 34. Because Dreamland does not allege that CPSC was involved in the production of NIH's statement, its argument that CPSC had to clear NIH's statement under rules applying to Joint Projects fails. As a result, the Court will dismiss Count 5.

B. Ultra Vires Claims

The Court next considers Dreamland's claims against the HHS, CDC, NIH, and Trumka alleging *ultra vires* actions. An *ultra vires* claim "is available where (i) there is no express statutory preclusion of all judicial review; (ii) there is no alternative procedure for review of the

statutory claim; and (iii) the agency plainly acts in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory." Fed. Express Corp. v. U.S. Dep't of Com., 39 F.4th 756, 763 (D.C. Cir. 2022) (citation modified) (quoting Nyunt v. Chairman, Broad. Bd. of Governors, 589 F.3d 445, 449 (D.C. Cir. 2009)). These claims "are confined to 'extreme' agency error where the agency has 'stepped so plainly beyond the bounds of [its statutory authority], or acted so clearly in defiance of it, as to warrant the immediate intervention of an equity court[.]" Id. at 764 (alterations in original) (quoting Griffith v. FLRA, 842 F.2d 487, 493 (D.C. Cir. 1988)). Accordingly, "a challenged action must 'contravene[] a clear and specific statutory mandate' to be susceptible to ultra vires review." Nat'l Ass'n of Postal Supervisors v. U.S. Postal Serv., 26 F.4th 960, 971 (D.C. Cir. 2022) (alteration in original) (quoting Nat'l Air Traffic Controllers Ass'n AFL-CIO v. Fed. Serv. Impasses Panel, 437 F.3d 1256, 1264 (D.C. Cir. 2006)). Given this stringent standard, the D.C. Circuit has aptly analogized this claim to "a Hail Mary pass—and in court as in football, the attempt rarely succeeds." Nyunt, 589 F.3d at 449. The parties agree that this standard applies, and dispute only the third element: whether Defendants plainly acted in excess of delegated power and contrary to a specific prohibition in the statute that is clear and mandatory. See MTD at 24–25, 28–31; Pl.'s Opp'n at 23, 27.

1. Against the Public Health Agencies

Dreamland has failed to allege that the NIH, CDC, or HHS violated any clear and mandatory statutory prohibition. Dreamland's entire argument is premised on its "key contention" that "CPSC, and only CPSC, is authorized by statute to make consumer product safety determinations in the first instance." *See* Pl.'s Opp'n at 22–23. But what statute clearly prohibits the NIH and CDC from speaking on matters of consumer product safety related to

public health? To the Court's knowledge, none. Dreamland's theory is untethered to either statutory text or precedent.

Dreamland acknowledges that, "[u]nlike 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." Pl.'s Opp'n at 23–24. But Dreamland offers no legal support for this abnormal theory of an *ultra vires* claim. *See id.* at 22–27.

As Dreamland's Complaint concedes, the Public Health Service Act ("PHSA") "empowers HHS to develop, support, and maintain programs addressing sudden unexpected infant death and sudden unexpected death in childhood." Compl. ¶ 162; see 42 U.S.C. § 300c-11(a). Dreamland argues, however, that "the PHSA's general provisions are not the controlling provisions, the CPSA is." Pl.'s Opp'n at 24. Dreamland provides no citation to support that proposition. Dreamland advocates for a regulatory scheme in which public health agencies like the CDC and NIH are unable to speak on matters of public health regarding consumer products unless the CPSC speaks first. See id. at 24–26. While Congress certainly could have created such a scheme, it is not apparent from the text of the relevant statutes. This ultra vires claim is not the appropriate vehicle for testing Dreamland's new legal theory.

In fact, Dreamland gives the game away when it argues that "it is questionable that CDC's and NIH's determinations even meet the requirements of the PHSA." *See* Pl.'s Opp'n at 26. Because HHS, CDC, and NIH have not "plainly act[ed] in excess of [their] delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory," Count 2 must be dismissed. *See Fed. Express*, 39 F.4th at 763 (quoting *Nyunt*, 589 F.3d at 449).

2. Against Commissioner Trumka

Dreamland's *ultra vires* claim against Trumka starts out on better footing, as Dreamland identifies a statute Trumka allegedly violated, 15 U.S.C. § 2055(b)(1). *See* Pl.'s Opp'n at 27–33. But ultimately, this claim similarly fails. Though Dreamland's interpretation of the statute is possible, any violation by Trumka is questionable at best, and certainly not clear. Section 2055(b)(1) provides in relevant part:

[N]ot less than 15 days prior to its public disclosure of any information obtained under this Act, or to be disclosed to the public in connection therewith... the Commission shall, to the extent practicable, notify and provide a summary of the information to, each manufacturer or private labeler of any consumer product to which such information pertains, 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, and shall provide such manufacturer or private labeler with a reasonable opportunity to submit comments to the Commission in regard to such information. 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 this Act.

15 U.S.C. § 2055(b)(1) (emphases added).³ Thus, the requirements of this provision apply only to disclosures that "permit the public to ascertain readily the identity" of a manufacturer.⁴ *Id*.

Here, Dreamland alleges that "Commissioner Trumka's public statements, letters, and social media posts . . . allowed the public to readily ascertain its identity because the statements included citations to a news article that specifically identified Dreamland and searches that

22

 $^{^3}$ This provision also applies "whenever information is to be disclosed by . . . any member of the Commission." 15 U.S.C. § 2055(d)(2).

⁴ The parties dispute whether a clear violation of a regulation can support an *ultra vires* claim. *See* Pl.'s Opp'n at 29–30; Defs.' Reply at 12. But the Court need not address this argument because Dreamland also argues that § 2055(b)(1)'s implementing regulations "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." Pl.'s Opp'n at 30 (citing 15 U.S.C. § 2055(b), 16 C.F.R. §§ 1101.1(b)(1), 1101.13).

included its products on its retailers' websites." Pl.'s Opp'n at 31 (citing Compl. ¶¶ 88, 107–09). Defendants argue that "section 2055(b)(1) is not triggered by the contents of third-party documents merely referenced by Commissioner Trumka." Defs.' Reply at 15; see 16 C.F.R. § 1101.13 ("The advance notice and analysis provisions of section 6(b)(1) apply only when a reasonable person receiving the information in the form in which it is to be disclosed and lacking specialized expertise can readily ascertain from the information itself the identity of the manufacturer or private labeler of a particular product." (emphasis added)).

Though the Court agrees with Dreamland that Trumka did not merely repeat CPSC's statement, Pl.'s Opp'n at 28, and is skeptical of Defendants' arguments that linking to another previously published source that specifically identifies a manufacturer would never trigger § 2055(b)(1), Defs.' Reply at 15, the reasonable arguments presented on both sides support the Court's conclusion that regardless of whether Trumka may have violated the CPSA, any error was not plainly contrary to a specific, clear, and mandatory statutory prohibition. *See Fed. Express*, 39 F.4th at 763. For this reason, the Court must also dismiss Count 3.

C. Constitutional Claims

Dreamland brings two constitutional claims: one against Trumka alleging he is impermissibly biased, in violation of the Fifth Amendment's due process clause, and one against the CPSC based on its for-cause removal protection for Commissioners. As discussed above, all of the relevant Commissioners have now been removed from the CPSC and are no longer serving. *See* Defs.' Reply at 19. Consequently, the Court concludes it lacks subject-matter jurisdiction over these claims.

1. Due Process Claim

To the extent Defendants previously argued that Dreamland's claims of future imminent harm by Trumka were speculative, Dreamland's risk of future harm is now virtually nonexistent. See id.; MTD at 38. Dreamland's Complaint seeks "[a] permanent injunction enjoining Commissioner Trumka from participating in any future CPSC actions, including votes, regarding Dreamland's weighted infant sleep products and the class of weighted infant sleep products generally." Compl. at 43. Dreamland alleged that this relief was justified because "[i]t is obvious from [Trumka's] statements and actions that he has clearly formed a strong negative impression of this class of products and is incapable of an unbiased consideration of actions affecting these products in the future." Id. ¶ 206. In its opposition brief, Dreamland argued that "[a]s long as Commissioner Trumka is a member of the Commission, he still wields power that can continue to harm those protected interests," and that "there is nothing stopping him" from causing harm in the future. Pl.'s Opp'n at 39-40. Dreamland later argues that "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." *Id.* at 45. The Court agrees. Because Trumka no longer serves as a Commissioner, Dreamland lacks standing to seek prospective injunctive relief related to his service. Accordingly, Count 6 must be dismissed.

2. For-Cause Removal Challenge

To the extent Dreamland seeks prospective relief based on 15 U.S.C. § 2053(a)'s forcause requirement for removal, it lacks standing to seek that relief. In light of the Supreme Court's decision to allow the Commissioners to be removed while their case is appealed, the forcause provision clearly serves as no impediment to removal. *But see* Pl.'s Opp'n at 43. And to the extent Dreamland seeks retrospective relief, it has failed to show it suffered the type of "compensable harm" necessary to be entitled to that relief. *See Collins v. Yellen*, 594 U.S. 220, 259–60 (2021). Specifically, the challenged actions all occurred during the Biden presidency, and Dreamland has not alleged that President Biden had any desire to remove any of the Commissioners—all three of whom he appointed—let alone that the statutory provision obstructed his efforts to do so. *See id.* Lastly, though Dreamland argued before the Supreme Court intervened in July that without the three Biden-appointed Commissioners, "the remaining two Commissioners . . . could have conducted official CPSC business for up to six months," the remaining Commissioners are no longer encumbered by their former colleagues. *See* Pl.'s Opp'n at 44. Thus, Dreamland's speculative theory of redressability has not played out in reality, further supporting that Dreamland lacks standing to pursue relief for this claim. Accordingly, the Court will also dismiss Count 7.

* * *

In sum, the Court agrees with Defendants that Dreamland has failed to state an APA claim against the CPSC based on agency action taken in excess of statutory authority or without required procedures. The Court also concludes that Dreamland failed to state an *ultra vires* claim against the other Defendants. And because President Trump has removed Commissioner Trumka and the other Commissioners who voted against Dreamland on its retraction request, Dreamland lacks standing to bring its constitutional claims against Trumka in his official capacity and against the CPSC based on the for-cause removal provision of the CPSA. Thus, the Court grants Defendants' Rule 12(b)(6) motion as to Counts 1–3 and 5, and grants Defendants' Rule 12(b)(1) motion as to Counts 6–7.

But the Court determines that based on the facts here, dismissal of Dreamland's arbitrary and capricious APA claim against the CPSC would be premature and that a review of the Administrative Record is necessary. Accordingly, the Court denies Defendants' Rule 12(b)(6) motion as to Count 4.

V. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss (ECF No. 6) is **GRANTED in part** as to Counts 1–3 and 5–7, and **DENIED in part** as to Count 4. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: September 26, 2025 RUDOLPH CONTRERAS United States District Judge