UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of	)	
LEACHCO, INC.	)	CPSC DOCKET NO. 22-1
	)	Hon. Michael G. Young
	)	Presiding Officer
Respondent.	)	

COMPLAINT COUNSEL'S RESPONSE IN OPPOSITION TO LEACHCO, INC.'S MOTION FOR SUMMARY DECISION AND SUPPORTING MEMORANDUM

Pursuant to 16 C.F.R. §§ 1025.23 and 1025.25(b), Complaint Counsel respectfully submits this response in opposition to Leachco's Motion for Summary Decision [Dkt. No. 91]. As explained in further detail below, summary decision in Leachco's favor should be denied because: (1) this Court has already ruled that the Commission's defect regulation and not common law controls, and thus, under the law of the case doctrine, this Court's decision controls and should not be relitigated; moreover, there are genuine issues of material fact concerning whether the Podster contains a defect that preclude summary decision; (2) Leachco's arguments about causation and the definition of substantial risk of injury find no legal support in the Consumer Product Safety Act ("CPSA") because a Substantial Product Hazard claim under Section 15 of the CPSA does not require a "but for" causal link between the product and injuries or deaths; and, more fundamentally, the CPSA does not require the Commission to await actual incidents of injuries or death before action can be taken to remedy a substantial product hazard; and, (3) Leachco's slapdash collection of Constitutional arguments are misplaced or, by

Leachco's own admission, not appropriately raised in this forum.

I. INTRODUCTION

Leachco's motion for summary decision is a scattershot attempt to prevent a trial on the merits regarding whether its infant lounging pillow, the Podster, presents a potentially fatal hazard to the most vulnerable category of consumers, infants. Leachco first suggests that Complaint Counsel cannot establish a defect under the CPSA. But Leachco's arguments are unsupported by the law and directly contradict this Court's prior ruling that the Commission's defect regulation, and not common law, controls in this proceeding. As such, the law of the case doctrine dictates that this issue should not be relitigated. Besides being wrong on the law, Leachco's motion on the question of defect is also unavailing as a matter of fact. Specifically, there are genuine issues of material fact that need to be resolved on a full record regarding whether the Podster is defective. [redacted] Thus, a factfinder will need to assess the competing evidentiary narratives, and it is clear that the matter of defect is not amenable to summary decision.

Second, Leachco's motion also claims there is a "but for" or proximate causation requirement in the CPSA. However, contrary to Leachco's claim, there is no requirement that Complaint Counsel demonstrate that the Podster caused any injuries or deaths. Indeed, the express statutory language, Commission regulations, legislative history and case law all conclude that actual incidents are only one small part of a multifactor analysis that is based on the potential for harm, and actual causation is not required.

Leachco's third primary argument in its summary decision motion bears some similarity to its causation argument—suggesting that a substantial risk of injury means there are actual injuries and deaths, and those must be in sufficient numbers as compared to a denominator of products in commerce and lifetime uses such that there is a "high probability" of harm. This argument is made up of whole cloth and fails as a matter of law. Indeed, the statutory text, interpretive regulations, and case law all direct that no particular incident rate governs an analysis of the existence of a substantial product hazard.

Finally, Leachco's last-resort Constitutional arguments are without merit and, by its own admission, most are procedurally improper and premature. Try as it might to make this a case about irrelevant Constitutional claims, this case is really about the scientific analysis of a product that can suffocate infants and has in three tragic instances taken the life of infants placed on Podsters. Because Complaint Counsel's claim is supported by the plain language of the CPSA, the Commission's regulations, relevant case law, and the detailed expert testimony presented to date, this Court must reject Leachco's distraction tactics and hear this case on the merits. Leachco's motion for summary decision must be denied in its entirety.

II. STATEMENT OF GENUINE ISSUES OF MATERIAL FACTS

Leachco's motion for summary decision is replete with factual inaccuracies and factual claims that are at odds with the record evidence. This Statement will highlight several of the misleading representations made by Leachco and many of the facts that are subject to a genuine dispute. For additional factual background, Complaint Counsel refers the Court to Complaint Counsel's Memorandum in Support of its Motion for Partial Summary Decision and Statement of Undisputed Material Facts [Dkt. No. 89].

A. Respondent Leachco, Inc.

Leachco's motion for summary decision makes several assertions about the company itself that are at odds with other record evidence. For instance, Leachco claims it is a "small, family business."[1]

Leachco's recitation of facts regarding its founders' roles in its motion for summary decision is also contradicted by the record evidence in this case. For example, Leachco asserts that "Jamie and Clyde wore many hats—designer, managers, manufacturers, bookkeepers, sale representatives, human-resource managers, custodians, construction managers . . . ."[5] This statement is in stark contrast to other record evidence—

[1] Dkt. No. 91 at 1, 6.
[2] Clyde Leach Deposition, February 28, 2023 at 88:21-89:8 (Declaration of Michael J. Rogal in Support of Complaint Counsel's Motion for Partial Summary Decision, June 9, 2023 [Dkt. 90] ("Rogal Decl."), Exhibit 4).
[3] *Id.* at 88:21-89:4.
[4] Jamie Leach Deposition, March 1, 2023 at 12:6-13, 22:17-23:15 (Rogal Decl., Exhibit 1).
[5] Dkt. No. 91 at 4-5.
[6] Clyde Leach Deposition, February 28, 2023 at 36 (Declaration of Brett Ruff in Support of Complaint Counsel's

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[redacted]

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[redacted]

Response to Leachco Inc.'s Motion for Summary Decision ("Ruff Decl."), June 23, 2023, Exhibit 1).
[7] *Id.* at 37.
[8] *Id.* at 38.
[9] *Id.* at 109.
[10] *Id.* at 110.
[11] *Id.* at 114.

Leachco's motion for summary decision also suggests that "CPSC's actions threaten everything Jamie and Clyde created" and "[b]ecause of the Commission's public allegations, Leachco's revenues decreased and the company incurred significant legal expenses."[12] Yet there is a genuine issue of material fact regarding these claims. First, Leachco's portrayal of its business omits evidence that it manufactures, distributes, and offers for sale more than 90 products, including pillows for infants, children, and nursing caregivers.[13] [redacted] Each of these facts calls into question Leachco's sweeping assertion that this action threatens the company's finances and, at a minimum, suggests there are facts in dispute that need to be resolved by the factfinder at trial.

Indeed, Leachco also claims it is in dire financial circumstances, claiming "Clyde and Jamie are foregoing salaries and living off savings to ensure Leach remains solvent and its employees have jobs."[16] [redacted]

[12] Dkt. No. 91 at 7.
[13] Web Data Collection, February 7, 2023 for www.leachco.com/collections/leachco-catalog (Rogal Decl., Exhibit 6).
[14] *Id.*; Alex Leach Deposition, February 15, 2023 at 83:18-21 (Rogal Decl., Exhibit 2); Clyde Leach Deposition, February 28, 2023 at 99:10-104:7 (Rogal Decl., Exhibit 4).
[15] Alex Leach Deposition, February 15, 2023 at 83:8-13 (Rogal Decl., Exhibit 2); Clyde Leach Deposition, February 28, 2023 at 104:7-105:7 (Rogal Decl., Exhibit 4).
[16] Dkt. No. 91 at 7.
[17] Clyde Leach Deposition, February 28, 2023 at 92:15-93:12 (Ruff Decl., Exhibit 1). [redacted] *Id.* at 93:16-94:14.

[redacted]

B. The Subject Products

There is a genuine dispute of fact regarding Leachco's testing of the Podster. Leachco provided written discovery responses where it denied that it did not conduct tests to assess infant movement, whether the Podster poses a suffocation risk, how consumers may use the Podster, or the effectiveness of its warnings and instructions.[20] [redacted] These facts relating to testing present genuine issues for trial, though the weight of the evidence certainly indicates that Leachco conducted no such product testing. Summary decision therefore is inappropriate at this stage of

[18] *Id.* at 89:7-90:5 (Ruff Decl., Exhibit 1).
[19] *Id.* at 90:4-14 (Ruff Decl., Exhibit 1).
[20] Leachco's Objections and Responses to CPSC's First Set of Requests for Admission, November 30, 2023 at 5-7 (Rogal Decl., Exhibit 10).
[21] Jamie Leach Deposition, March 1, 2023 at 87:14-20 (Rogal Decl., Exhibit 1); Tonya Barrett Deposition, February 1, 2023 at 77:11-21 (Rogal Decl., Exhibit 8).
[22] Jamie Leach Deposition, March 1, 2023 at 34:16-35:8 (Rogal Decl., Exhibit 1); Tonya Barrett Deposition, February 1, 2023 at 36:15-37:14, 76:21-77:13 (Rogal Decl., Exhibit 8); Clyde Leach Deposition, February 28, 2023 at 116:2-121:6 (Rogal Decl., Exhibit 4); Clyde Leach Deposition Exhibit No. 3, Podster Test Reports, LC-88-167 (Rogal Decl., Exhibit 9).

the proceeding.

C. Fatal Incidents Caused by the Podsters

There is also a genuine issue of material fact regarding the three fatal incidents involving infants placed on a Podster for sleep. [redacted] Although its motion for summary decision does not explicitly state it, Leachco is really arguing, as it has in related litigation, that "three infants died because of consumer misuse."[25]

Yet there is a genuine dispute as to what caused the deaths of the three infants in this case, and thus summary judgment is not warranted. [redacted] At a minimum, the documentary evidence regarding the fatal incidents has material facts in dispute that preclude a factfinder from entering summary decision.[27] [redacted]

[23] Dkt. No. 91 at 11.
[24] *Id.* at 14.
[25] Leachco, Inc.'s Motion for Injunction Pending Appeal and Brief in Support, June 13, 2023 filed in *Leachco, Inc. v. CPSC*, Case No. 6:22-cv-00232-RAW (E.D.Ok.) (Ruff Decl., Exhibit 2).
[26] Alabama incident (IDI160519CCC2600) (Ruff Decl., Exhibit 3); Texas Incident (IDI200917CCC3888) (Ruff Decl., Exhibit 4), Virginia Incident, (IDI220916HCC1454) (Ruff Decl., Exhibit 5).
[27] Dkt. No. 91 at 11-14.
[28] Expert Testimony of Celestine Kish, May 2, 2023 at 67-70 (Rogal Decl., Exhibit 10).

[redacted]

[redacted] At trial, the factfinder can make a determination as to any particular cause or multiple causes of death in the three reported incidents. Since there are genuine issues of material fact regarding the cause of the infant fatalities, summary decision must be denied so the Court can hear this evidence and make a finding based on a full record.[30]

D. Genuine Issues of Material Fact Exist Regarding Mechanical Engineering, Human Factors Engineering, and Medical Expert Opinion Testimony

[redacted]

[29] Expert Testimony of Umakanth Katwa, April 28, 2023 at 26-29 (Rogal Decl. Exhibit 13).
[30] As discussed in further detail later, the Presiding Officer also does not need to find that the Podster caused the death of any of the three infants in order to hold that the Podster poses a substantial product hazard. A product may be a substantial product hazard even if the Podster has not yet resulted in any injuries or deaths. *See In re Dye*, 1989 WL 435534, *6 (CPSC 1991) ("With regard to the absence of known fatalities, such evidence is not determinative of whether a product creates a 'substantial risk of injury to the public' under section 15. There is no provision in the CPSA that requires proof of actual injuries or deaths in order to show that a product contains a defect that creates a substantial risk of injury to the public.").
[31] Dkt. No. 91 at 15.
[32] Zach Foster Deposition, March 8, 2023 at 115:6-9, 126:23-25, 130:1-2, 136:23-137:1; 140:8-12, 172:23-173:3, 174:23-175:4 (Ruff Decl., Exhibit 10); Hope Nesteruk Deposition, March 15, 2023 at 47:22-48:7, 48:21-49:5, 50:2-17 (Ruff Decl., Exhibit 11); Suad Wanna-Nakamura Deposition, March 13, 2023 at 21:20-22:24, 23:3-5, 26:2-6 (Ruff Decl., Exhibit 12).

[redacted] That is obviously not a fair or reasonable way to interpret Complaint Counsel's expert testimony.

In contrast to Leachco's estimation of Complaint Counsel's expert testimony, Complaint Counsel submits there is a genuine issue of fact regarding that testimony, and that such testimony is scientifically valid and the opinions were provided within a reasonable degree of scientific certainty. In summary, Complaint Counsel's biomechanical expert Dr. Mannen testified that the design of the Podster:

[redacted]

[33] *See* PSA 0598.21, November 24, 2021 at 2, 14-16 (Ruff Decl., Exhibit 6); PSA 0597.21, October 15, 2021 at 9 (Ruff Decl., Exhibit 7); PSA 0600.21, October 22, 2021 at 2 (Ruff Decl., Exhibit 8).
[34] Dkt. No. 91 at 3-20.
[35] *Id.* at 36.
[36] *Id.*

[redacted] As such, a factfinder's full evaluation of this testimony, along with Leachco's response, are necessarily an issue for trial on a full record, and not for summary decision.

Moreover, Ms. Kish, Complaint Counsel's human factors expert, testified in summary that:

[redacted]

[37] Expert Testimony of Erin Mannen, Ph.D., April 28, 2023 at 5-6 (Ruff Decl., Exhibit 9).

[redacted] This cannot form the basis of summary decision in favor of Leachco.[39]

Finally, Dr. Katwa, Complaint Counsel's medical expert opinion can be summarized as follows:

[redacted]

[38] Expert Testimony of Celestine T. Kish, M.A., at 1-2 (Rogal Decl., Exhibit 10).

[39] To the contrary, the Kish expert testimony supports the entry of partial summary decision in Complaint Counsel's favor that [redacted] *See* Complaint Counsel's Motion for Partial Summary Decision and Memorandum in Support, June 9, 2023, Dkt. Nos. 88 & 89.

[redacted] Thus, summary decision on substantial risk of injury could not appropriately be entered in Leachco's favor. Rather, summary judgment on substantial risk of injury is proper in favor of Complaint Counsel pursuant to its motion for partial summary decision.[41]

III. LEGAL STANDARD FOR SUMMARY DECISION

Under the Commission's Rules of Practice for Adjudicative Proceedings, a motion for summary decision "shall be granted if the pleadings and any depositions, answers to interrogatories, admissions, or affidavits show that there is no genuine issue as to any material fact and that the moving party is entitled to a Summary Decision and Order as a matter of law." 16 C.F.R. § 1025.25(c).

Section 1025.25's Summary Decision standard is similar to Rule 56(a) of the Federal Rules of Civil Procedure, which states in relevant part:

> **(a) Motion for Summary Judgment or Partial Summary Judgment.** A party may move for summary judgment, identifying each claim or defense—or the part of each claim or defense—or the part of each claim or defense on which summary judgment is sought. The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled

[40] Expert Testimony of Umakanth Katwa, April 28, 2023 at 4-5 (Rogal Decl., Exhibit 13).
[41] Complaint Counsel's Motion for Partial Summary Decision, June 9, 2023, Dkt. Nos. 88 and 89.

to judgment as a matter of law.[42]

In interpreting the Rule 56 standard, the Supreme Court of the United States has held that the appropriate inquiry at summary judgment is not whether issues of fact exist, but whether any issue of "material fact" exists: "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The standard holds that if "the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.'" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (citing *First Natl. Bank of Ariz. Co. v. Cities Service*, 391 U.S. 253, 289 (1968)).

The record taken as a whole could, and should, lead a rational trier of fact to find for Complaint Counsel, and so Leachco's motion for summary decision should be denied.

IV. ARGUMENT

A. The Court has Already Ruled That the CPSA Regulation Definition of "Defect" Controls in this Proceeding and There are Genuine Issues of Material Fact Concerning Whether the Podster is Defective

1. The Law of the Case Doctrine Directs the Court to Follow Its Prior Ruling

Leachco argues that the term "defect" for purposes of this Section 15 action should be understood under traditional common law, and not based on CPSA regulations (and in particular 16 C.F.R. § 1115.4). But this Court already ruled on this very issue in its December 16, 2022 Order Denying Leachco's Motion for Protective Order, Order Granting Complaint Counsel's Motion to Compel Production of Electronic Communications Pursuant to Complaint Counsel's

[42] Although the Federal Rules of Civil Procedure do not govern here, many administrative proceedings have looked to case law applying analogous Federal Rules for guidance in construing administrative rules of practice. *See, e.g.*, *In re Healthway Shopping Network*, Exch. Act Rel. No. 89374, 2020 WL 4207666, at *2 (SEC Jul. 22, 2020) (SEC guided by precedent applying Federal Rules in interpreting its own administrative rules of practice).

Second Set of Requests for Production of Documents to Respondent [Dkt. 51] ("December 16, 2022 Order").

In that Order, this Court ruled that "[t]he claim in this proceeding is governed by Commission regulations and not by common law products liability." December 16, 2022 Order at 7-8. The Order specifically outlined that the term "defect" is defined by 16 C.F.R. § 1115.4. *Id.* Thus, the Court already settled this issue, and Leachco's argument to the contrary is constrained by the law of the case doctrine. That doctrine provides: "'when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case.'" *See In Re Pharmacy Benefit Managers Antitrust Litigation*, 582 F.3d 432, 439 (3d Cir. 2009) (applying law of the case doctrine to overrule the vacating of an order compelling arbitration entered by the original judge handling the case by a subsequent judge in another court) (quoting *Arizona v. California*, 460 U.S. 605, 618 (1983) (explaining law of the case doctrine but declining to impose it under the particular facts relating to a dispute between two states). The purpose of the law of the case doctrine is "'to maintain consistency and avoid reconsideration of matters once decided during the course of a single continuing lawsuit.'" *Id.* (citing *Casey v. Planned Parenthood*, 14 F.3d 848, 856 (3d Cir. 1994) (quoting Wright & Miller, Federal Practice and Procedure § 4478); *see also Pit. River Home v. United States*, 30 F.3d 1088, 1096 (9th Cir. 1994) (applying law of the case to uphold district court's earlier decision against a later challenge and claim of new evidence, and finding that "[t]he law of the case doctrine is a discretionary one created to maintain consistency and avoid reconsideration, during the course of a single continuing lawsuit, of those decisions that are intended to put a matter to rest."); *Retail Clerks Union v. NLRB*, 463 F.2d 316, 322 (D.C. Cir. 1972) (upholding administrative order in labor relations case pursuant to law of the case doctrine in which the court stated that "[j]ustice

requires that a party have a fair chance to present [its] position. But overall interests of administration do not require or generally contemplate that [it] will be given more than one fair opportunity."). The United States Court of Appeals for the D.C. Circuit explicitly found that "law of the case . . . [has] a rightful and reasonable application to the workings of administrative agencies." *Id.*

Here, this Court correctly ruled in its December 16, 2022 Order that "defect" for purposes of this action is defined by 16 C.F.R. § 1115.4 and not common law. In that December 16, 2022 Order, this Court recognized that under § 1115.4:

> defect includes the dictionary or commonly accepted meaning of the word. Thus, a defect is a fault, flaw, or irregularity that causes weakness, failure, or inadequacy in form or function. A defect, for example, may be the result of a manufacturing or production error; that is, the consumer product as manufactured is not in the form intended by, or fails to perform in accordance with, its design. In addition, the design of and the materials used in a consumer product may also result in a defect. Thus, a product may contain a defect even if the product is manufactured exactly in accordance with its design and specifications, if the design presents a risk of injury to the public. A design defect may also be present if the risk of injury occurs as a result of the operation or use of the product or the failure of the product to operate as intended. A defect can also occur in a product's contents, construction, finish, packaging, warnings, and/or instructions. With respect to instructions, a consumer product may contain a defect if the instructions for assembly or use could allow the product, otherwise safely designed and manufactured, to present a risk of injury.[43]

The Court's December 16, 2022 Order also correctly recognized that "defect" includes "reasonably foreseeable consumer use or misuse and consumer reliance on expected function."[44] In addition, this Court found that the defect definition was promulgated through agency action and significant public comments, which makes it authoritative, and this definition of defect may

[43] December 16, 2022 Order at 8 (quoting 16 C.F.R. § 1115.4.)
[44] *Id.*

be afforded expansive interpretation because of the remedial nature of the CPSA.[45] The law of the case doctrine directs that this Court continue to apply the regulation to Leachco's summary decision motion "in the absence of extraordinary circumstances such as where the initial decision was clearly erroneous and would make a manifest injustice." *Pharmacy Benefit*, 582 F.3d at 439 (quoting *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 816 (1988) (upholding exceptional deviation from law of the case due to a clearly erroneous jurisdictional determination)). Leachco has not identified any "extraordinary circumstances" here.[46]

2. There Are Genuine Issues of Material Fact Concerning Whether the Podster Is Defective

Leachco argues that Complaint Counsel cannot show that the Podster has a design defect.[47] But as explained above, pursuant to the definition of "defect" ordered by this Court to control this proceeding—16 C.F.R. § 1115.4—there are numerous genuine issues of fact that preclude the entry of summary decision.[48] Dr. Mannen, Complaint Counsel's biomechanical engineering expert, [redacted]

[45] *Id.*

[46] Not only are there no extraordinary circumstances justifying a departure from the law of the case, the Presiding Officer was correct to rule that the regulatory definition of "defect" should control in this proceeding. *Zen Magnets LLC v. CPSC*, 2018 WL 2938326, *6-7 (D. Colo. June 12, 2018) (affirming the CPSC's reliance on Section 1115.4's definition of "defect" in a substantial product hazard case), *aff'd in part and rev'd in part on other grounds*, 968 F.3d 1156 (10th Cir. 2020).

[47] Dkt. No. 91 at 29-31.

[48] Leachco raises a host of irrelevant arguments about what Complaint Counsel is *not* alleging. For example, Leachco argues that the Podster is not an Infant Sleep Product subject to 15 U.S.C. § 2057d(b) because it is not marketed as a sleep product. Dkt. No. 91 at 9-10. This is irrelevant because Complaint Counsel is not alleging a violation of 15 U.S.C. § 2057d(b). Rather the claim at issue is whether the Podster is a substantial product hazard pursuant to 15 U.S.C. § 2064(a)(2). Leachco also argues that Complaint Counsel is not alleging a manufacturing or warning defect. Dkt. No. 91 at 26. Again, since Complaint Counsel is not alleging those claims, any argument on summary decision is irrelevant.

[redacted]

In response, Leachco merely cites common law authorities defining "defect" with elements that are not required by § 1115.4, and [redacted] However, Dr. Mannen's testimony was presented within a reasonable degree of engineering certainty, and it is well supported by scientific methods and sources. [redacted]

[redacted]

[49] Expert Testimony of Erin Mannen, Ph.D., April 28, 2023 at 5-6 (Ruff Decl., Exhibit 9).
[50] *Id.* at 32-34.

[redacted]

[51] *Id.* at 46-48.
[52] *Id.* at 47 (emphasis in original).
[53] *Id.* at 48-49.
[54] *Id.* at 48 (emphasis in original).
[55] *Id.* at 52.
[56] *Id.* at 53.

[redacted]

Indeed, as a general matter, Leachco has failed to demonstrate that there are no facts in dispute regarding whether the Podster contains "a fault, flaw, or irregularity that causes weakness, failure, or inadequacy in form or function." 16 C.F.R. § 1115.4.

Leachco also claims that Complaint Counsel's allegations are an attempt to create a "previously unknown" category of defect. This blatantly ignores the regulatory definition of defect found by this Court to control in this proceeding. There, § 1115.4 explicitly says that "a design defect may also be present if the risk of injury occurs as a result of the operation or use of the product or the failure of the product to operate as intended." The regulation also explicitly says consideration of whether a product is defective shall include, among other things, "the role of consumer misuse of the product and the foreseeability of such misuse." 16 C.F.R. § 1115.4(e). *See also Zen Magnets*, 2018 WL 2938326 at *7 (finding that under 1115.4 "[a]lthough adequate

[57] *Id.* at 49-51.
[58] *Id*. at 49-50.

instructions and safety warnings might prevent misuse . . . misuse can be a basis for finding a product defective"); *In the Matter of Zen Magnets*, 2017 WL 11672449, *10 (CPSC October 26, 2017) ("[T]he concept of 'foreseeable misuse' has been an integral part of consumer product safety analysis for more than 40 years, including before the creation of this agency.") *aff'd in part and rev'd in part on other grounds,* 2018 WL 2938326, *7 (D. Colo. June 12, 2018), *aff'd in part and rev'd in part on other grounds*, 968 F.3d 1156 (10th Cir. 2020); *see also Southland Mower Co. v. CPSC*, 619 F.2d 499, 513 (5th Cir. 1980) (stating that "Congress intended for injuries resulting from foreseeable misuse of a product to be counted in assessing risk"). [59] In fact, the Commission has expressly found that it may pursue an action under Section 15 under a defect theory "based *solely* on reasonably foreseeable misuse," including where consumers were injured because they had "disobeyed, did not receive, or did not read [product] warnings." *Zen Magnets*, 2017 WL 11672449 at *11 (emphasis added), *15.

Leachco cannot show that its common law definition of defect controls nor that even if it did apply, that there are no genuine issues of fact precluding summary decision. To the contrary, in this case, this Court—and others—have ruled that the administrative regulation controls in these types of cases. That regulation permits a factfinder to inquire as to whether foreseeable use as well as misuse poses a defect. Here Complaint Counsel has alleged there is a risk of suffocation by consumers' use of the Podster and has supported those allegations with expert

[59] In *Southland Mower*, the court reviewed a power lawn mower safety standard promulgated by the Commission. 619 F.2d at 513. The Commission standard required, *inter alia*, a safety shield on the back of the mower to prevent an operator from accidentally placing his feet within reach of the blades. *Id.* Based on evidence that consumers sometimes removed safety shields when they interfered with the mower's mobility, the Commission standard also required manufacturers to subject the shields to an "obstruction test" to ensure that they do not catch on certain surface obstructions. *Id.* Petitioners in *Southland Mower* challenged the obstruction test, contending that "the risk of injury from consumer defeat of safety shielding is not 'unreasonable' because consumers would have chosen to incur the risk, and their judgment must be respected." *Id.* The Fifth Circuit rejected this argument, holding that "Congress intended for injuries resulting from foreseeable misuse of a product to be counted in assessing risk." *Id.* (citation omitted).

testimony that presents genuine issues of material facts as to whether the Podster is defective. Summary decision is not appropriate in light of these genuine issues.

B. "But-for" Causation is Not an Element of a Section 15 Substantial Product Hazard Claim Under the CPSA

Leachco claims that Complaint Counsel must prove "but for" causation as defined by common law in order to demonstrate a substantial product hazard under Section 15 of the CPSA.[60] Leachco further argues that Complaint Counsel cannot establish that the Podster was the "but for" or proximate cause of the deaths in the three reported fatal incidents and thus summary decision is appropriate.[61] Each of these arguments fail because: (1) as a matter of law, "but for" causation as defined by common law is not required under Section 15 of the CPSA; (2) even if causation were required, Complaint Counsel is not required to demonstrate there are actual incidents of injury or death; and, (3) there are genuine issues of material fact that preclude the entry of summary decision regarding the three fatal incidents.

First, nowhere within the CPSA is there a requirement that, to prove a consumer product is a substantial product hazard, the Commission must show that the consumer product was the common law "but-for" or "proximate" cause of an actual injury or death. Under CPSA Section 15(a)(2), a "substantial product hazard" is a "product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public." 15 U.S.C. § 2064(a)(2). From its plain language, the statute contains no reference to "but-for" or "proximate" causation.

As discussed *supra* in Section IV.A.1 of this Response, this Court has already ruled that "[t]he claim in this proceeding is governed by Commission regulations and not by common law

[60] Dkt. No. 91 at 33-34.
[61] *Id.* at 34.

products liability."[62] The law of the case doctrine therefore applies here and obviates the need to relitigate Leachco's claim to the contrary that common law causation should apply.[63] Unlike product liability law, which addresses the harm to individual consumers from individual injury incidents, the Commission's authority allows the agency to address risks present across an entire product line by taking proactive measures to avoid or mitigate a "substantial risk of injury to the public."

The Commission regulation that bears on the hazard created by the defect is 16 C.F.R. § 1115.12(g)(1). That regulation is not limited to whether the product is the "but for" or proximate cause of the injuries or deaths. To the contrary, this regulation is titled in part "evaluating substantial product hazard," and it provides a broad-based and detailed four-factor test regarding whether a defect creates a substantial risk of injury:

> (g) Evaluating substantial risk of injury. Information which should be or has been reported under section 15(b) of the CPSA does not automatically indicate the presence of a substantial product hazard. On a case-by-case basis the Commission and the staff will determine whether a defect or noncompliance exists and whether it results in a substantial risk of injury to the public. In deciding whether to report, subject firms may be guided by the following criteria the staff and the Commission use in determining whether a substantial product hazard exists:
>
> (1) Hazard created by defect. Section 15(a)(2) of the CPSA lists factors to be considered in determining whether a defect creates a substantial risk of injury. These factors are set forth in the disjunctive. Therefore, the existence of any one of the factors could create a substantial product hazard. The Commission and the staff will consider some or all of the following factors, as appropriate, in determining the substantiality of a hazard created by a product defect:
>
> (i) Pattern of defect. The Commission and the staff will consider whether the defect arises from the design, composition, contents, construction, finish,

[62] December 16, 2022 Order at 7.
[63] *See* Section IV.A.1 *supra* discussing the law of the case doctrine and citing cases.

packaging, warnings, or instructions of the product or from some other cause and will consider the conditions under which the defect manifests itself.

(ii) Number of defective products distributed in commerce. Even one defective product can present a substantial risk of injury and provide a basis for a substantial product hazard determination under section 15 of the CPSA if the injury which might occur is serious and/or if the injury is likely to occur. However, a few defective products with no potential for causing serious injury and little likelihood of injuring even in a minor way will not ordinarily provide a proper basis for a substantial product hazard determination. The Commission also recognizes that the number of products remaining with consumers is a relevant consideration.

(iii) Severity of the risk. A risk is severe if the injury which might occur is serious and/or if the injury is likely to occur. In considering the likelihood of any injury the Commission and the staff will consider the number of injuries reported to have occurred, the intended or reasonably foreseeable use or misuse of the product, and the population group exposed to the product (e.g., children, elderly, handicapped).

(iv) Other considerations. The Commission and the staff will consider all other relevant factors.

16 C.F.R. § 1115.12(g)(1). According to the explicit language of the regulation, which this Court held controls, there is no one factor that is dispositive because the statutory language is set forth in the disjunctive. The only factor that speaks to actual injuries caused by the hazard is subsection (iii), which discusses a consideration of "the number of injuries reported to have occurred" but this is only one factor among multiple factors that can inform whether there is a substantial product hazard. Indeed, the statute does not refer to causation or proximate cause and the only reference to the term in the regulation is in subsection (ii), which relates to the number of defective products distributed in commerce. And that reference specifically discusses

defective products in the context of "potential for causing injury" and not *actually* causing injuries.

The case law that Leachco cites in favor of its "causation" requirement is also inapposite. For example, Leachco cites the Seventh Circuit decision in *Zepik v. Tidewater Midwest, Inc.* for the proposition that "the CPSA follows the common-law background of traditional tort liability."[64] However, *Zepik* is a case that involved a *private right of action* under Section 23 of the CPSA. 856 F.2d 936, 942. In contrast, this action is being brought by CPSC staff pursuant to Section 15 of the CPSA and so dicta concerning Section 23 do not control. Indeed, the phrase called out by Leachco from the *Zepik* case and Section 23 of the CPSA is "by reason of." But this term does not appear in Section 15—in that section a product defect "because of" the factors enumerated can create a substantial product hazard.

Leachco's citation to the *Kirkbride v. Terex* case is also misplaced because it has to do with state product liability law, not a substantial product hazard claim under Section 15 of the CPSA. 798 F.3d 1343, 1349 (10th Cir. 2015) (state products liability claim removed to federal court). The Tenth Circuit's statements regarding the Utah common law of causation simply has no application in this case.

The *Bostock v. Clayton County* case cited by Leachco also is distinguishable and arises in an entirely different statutory context. 140 S. Ct. 1731 (2020). *Bostock* involved an employment discrimination suit under Title VII of the Civil Rights Act, which proscribes "discriminat[ion] against any individual . . . because of such individual's race, color, religion, sex, or national origin." *Id.* at 1738 (quoting 42 U.S.C. § 2000e-2(a)(1)). In other words, "an employer who intentionally treats a person worse because of sex—such as by firing the person for actions or

[64] Dkt. No. 91 at 33.

attributes it would tolerate in an individual of another sex—discriminates against that person in violation of Title VII." *Id.* at 1740. It therefore makes sense in that statutory context that "because of" has a causal component: Title VII bars situations where, "but for" the race, color, religion, sex, or national origin of an employee, the employer would not have treated the employee worse. "Because of" is used in an entirely different context in Section 15 of the CPSA. Section 15 does not require a consumer to actually be injured "because of" the defective consumer product. Rather, "because of" is used in the definition of substantial product hazard to explain circumstances that can give rise to a substantial risk of injury: "a product defect which (*because of* the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public." 15 U.S.C. § 2064(a)(2) (emphasis added).

Thus, Leachco's argument that the statute requires proof of a product causing actual injuries or deaths is without support. And indeed, Leachco's argument that Complaint Counsel must prove that the Podster caused actual injuries and deaths is wholly inconsistent with the statutory framework of the CPSA that does not require the Commission to await actual injuries and deaths before taking remedial action. *See In re Dye*, 1989 WL 435534, *14 (CPSC July 17, 1991) (explaining that "the Commission is not required to have evidence of actual injuries in order to address a risk"); 16 C.F.R. § 1115.6(a) (regulation relating to firm reporting noting: "Firms that obtain information indicating that their products present an unreasonable risk of serious injury or death should not wait for such serious injury or death to actually occur before reporting."). As the Commission previously has held: "With regard to the absence of known fatalities, such evidence is not determinative of whether a product creates a 'substantial risk of injury to the public' under section 15. *There is no provision in the CPSA that requires proof of*

actual injuries or deaths in order to show that a product contains a defect that creates a substantial risk of injury to the public." *In re Dye*, 1989 WL 435534 at *6 (emphasis added).

As explained above, Leachco is wrong on the law regarding causation. But even if a common law causation standard governed this action, there are genuine issues of material fact regarding the facts surrounding the three fatal incidents, such that summary decision should be denied. [redacted]

[65] *Id.* at 34.
[66] *Id.* at 34-35.
[67] *See* discussion in Section II.C, *supra*.
[68] Expert Testimony of Celestine Kish, May 2, 2023 at 67-70 (Rogal Decl., Exhibit 10).

[redacted] Therefore, even if common law causation were an element of a substantial product hazard case under the CPSA (it is not), summary decision is not appropriate because Complaint Counsel has proffered testimony about the Podster causing death in infants and there thus are genuine issues of material fact to be resolved at trial.

C. Leachco's Incorrectly Interprets "Substantial Risk of Injury" under Section 15 of the CPSA; Summary Decision Should be Entered in Favor of Complaint Counsel Based on a Correct Reading of the Law

Leachco contends that, to establish a substantial risk of injury under Section 15 of the CPSA, Complaint Counsel must prove "a significantly high probability of injury."[71] But this contention is baseless. The plain language of the statute, CPSC's regulations, and the relevant case law all establish that Complaint Counsel need not prove a significantly high probability of injury in a substantial product hazard case.

1. The Plain Language of the CPSA Undermines Leachco's Interpretation of "Substantial Risk of Injury"

The plain language of the CPSA does not support Leachco's contention that substantial risk of injury "means a significant likelihood that a product defect will cause an injury."[72]

With respect to questions of statutory construction, the inquiry should begin with the text of the statute, "and proceed from the understanding that unless otherwise defined, statutory terms are generally interpreted in accordance with their ordinary meaning." *Sebelius v. Cloer*, 569 U.S. 369, 376 (2013) (internal quotations omitted). Here, Section 15(a)(2) of the CPSA defines

[69] Expert Testimony of Umakanth Katwa, April 28, 2023 at 26-29 (Rogal Decl. Exhibit 13).
[70] *See, e.g.*, *id.* at 30.
[71] Dkt. No. 91 at 45.
[72] Dkt. No. 91 at 37.

"substantial product hazard" as "a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public." 15 U.S.C. § 2064(a)(2). Nowhere in that definition or elsewhere in the CPSA is "substantial risk of injury" defined as requiring a significantly high probability of injury. Rather, the statute makes clear that "the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise" can create a substantial risk of injury.

Leachco, however, tries to isolate "substantial risk of injury" from this statutory context and bend its meaning to suit Leachco's arguments. But as Leachco's own authorities establish: "'A word is given more precise content by the neighboring words with which it is associated.'" *Life Technologies Corp. v. Promega Corp.*, 580 U.S. 140, 146 (2017) (quoting *U.S. v. Williams*, 553 U.S. 285, 294 (2008)).[73] Indeed, as the Court stated in *Abramski v. United States*, also cited by Leachco, "[w]e must … interpret the relevant words not in a vacuum, but with reference to the statutory context, structure, history, and purpose." 573 U.S. 169, 179 (2014) (internal quotations omitted).

The term "substantial risk of injury" does not appear in a vacuum in Section 15(a)(2) and it must therefore be read in context with its neighboring words, which explain that a substantial risk of injury may be present "because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise." There is no requirement in the statute that, in order for a substantial risk of injury to exist, there must be a significantly high probability of injury, as Leachco advocated.

[73] In *Life Technologies*, the Supreme Court concluded in a different statutory context that "substantial" had a quantitative meaning when it was part of the phrase referring to a portion of components: "a substantial portion of the components of a patented invention." *Id.* at 146–47.

Ignoring this statutory context, Leachco turns to the CPSA's definition of "risk of injury," which the CPSA defines as "a risk of death, personal injury, or serious or frequent illness." 15 U.S.C. § 2052(a)(14). From this definition, Leachco argues—with no statutory or regulatory support—that "because the 'risk of injury' includes *substantial* or *significant* effects including, most obviously, death—the phrase 'substantial' cannot itself mean 'substantial or significant injury," because this would cause section 15(a)(2) to be redundant.[74] However, Leachco's reading is simply incorrect—"risk of injury" as defined in the CPSA, includes the risk of consequences short of death or even "substantial or significant" effects. Specifically, "[p]ersonal injury" is included without qualification, but illness must be either "serious" or "frequent." Nor does this definition state or even imply that a risk of "substantial" or "significant" injury is a prerequisite for a finding of a substantial product hazard.

Based on its novel and mistaken interpretation, Leachco incorrectly proceeds as if "substantial" is actually part of the definition of "risk of injury," and then claims that in order to give meaning to both instances of "substantial" in section 15(a)(2) (again, only one of which is in the text and one of which was created by Leachco), "'substantial' must be read to mean the likelihood or probability of the risk occurring."[75] Notably, Leachco does not point to any authority interpreting substantial risk of injury under Section 15 of the CPSA in such a manner.

In support of its position, Leachco quotes *Life Technologies* for the proposition that "courts 'should favor an interpretation that gives meaning to each statutory provision,'" and cites *Corley v. United States*, 556 U.S. 303, 314 (2009) ("'[a] statute should be construed [to give effect] to all its provisions, so that no part will be inoperative or superfluous, void or

[74] Dkt. No. 91 at 38–39 (emphasis in original).
[75] *Id.* at 39.

insignificant'") (quoting *Hibbs v. Winn*, 542 U.S. 88, 101 (2004)).[76] But Leachco's argument was flawed from the outset because it began the analysis by removing "substantial risk of injury" from its context: after initially quoting the whole of section 15(a)(2), Leachco never again mentions the words "because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise," and does not attempt to explain why it chooses to disregard them. Leachco itself rendered a large portion of the text inoperative in order to support its own preferred interpretation.

Leachco then argues, falsely, that its chosen interpretation of "substantial risk" "follows well-worn paths taken by courts around the country." Leachco quotes two California state court cases, which it misleadingly characterizes as "defect cases": *Fredette v. City of Long Beach* and *Cordova v. City of Los Angeles*. Both cases involved actions brought under the California Government Claims Act, a statute that pertains to tort claims against public entities for injuries caused by a dangerous condition of public property—and hence, not "defect" cases. The California statute contains the phrase "substantial risk of injury," but any similarity to the CPSA ends there. The California Government Claims Act is an entirely separate statutory scheme and there was legislative history suggesting that "substantial" in that context related to the probability of injury. *See Fredette*, 187 Cal. App. 3d 122, 130 n.5 (1986) (quoting legislative history discussing the "possibility of injury" and then explaining that a law professor's conclusion from that legislative history was that "The Legislature was apparently concerned not with the extent of injury, but with the *probability* that an injury would occur." (emphasis in original)). Leachco has pointed to no such legislative history here, nor is Complaint Counsel aware of any. *Fredette* and *Cordova* lend absolutely nothing to the understanding of the definition of "substantial risk of

[76] Dkt. No. 91 at 39.

injury" as it appears in the CPSA, and certainly do not demonstrate that there is a "well-worn path" for this phrase in "defect cases."

Nor do the Supreme Court cases cited by Leachco support its selective interpretation of Section 15(a)(2). Leachco cites *Johnson v. U.S.*, which holds that a portion of the Armed Career Criminal Act ("ACCA") which defines "violent felony," in part, as an offense "involv[ing] conduct that presents a serious potential risk of physical injury to another" violates the Due Process Clause due to its vagueness. 576 U.S. 591 (2015). In explaining why its ruling did not jeopardize other criminal statutes which include phrases like "substantial risk," the Court emphasized that it was only analyzing the phrase as it was used *in the context of the ACCA*, where it was found among "a confusing list of examples." *Id.* at 603. As in *Life Technologies*, the meaning of statutory language depends on the context in which the language appears, and *Johnson* contributes nothing to Leachco's argument.

Leachco cites two other cases, *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139 (2010), and *Susan B. Anthony List v. Driehaus*, 573 U.S. 149 (2014), that are not helpful to its argument. Both involve the question of whether a party established for the purposes of Article III standing that they would suffer future harm, i.e., that there was a "substantial risk that the harm will occur." *See* 573 U.S. at 158. Such standing cases have nothing to do with the CPSA or statutory interpretation, and they necessarily are concerned with the probability that harm will occur: they are assessing whether a party articulated sufficient future harm to be able to bring a suit in federal court. They therefore are irrelevant here.

Nor does *Bragdon v. Abbott*, 524 U.S. 624 (1998) save Leachco's argument. *Bragdon* explains that: "When administrative and judicial interpretations have settled the meaning of an existing statutory provision, repetition of the same language in a new statute indicates . . . the

intent to incorporate its administrative and judicial interpretations as well." *Id.* at 645. But, here, Leachco has pointed to no case law interpreting federal statutes that use the term "substantial risk of injury" similarly to the CPSA. California state cases related to a state statute, cases evaluating the risk of future harm in the Article III context, and a case evaluating a criminal statute do not "settle the meaning" of "substantial risk of injury" in the CPSA context. To the contrary, "administrative . . . interpretations"—language from *Bragdon* that Leachco conspicuously omits—including such interpretations found at 16 C.F.R. Part 1115, have settled that "substantial risk of injury" does not require there to be a significantly high probability of injury.

2. Leachco's Interpretation of "Substantial Risk of Injury" Is Contrary to CPSC's Implementing Regulations and Relevant Legislative History

CPSC's regulations and relevant legislative history establish that "substantial risk of injury" does not require a significantly high probability of injury. It is clear from the Commission's regulations that the Commission does not reduce its evaluation of whether a product defect creates a "substantial risk of injury" to a mere question of the likelihood of injury occurring.

The Commission's regulations track the plain text of the statute. Because the factors listed in Section 15(a)(2) are disjunctive, "the existence of any one of the factors could create a substantial product hazard." 16 C.F.R. § 1115.12(g)(1). For example, the Commission considers the number of defective products distributed in commerce in determining the risk of injury to the public, but "[e]ven one defective product can present a substantial risk of injury … *if the injury which might occur is serious and/or the injury is likely to occur*." 16 C.F.R. § 1115.12(g)(1)(ii) (emphasis added). Contrary to Leachco's interpretation, and consistent with the CPSA's definition of "risk of injury" discussed above, the likelihood of injury is but one factor that may weigh in favor of finding a substantial risk of injury, but a substantial risk of injury also may lie

where, as here, "the injury which might occur is serious." Although Leachco tries to ignore the applicability of 16 C.F.R. Part 1115, this Court has already noted that "[t]he claim in this proceeding is governed by Commission regulations and not by common law products liability."[77]

And, as courts have stated in the context of the Commission's rulemaking powers under the CPSA, "even a very remote possibility that a product would inflict an extremely severe injury could pose" a risk of injury. *See Southland Mower*, 619 F.2d at 509 n.22 ("For example, in *Aqua Slide* this court ruled that the severity of paraplegic injury from swimming pool slides was so great that a one in ten million risk of such injury, which is less than the risk that an average person will be killed by lightning, would be an 'unreasonable risk.'").[78] As discussed above, this is in line with the flexible approach and latitude given to the Commission under the CPSA to protect the public from defective consumer products.

Relevant legislative history also makes clear that no statistical showing or "body count" of actual injuries is required to show a substantial risk of injury. Arnold Elkind, Chairman at the time of the National Commission on Product Safety, was favorably quoted in the 1969 Senate Report regarding the Federal Hazardous Substances Act ("FHSA"), an analogous statute to the CPSA that is also enforced by the Commission,[79] as explaining that: "When your intelligence

[77] December 16, 2022 Order at 7-8 (noting that the term "defect" is defined by 16 C.F.R. § 1115.4).
[78] While the *Southland* court was reviewing a challenge to a consumer product safety standard, its interpretation of the CPSA and the Commission's authority need not be limited to that context. Prior to promulgating a consumer product safety rule, the Commission is required to show that an "unreasonable risk of injury" exists and that the standard is "reasonably necessary" to prevent or reduce that risk. 15 U.S.C. § 2056. Although the analysis the Commission must undertake in evaluating the reasonableness of a risk of injury in the rulemaking context is more detailed and quantitative than the "substantial risk of injury" analysis required by section 15(a)(2), *see* 16 U.S.C. 2058(e), neither standard requires the showing of "significantly high probability" suggested by Leachco.
[79] Section 15(c)(1) of the FHSA empowers the Commission to recall toys or other articles intended for use by children that contain a defect resulting in a substantial risk of injury to children. 15 U.S.C. § 1274(c)(1). FHSA Section 15(c) was specifically intended to give the Commission the same recall authority under the FHSA that it had under the CPSA. *See* S. Rep. No. 98-591, at 2 (1984) (this provision "will permit the CPSC to use the same procedures to recall hazardous toys and children's articles that it now uses to recall other consumer products."). Indeed, closely paralleling the language of CPSA Section 15(d), FHSA Section 15(c)(1) provides, in part, that the Commission may recall "any toy or other article intended for use by children which creates a substantial risk of injury to children (because of the pattern of defect, the number of defective toys or other articles distributed in

tells you that something will create an injury and that it seems conceptually clear that an injury will occur, it is primitive to wait until a number of people have lost their lives, or sacrificed their limbs before we attempt to prevent those accidents." S. Rep. No. 91-237 at 2-3 (1969), *quoted in Forester v. Consumer Prod. Safety Comm'n*, 559 F.2d 774, 788–89 (D.C. Cir. 1977); *Consumer Product Safety Commission Reauthorization: Hearing Before the Subcomm. On Commerce, Consumer Protection, and Competitiveness of the H. Comm. On Energy and Commerce*, 100th Cong. 125 (1987) ("If done right, recalls occur before there are many injuries and before the full potential for injury or death can be calculated.") (Statement of former CPSC Commissioner R. David Pittle on June 4, 1987).[80]

The Commission also has explained: "There is no provision in the CPSA that requires proof of actual injuries or deaths in order to show that a product contains a defect that creates a substantial risk of injury to the public. The legislative history indicates that such proof is not a prerequisite to Commission action." *In re Dye*, 1989 WL 435534, at *6. A contrary conclusion would be detrimental to consumer safety and to the Commission's statutory mandate to "protect the public against unreasonable risks of injury associated with consumer products." 15 U.S.C. § 2051(b)(1).

3. Leachco's Podster Creates a Substantial Risk of Injury to the Public

As Complaint Counsel showed in its Motion for Partial Summary Decision, the Podster

commerce, the severity of the risk, or otherwise)." 15 U.S.C. § 1274(c)(1).

[80] *See also* Consumer Product Safety Commission Reauthorization: Hearing on H.R. 2271 and H.R. 2201 Before the H. Subcomm' on Health and the Environment of the Comm' on Energy and Commerce, 97th Cong. 315 (1981) (Statement of Comm'r Stuart Statler) ("The Commission's selection of priority hazards is equally strategic. We consider the severity of the risk, the size of the population exposed, the characteristics of the population exposed—for example, whether it is infants, the elderly or the handicapped—and the circumstances of exposure—not only its intensity or duration, but also where it occurs—at home, during the night, and whether it is foreseeable or avoidable. Careful priority setting insures that we target our resources on the most serious hazards and those which most require and are most amenable to remedial measures.").

creates a substantial risk of injury to the public.[81] Specifically, and as noted above, the CPSA sets forth the factors to be considered in determining whether a substantial product hazard exists as a result of a defect which creates a substantial risk of injury: (1) pattern of defect; (2) the number of defective products distributed in commerce; (3) the severity of the risk; or (4) otherwise. 15 U.S.C. § 2064(a)(2). *See also* 16 C.F.R. § 1115.12(g)(1). These factors are disjunctive: any one of the factors standing alone could create a substantial product hazard. 16 C.F.R. § 1115.12(g)(1). Complaint Counsel's motion for partial summary decision addressed the third factor: the severity of the risk.[82]

In its own Motion for Summary Decision, Leachco states that Complaint Counsel cannot prove a substantial risk of injury, by mistakenly focusing on injury rate and mischaracterizing Complaint Counsel's expert testimony.

Leachco first spends time calculating an injury rate for the Podster. However, and not surprisingly, Leachco cites no authority supporting such an approach. That is because, as discussed above, the CPSA and its regulations do not require such a calculation. In fact, the Commission's regulations state the opposite: "Even one defective product can present a substantial risk of injury and provide a basis for a substantial product hazard determination under section 15 of the CPSA if the injury which might occur is serious and/or if the injury is likely to occur." 16 C.F.R. § 1115.12(g)(1)(ii). *See also Southland Mower Co*, 619 F.2d at 509 n.22. Thus, Leachco's incident rate argument is not supported by law and should be disregarded.

Next, Leachco attempts to attack Complaint Counsel's experts [redacted]

[81] *See* Dkt. Nos. 88-89.
[82] *See* Dkt. 89 at 21-24.

[redacted] In addition, "it is undisputed that there were three incidents associated with the use of a Podster that resulted in fatalities to infants, a uniquely vulnerable population."[85]

For these reasons, Leachco's Motion for Summary Decision regarding the substantial risk of injury should denied. Nothing raised by Leachco viably refutes the substantial risk of injury posed by the Podster or rebuts the expert testimony presented by Complaint Counsel showing that the Podster creates a substantial risk of injury. As such, summary decision should be entered for Complaint Counsel on this topic, as the Podster creates a substantial risk of injury to the public.

D. Leachco's Constitutional Arguments Are Unavailing and Are Not a Basis for Summary Decision

Leachco also makes several purely legal arguments that it could have, and should have, raised before the deadline for motions for summary decision. Section 1025.25(c) provides that such motions look to "the pleadings and any depositions, answers to interrogatories, admissions, or affidavits" to assess whether "there is no genuine issue as to any material fact and that the moving party is entitled to a Summary Decision and Order as a matter of law." But the purely

[83] Expert Testimony of Erin Mannen, April 28, 2023, Ruff Decl., Exhibit 9 at 61-62.
[84] Expert Testimony of Umakanth Katwa, April 28, 2023, Rogal Decl., Exhibit 13 at 28.
[85] *See* Dkt. No. 89 at 23.

legal arguments raised by Leachco do not rely on facts developed during discovery through "depositions, answers to interrogatories, admissions, or affidavits." They are arguments that could have been raised at the outset of the case. Rather than present these arguments early in the case so that they may be efficiently and timely resolved, Leachco has raised them in a cursory manner and on the eve of trial to compound the number of issues the Presiding Officer must address.

Regardless of Leachco's delay in raising these purely legal arguments, each of them fails. Leachco acknowledges that some are not even properly raised in this forum, and the others are without merit.

1. Leachco's Arguments That This Action Violates the Major Questions, Nondelegation, or Void for Vagueness Doctrines Fail

a. This Action Does Not Implicate the Major Questions Doctrine

Leachco's argument that this action represents an unconstitutional expansion of the CPSC's regulatory authority fails because the action is clearly authorized by the CPSA and its corresponding regulations, and is entirely consistent with past corrective actions undertaken by the CPSC. Despite Leachco's hyperbolic claim that the Commission's allegations with respect to the elements underlying the substantial product hazard determination prescribed by Section 15(a)(2) of the CPSA "stretch CPSC's product hazard authority to every consumer good," the CPSC is not relying on a novel or unprecedented interpretation of the terms "product defect" or "substantial risk of injury" as they appear in Section 15.[86] Leachco's reliance on the Major Questions Doctrine is therefore misplaced.

As a threshold matter, Leachco is wrong to suggest that a finding of defect in a product that "contains express warnings against foreseeable misuse" would be somehow

[86] *See supra,* Sections IV.A & IV.C.

unprecedented.[87] Far from representing a "transformative expansion" of CPSC authority,[88] the consideration of "foreseeable misuse" as part of a product defect determination "has been an integral part of consumer product safety analysis for more than 40 years, including before the creation of [the] agency." *In the Matter of Zen Magnets*, 2017 WL 11672449, *10 (CPSC 2017). Indeed, this Court specifically recognized that the definition of "defect" that appears in the Commission regulations governing this proceeding "includes reasonably foreseeable consumer use or misuse and reliance on expected function."[89] As explained in Section IV.A.2 above, the Commission has expressly found that it has the authority to pursue an action under Section 15 even under a defect theory "based *solely* on reasonably foreseeable misuse," including where consumers were injured because they had "disobeyed, did not receive, or did not read [product] warnings." *Id.* at *11 (emphasis added) & *15. Moreover, contrary to Leachco's claims that Complaint Counsel's defect theory "rewrite[s] the CPSA," the Commission in *Zen Magnets* determined both that "Congress intended the Commission to regulate products that present a risk of injury . . . aris[ing] out of consumer behavior characterized as misuse of a product" and that "the Commission's case law reflects the CPSC's authority to address reasonably foreseeable consumer misuse." 2017 WL 11672449 at *11-12.

Similarly, Leachco is wrong to suggest that any consideration of factors beyond the statistical likelihood of injury in the "substantial risk of injury" analysis would represent a departure from the Commission's ordinary approach. For the reasons discussed in Sections IV.B & C above, nothing in either the statutory language or the interpretive regulations restricts the

[87] Leachco's Motion also incorrectly implies that the Commission does not allege a design defect and concedes the Subject Products are "perfectly safe as designed for its intended use." To the contrary, as noted in Paragraphs 20-34 of the Complaint, the Podster contains a design defect posing a suffocation hazard in foreseeable scenarios in which the Podster is used unsupervised or for infant sleep.
[88] Dkt. No. 91 at 45-46.
[89] December 16, 2022 Order at 8.

Commission's analysis to a quantitative assessment of the number of injuries compared to the number of products sold. To the contrary, both CPSA Section 15(a)(2) and 16 C.F.R. § 1115.12(g) clearly contemplate that factors like the severity of possible injury, the vulnerability of the population exposed to the product, and the likelihood that a defect will manifest in any particular unit, are all important in determining whether the risk of injury is substantial. The Commission's past actions under Section 15 have long reflected this approach, including the *Zen Magnets* case, in which the Commission expressly rejected an argument that there could be no substantial risk of injury where there was evidence of only two injuries associated with the Subject Product (magnets) out of over ten million units sold. The Commission explained that "quantitative cost-benefit evidence is not required" and that "likelihood of injury is only one element of this analysis," concluding that the magnets posed a substantial risk of injury based on the statutory factors: "the pattern of defect," "the number of defective products distributed in commerce," and the "severity of risk." 2017 WL 11672449 at *33-36. Likewise, in the earlier case of *In re Dye*, the Commission made a finding of substantial risk of injury even though there were no injuries attributable to the Subject Products in the case. *See* 1989 WL 435534 at *6, *15-20.

In contrast to the ordinary exercise of longstanding authority under Section 15 in this action, the Supreme Court's recent cases finding violations of the Major Questions Doctrine involved significant and extensive changes to past agency rules or practice that are not at all analogous to these proceedings. In *West Virginia v. EPA,* for example, the Court reviewed a "new rule" issued by the Environmental Protection Agency ("EPA") representing an "unprecedented . . . 'fundamental revision'" to the approach the agency had taken to emissions standards for 50 years. 142 S.Ct. 2587, 2596 (2022) (citation omitted). The Court found that the

rule in question was impermissible because it would have newly given the EPA decisional authority over "vital considerations of national policy," including "how much coal-based generation there should be over the coming decades." *Id.* at 2612-13. Likewise, the Court's decision in *Nat'l Fed'n of Indep. Bus. v. OSHA*, rejected a COVID-19 vaccination or testing mandate proposed by the Occupational Safety and Health Administration on the grounds that it would impact "84 million people" and raise "a question of vast national significance." 142 S. Ct. 661, 667 (2022). Neither case is relevant to the present action, which represents a routine application of well-established precedents to a single product and a single firm.[90]

b. Section 15 of the CPSA Does Not Violate the Nondelegation Principle

Leachco also wrongly suggests that the CPSA, in violation of the Nondelegation Principle, grants the Commission "unfettered discretion" to make substantial product hazard determinations. The Supreme Court has made clear that the standard for a proper Congressional delegation is "not demanding," and that "a delegation is permissible if Congress has made clear to the delegee 'the general policy' he must pursue and the 'boundaries of [his] authority.'" *Gundy v. United States*, 139 S. Ct. 2116, 2129 (2019) (*citing American Power & Light Co. v. SEC,* 329 U.S. 90, 105 (1946)). Accordingly, only statutes lacking "'*any* policy or standard' to confine discretion" present a nondelegation problem. *Gundy*, 139 S. Ct. at 2129. Notably, in light of the discretion inherent in regulatory enforcement, the Court has also rejected arguments that statutes must specify a "'determinate criterion' for saying 'how much [of the regulated harm] is too much'" in order to pass Constitutional muster. *See Whitman v. Am. Trucking Ass'ns*, 531 U.S.

[90] Furthermore, Leachco's misleading claim that the Commission is impermissibly seeking to impose a product ban that Congress declined to enact itself completely ignores the fact that Congress empowered the agency to order recalls of hazardous products in Section 15 proceedings. *See also* Complaint Counsel's Opposition to Leachco's Motion to Compel Discovery, Dkt. No. 29, at 18-19 (Aug. 29, 2022) ("Leachco baselessly claims that Commission should have initiated rulemaking instead of seeking a recall . . . . Congress granted the Commission the authority to use adjudicative proceedings to compel firms to recall hazardous products and take other remedial action, and *also* gave it the authority to enact product safety rules.").

457, 475 (2001). Given this flexible standard, the Supreme Court in 2019 explained that it has "only twice in this country's history" found that Congress had violated the Nondelegation Principle[91] and has upheld many delegations invoking broad language like "public interest," "fair and equitable," or "requisite to protect the public health." *Gundy*, 139 S. Ct. at 2129.

Here, the Commission's discretion to determine whether a product presents a "substantial product hazard" is bounded by the factors Congress expressly set forth in Section 15 of the CPSA, as well as the general statutory context and purposes. This includes Congress's specific instruction that the Commission consider "pattern of defect" and "severity of the risk" as part of a substantial risk of injury analysis, 15 U.S.C. § 2064(a)(2), as well as the general direction that the goals of the agency include addressing "complexities of consumer products" that may "result in an inability of users to anticipate risks and to safeguard themselves adequately." 15 U.S.C. § 2051(a)(2). For the reasons discussed above, Complaint Counsel's allegations of a substantial product hazard in this case are wholly consistent with this statutory guidance, and they in no way represent an unfettered use of agency discretion.

c. CPSA Section 15 Is Not Unconstitutionally Vague

For the same reasons, Leachco's claims that Section 15 of the CPSA is unconstitutionally vague also fail. In *United States v. Spectrum Brands, Inc.*, a federal court squarely rejected an argument that Section 15's reporting requirement—specifically, Section 15(b)(3), which invokes the "substantial product hazard" standard— was so vague as to violate regulated firms' due process rights to fair notice. 218 F. Supp. 3d 794 (W.D. Wisc. 2016), *affirmed* 924 F.3d 337 (7th Cir. 2019). The court explained that "the CPSA and interpretive regulations establish an

[91] At the time of the filing of this brief, this statement in *Gundy* remains accurate, as there have been no subsequent Supreme Court opinions finding a violation of the Nondelegation Principle since 2019. *See, e.g., Consumer Fin. Prot. Bureau v. L. Offs. of Crystal Moroney, P.C.*, 63 F.4th 174, 184 (2d Cir. 2023) (explaining, in a March 2023 opinion, "In its history, the Supreme Court has found an improper delegation only twice").

enforceable standard for a 'substantial product hazard'" and that any doubts about reporting obligations were not the type of "existential doubt" that would raise due process concerns, but rather "concrete, quantifiable doubt born out of the existence of the factors identified in the statute and regulations." *See id.* at 809-10; *see also Toy Mfrs. Of America, Inc. v. Blumenthal*, 806 F. Supp. 336, 347 (D. Conn 1992) ("When a statute is challenged as void for vagueness, great latitude is afforded to a regulatory statute enacted to protect public health and safety; the standard requires only that the meaning of the statute be discoverable from its context, or even by resorting to an administrative process."). "While defendant would prefer a more specific, unambiguous standard," the court continued, "the common law, state and federal statutes and regulations are all replete with such so-called 'vague' standards that shift the burden to the party with the most information, which in this case is the manufacturer." 218 F. Supp. 3d at 810.

The Presiding Officer in *In the Matter of Sun and Sand Imports, Ltd.*, 1984 WL 186688, at *4 (CPSC January 5, 1984), in a decision adopted by the Commission, made a similar point when rejecting a vagueness challenge to the definition of "children's sleepwear" in 16 C.F.R. § 1615.1(a), noting that "[t]he fact that experts may disagree . . . does not make the regulation so vague as to be unenforceable," and reasoning that no conceivable regulation could "remove all shadow of doubt as to exactly which items" it covers, "short of attempting to list every conceivable item which is to be regulated." *See also United States v. Sun and Sand Imports, Ltd.*, 725 F.2d 184, 187 (2d Cir. 1984) (holding that definition of "children's sleepwear" was not unconstitutionally vague).

Furthermore, given that the allegations of a substantial product hazard in this case are entirely consistent with past Commission practice, Leachco's claims that it lacked "fair notice" are unavailing. Leachco's reliance on the *FCC v. Fox Television Stations, Inc.* case is misplaced,

given that the case involved an attempt by the Federal Communications Commission to retroactively apply a new interpretation of an enforcement policy to an incident that occurred prior to the order announcing the change. *See* 567 U.S. 239, 249 (2012). As discussed above, there has been no relevant change in policy whatsoever here, and the precedents that form the basis of the present action are decades old.

2. Leachco Concedes that Its Additional Constitutional Arguments Cannot Be Decided in This Proceeding

Given Leachco's express acknowledgement that its arguments concerning its rights to due process, an Article III tribunal, and a jury trial "cannot be addressed by this Court or the Commission,"[92] Complaint Counsel will not address those claims in substance at this stage and requests that the Court deny Leachco's motion to the extent it rests on those admittedly improper grounds. To the extent the Presiding Officer wishes to consider those topics despite Leachco's admission that they are inappropriate here, Complaint Counsel would ask that the Presiding Officer permit it leave to file a supplemental response on those topics. Complaint Counsel also refers the Presiding Officer to the U.S. Department of Justice's briefings in the ongoing parallel proceedings in federal court. Specifically, many of Leachco's arguments that are admittedly improper in this forum are addressed in Defendant's Opposition to Plaintiff's Motion for Preliminary Injunction in the Eastern District of Oklahoma, which explains why Leachco's constitutional claims are unlikely to succeed on the merits.[93] The claims are further discussed in the Brief For Appellees before the Court of Appeals for the Tenth Circuit.[94] Complaint Counsel agrees that, in addition to being wrong on the merits for the reasons explained in depth in those briefings, these arguments are not appropriate for this forum and should therefore be rejected.

[92] Dkt. No. 91 at 54.
[93] *Leachco, Inc. v. Consumer Product Safety Commission,* No. 6:22-cv-00232-RAW, Dkt. No. 39 at 14-24 (E.D. Ok. Sept. 16, 2022).
[94] *Leachco, Inc. v. Consumer Product Safety Commission*, No. 22-7060, at 27-42 (10th Cir. Feb. 16, 2023).

V. CONCLUSION

In light of the foregoing, Complaint Counsel respectfully requests that the Presiding Officer deny Leachco's motion for summary decision. As explained above, there are genuine issues as to material facts and incorrect statements of law precluding summary decision in favor of Leachco.

Dated this 23rd day of June, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 23, 2023, I served Complaint Counsel's Response in Opposition to Leachco's Motion for Summary Decision and the Declaration of Brett Ruff in support of that Response on all parties and participants or record in these proceedings as follows:

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