UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of	)	
LEACHCO, INC.	)	CPSC DOCKET NO. 22-1
Respondent.	)	

COMPLAINT COUNSEL'S APPEAL BRIEF

Gregory M. Reyes, Supervisory Attorney
Michael J. Rogal, Senior Trial Attorney
Caitlin O'Donnell, Trial Attorney
Thomas J. Mendel, Trial Attorney
Serena Anand, Trial Attorney

Division of Enforcement and Litigation
Office of Compliance and Field Operations
U.S. Consumer Product Safety Commission
Bethesda, MD 20814
(301) 504-7220

Complaint Counsel for
U.S. Consumer Product Safety Commission

August 30, 2024

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Regulations

Pursuant to 16 C.F.R. § 1025.53(b), Complaint Counsel hereby submits its Brief appealing the Memorandum Opinion and Initial Order Denying Relief Sought in the Complaint (Dkt. 148) ("Initial Decision"), issued by Presiding Officer, Michael G. Young ("Presiding Officer"),[1] on July 3, 2024. Complaint Counsel requests that the U.S. Consumer Product Safety Commission ("Commission") set aside the Initial Decision in its entirety and order a mandatory recall. *See* 16 C.F.R. § 1025.55(b).

I. INTRODUCTION

The Podster infant pillow ("Podsters" or "Subject Products"), manufactured and distributed by Respondent, Leachco, Inc. ("Respondent" or "Leachco"), is a hazardous product that poses a hidden asphyxiation and suffocation risk that can be fatal to vulnerable infants. The Initial Decision, however, fails to recognize this deadly hazard or require a mandatory recall of the Podster to protect consumers. Rather, the Initial Decision makes numerous factual and legal errors that are fundamentally at odds with, and contradict the plain language of, the Consumer Product Safety Act ("CPSA"), the regulations promulgated thereunder, and legal precedent interpreting the CPSA. These errors include (1) incorrectly interpreting the legal standards for an adjudication under Section 15 of the CPSA; (2) applying additional legal standards not required under the CPSA; (3) conducting a legally improper and factually inaccurate analysis comparing the Podsters to other similar products; (4) failing to admit relevant, probative evidence and making findings based on improperly excluded evidence; and (5) failing to find that the Podsters present a substantial product hazard requiring remedial action under Section 15 of the CPSA.

In fact, when analyzed under the proper legal framework, a preponderance of the evidence shows that the Podsters present a substantial product hazard to infants. Accordingly, the

[1] Judge Young was duly appointed Presiding Officer in this case after having been detailed from the Federal Mine Safety and Health Review Commission. *See* Dkt. 18, at 1.

Commission should set aside the Initial Decision in its entirety and issue a Final Decision finding that the Podsters present a substantial product hazard and ordering Leachco to provide public notification and refunds to consumers (Proposed Order included as Exhibit A). *See* 16 C.F.R. § 1025.55(b).

II. STATEMENT OF THE CASE

On February 9, 2022, Complaint Counsel filed the Complaint commencing this action under Sections 15(c) and (d) of the CPSA, 15 U.S.C. § 2064(c)–(d).[2] The Complaint alleges that the Podsters manufactured and distributed by Respondent present a substantial product hazard under Section 15 of the CPSA, necessitating public notification and remedial action to protect consumers from the risk of injury and death. Respondent filed its Answer on March 2, 2022.[3]

Beginning in March 2022, the parties engaged in discovery. In August 2022, Leachco's original counsel withdrew, and its current counsel appeared, immediately seeking to disqualify the Presiding Officer, stay the proceeding, and/or stay discovery.[4] That same month, Leachco also commenced collateral litigation in federal district court in the Eastern District of Oklahoma seeking to enjoin this administrative action. On *ten* occasions between 2022 and 2024, Leachco has attempted to collaterally enjoin this action through federal courts in the Eastern District of Oklahoma, the United States Court of Appeals for the Tenth Circuit, and the Supreme Court. Leachco's collateral litigation questions the constitutionality of the Commission and is designed to delay the instant safety action. To date, none of Leachco's attempts have been successful.[5]

---

[2] Dkt. 1.
[3] Dkt. 2.
[4] Dkt. 22.
[5] *See Leachco v. CPSC*, Case No. 6:22-civ-00232-RAW, 2022 WL 17327494 (E.D. Okla. Nov. 29, 2022) (Order Denying Plaintiff's Mot. for Preliminary Inj.); *Leachco v. CPSC*, Case No. 6:22-civ-00232-RAW (E.D. Okla. Dec. 8, 2022) (Order Denying Mot. for Inj. Pending Appeal); *Leachco v. CPSC*, No. 22-7060, 2023 WL 5747726 (10th Cir. Jan. 30, 2023) (Order Denying Mot. for Inj. Pending Appeal and Denying Mot. to Expedite Appeal); *Leachco v. CPSC*, No. 22A730, 2023 WL 5728482 (Feb. 15, 2023) (Docket Entry Denying Appl. for Writ of Inj.) (Gorsuch, J.);

Discovery was ultimately concluded on April 28, 2023. Each side filed Motions for Summary Decision on June 9, 2023, and opposition briefs on June 23, 2023.[6] On July 6, 2023, the Presiding Officer denied both parties' respective motions.[7]

On July 14, 2023, the parties filed Pre-Hearing Briefs, witness and exhibit lists, and Motions *in Limine*.[8] Respondent subsequently filed a Motion to Strike Konica McMullen from the Commission's Witness List on July 17, 2023.[9] The Presiding Officer granted the Motion to Strike, and, in response to Respondent's other Motions *in Limine*, excluded portions of expert testimony proffered by Complaint Counsel's experts Celestine Kish and Dr. Umakanth Katwa, and required the redaction of certain documents found within the Virginia In-Depth Investigation ("IDI") that was admitted into evidence.[10] To preserve the record, Complaint Counsel filed Offers of Proof prior to and during the hearing to ensure that such testimony and documents would accompany the record for the Commission to consider on appeal.[11]

A four-day hearing was held from August 7, 2023 to August 10, 2023. Complaint Counsel called six witnesses: expert witnesses Dr. Erin Mannen, Senior Engineering Psychologist Celestine Kish, and Dr. Umakanth Katwa; a CPSC staff investigator; a former CPSC compliance officer; as well as Jamie Leach, Leachco's Vice President and Chief of Product Development. Leachco called one witness, its expert Ms. Peggy Shibata. After the

---

Leachco v. CPSC, No. 22-7060 (10th Cir. June 6, 2023) (Order Denying Mot. for Inj. Pending Appeal); *Leachco v. CPSC*, Case No. 6:22-civ-00232-RAW, 2023 WL 4934989 (E.D. Okla. Aug. 2, 2023) (Order Denying Mot. for Inj. Pending Appeal); *Leachco v. CPSC*, No. 22-7060, 2023 WL 5748128 (10th Cir. Aug. 4, 2023) (Order Denying Emergency Mot. for Inj. Pending Appeal); *Leachco v. CPSC*, No. 23A124, 2023 WL 5728468 (Aug. 7, 2023) (Docket Entry Denying Appl. for Inj. Pending Appeal) (Gorsuch, J.); *Leachco v. CPSC*, 103 F.4th 748 (10th Cir. 2024) (affirming district court's denial of Leachco's motion for preliminary injunction); and, *Leachco v. CPSC*, 2024 WL 3815314, No. 24-156 (Aug. 9, 2024) (Pet. for Writ of Cert.).

[6] Dkt. 88–92, 95–97.

[7] Dkt. 99.

[8] Dkt. 101–118.

[9] Dkt. 119.

[10] Dkt. 125, 127–129, 131.

[11] Dkt. 132–133, 135–137; *see also* 16 C.F.R. § 1025.43(f).

hearing, the parties filed Post-Hearing Briefs on September 29, 2023.[12] On July 3, 2024, the Presiding Officer issued the Initial Decision, which denied the relief sought in the Complaint.[13] Complaint Counsel filed a timely Notice of Intent to Appeal and Respondent subsequently filed a Notice of Intent to Cross Appeal.[14] On July 26, 2024, the Commission granted a joint motion to set the briefing schedule.[15]

Complaint Counsel provided a detailed recitation of the relevant facts in this matter in its Post-Hearing Brief,[16] and refers the Commission to that Brief for factual background.

III. STATEMENT CONTAINING THE REASONS WHY THE INITIAL DECISION IS INCORRECT

Pursuant to 16 C.F.R. § 1025.53(b)(3), and as further detailed below, Complaint Counsel provides the following reasons why "the Initial Decision is incorrect":

- The Presiding Officer Incorrectly Interpreted Section 15 and Its Corresponding Regulations;
- The Presiding Officer Imposed Additional Legal Standards Not Required by Section 15 of the CPSA;
- The Presiding Officer's Analysis of Products Other Than the Podster Was Both Legally Improper and Factually Erroneous
- The Presiding Officer Failed to Admit Relevant, Probative Evidence and Made Findings Contrary to the Evidence He Improperly Excluded;
- The Presiding Officer Held Incorrectly that the Podsters did not pose a Substantial Product Hazard under Section 15 of the CPSA; and,
- The Initial Decision Erred by Not Imposing a Mandatory Recall.

Accordingly, the Commission should set aside the Initial Decision in its entirety.

[12] Dkt. 143–144.
[13] *See* Dkt. 148. Pursuant to the Commission's Rules of Practice for Adjudicative Proceedings, the Presiding Officer "shall endeavor to file an Initial Decision with the Commission within sixty (60) days after the closing of the record or the filing of post-hearing briefs, whichever is later." 16 C.F.R. § 1025.51(a).
[14] *See* Dkt. 149; Dkt. 151.
[15] *See* Dkt. 152.
[16] Dkt. 143, at 2–16.

IV. ARGUMENT

A. *Legal Standard*

For an adjudication under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551–559, where, as here, an agency's statute does not provide a standard of review, the APA and the case law interpreting it establish that the preponderance of the evidence standard is the burden of proof in an adjudication. *In re Amazon.com, Inc.*, CPSC Dkt. No. 21-2, Dkt. 142, at 25 (July 29, 2024) (Decision and Order); *see also Steadman v. SEC*, 450 U.S. 91, 104 (1981) (determinations in agency adjudicatory proceedings "are made according to the preponderance of the evidence"), *reh'g denied*, 451 U.S. 933 (1981); *see also In re Zen Magnets, LLC* (Zen Magnets), CPSC Dkt. No. 12-2, 2017 WL 11672449, at *7 (Oct. 26, 2017) (Final Decision and Order) ("The CPSA is silent regarding the standard of proof governing Commission adjudications. Therefore, the Commission reaffirms that the preponderance of the evidence standard applies."), *vacated on other grounds*, 2018 WL 2938326 (D. Colo June 12, 2018), *amended in part*, 2019 WL 9512983 (D. Colo. Mar. 6, 2019), *aff'd in part*, *rev'd in part*, 986 F.3d 1156 (10th Cir. 2020).

When evaluating the Initial Decision and accompanying record, the Commission considers the whole record, but shall "exercise all the powers which it could have exercised if it had made the Initial Decision," and is free to "adopt, modify or set aside" any or all of the Presiding Officer's findings and conclusions. 16 C.F.R. § 1025.55. The Commission has interpreted CPSC's Rules of Practice for Adjudicative Proceedings ("Rules of Practice") as providing for *de novo* review. *See In re Amazon.com, Inc.*, CPSC Dkt. No. 21-2, Dkt. 142, at 24; *see also Landry v. FDIC*, 204 F.3d 1125, 1132 (D.C. Cir. 2000), *cert. denied*, 531 U.S. 924 (2000) (in administrative proceedings, the Presiding Officer has "purely recommendatory power" subject to *de novo* review). Under *de novo* review, the Commission "review[s] the matter

anew, the same as if it had not been heard before, and as if no decision previously had been rendered." *Freeman v. Directv, Inc.*, 457 F.3d 1001, 1004 (9th Cir. 2006). The Commission has previously held that "[*d*]*e novo* review means 'an independent determination of the issues,' and deference to the Initial Decision is not required." *Zen Magnets*, 2017 WL 11672449, at *6 (first quoting *United States v. First City Nat'l Bank of Houston*, 386 U.S. 361, 368 (1967); and then citing *La. Pub. Serv. Comm'n v. FERC*, 522 F.3d 378, 395 (D.C. Cir. 2008)) (internal citation omitted).

B. *The Initial Decision Should be Set Aside Because It Erroneously Interpreted Section 15 and its Corresponding Regulations*

The Initial Decision erred as a matter of law by failing to apply the correct legal standards to the facts. First, the Initial Decision relied on the legal standard applicable to rulemaking cases under Sections 7 and 9—"unreasonable risk"—instead of the appropriate substantial product hazard standard for a Section 15 adjudication. Second, the Initial Decision conducted an improper substantial risk of injury analysis. Thus, because the Presiding Officer incorrectly applied the law, the Initial Decision must be set aside.

1. *The Initial Decision Relied on an Improper Standard in Assessing the Defect and Substantial Risk of Injury Posed by the Podsters*

Pursuant to Section 15 of the CPSA, the Commission may order a mandatory recall of a consumer product, after notice and opportunity for a hearing, if a product poses a "substantial product hazard." *See* 15 U.S.C. § 2064(a), (c), (d). For the purposes of this adjudication, a substantial product hazard means "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." *Id.* § 2064(a)(2). The Commission has issued regulations that provide further guidance on the elements of this definition. *See generally* 16

C.F.R. Part 1115. Importantly, this substantial product hazard standard is distinct from the "unreasonable risk of injury" standard that is required for rulemakings and banned hazardous products under Sections 7, 8, and 9 of the CPSA. *See* 15 U.S.C. §§ 2056–2058. Notably, the definition of substantial product hazard does not contain the phrase unreasonable risk of injury. *See id.* § 2064(a).

Despite these clear statutory and regulatory criteria, however, the Presiding Officer ignored the plain language of Section 15 and improperly applied the "unreasonable risk of injury" standard to this adjudication. This error is not a matter of mere semantics. The unreasonable risk of injury standard is more stringent, involving other factors such as a balancing test weighing the costs and benefits of a *regulation*, which is explicitly not required by Section 15. *See Forester v. CPSC*, 559 F.2d 774, 789 (D.C. Cir. 1977). For example, the Presiding Officer reasoned that the "case against the Podster does not reflect a weighing of interests, costs, or alternative approaches *that would seem to be required*," relying on *Gulf South Insulation v. CPSC*, 701 F.2d 1137, 1148 (5th Cir. 1983), and *Southland Mower Co. v. CPSC*, 619 F.2d 499 (5th Cir. 1980), for the proposition that a Section 15 adjudication requires a determination of an "unreasonable risk of injury" using a "'balancing test' like that used in tort law, weighing severity and likelihood of injury against harm produced by the *regulation*." Initial Decision at 64 (quoting *Southland Mower*, 619 F. 2d at 508–09) (emphasis added). But *Gulf South* and *Southland Mower* dealt with rulemaking, not substantial product hazards under Section 15. This was not a singular reference; the Presiding Officer improperly relied on this incorrect standard throughout the Initial Decision, yielding a ruling that is contrary to the governing law. *See* Initial Decision at 37–38 (discussing procedures for promulgating consumer safety standards and banning hazardous products under 15 U.S.C. §§ 2056–2058), 50 ("Complaint Counsel must . . .

prove . . . an unreasonable risk of injury, created by the design."), 52 (again citing *Southland Mower* for "balancing test" to determine "unreasonable risk of injury").

Indeed, the Commission has clearly and repeatedly articulated that the rulemaking standard of "unreasonable risk" is distinctly considered in Section 7, 8, and 9 proceedings and has no place in a Section 15 substantial product hazard adjudication—because of clear differences in the standards and what they require:

> The regulatory analysis concerning "unreasonable risk" in the rulemaking context is not applicable in an adjudicatory proceeding seeking an order to address a "substantial product hazard." Where rulemaking is primarily concerned with a balancing of the hazard and economic impact of the proposed regulations, adjudications under Section 15 require no such balancing. . . .
>
> . . . .
>
> Additionally, when the Commission issued the Section 15 regulations, the Commission specifically declined to adopt the nomenclature "unreasonable risk" when considering the term "defect" under Section 15 of the CPSA. According to the Commission, the term "unreasonable risk" had taken on a "special meaning" within the agency with regard to rulemaking.

Zen Magnets, CPSC Dkt. No. 12-2, 2016 WL 11778211, at *13 (September 1, 2016) (Opinion and Order Denying Motion to Disqualify) (quoting Interpretation, Policy, and Procedure for Substantial Product Hazards, 43 Fed. Reg. 34,988 (Aug. 7, 1978)); *see also In re Dye and Dye* (Dye), CPSC Dkt. No. 88-1, 1989 WL 435534, at *10 (July 17, 1991) (Opinion and Order) ("In the context of the rulemaking procedures established by section 9 of the CPSA, 15 U.S.C. § 2058, Congress specifically requires the Commission to consider the effect of a rule on the 'utility, cost, or availability of such products to meet [the need of the public].' If Congress had intended for the Commission to be required to make similar findings under section 15, it is reasonable to conclude that such findings would also have been expressly required.").

The differences in the standards by which evidence is evaluated are significant because

rulemakings and adjudications are substantively different proceedings. *See, e.g.*, *ITServe Alliance, Inc. v. DHS*, 71 F.4th 1028, 1035 (D.C. Cir. 2023) ("[R]ulemaking typically announces 'generally applicable' legal principles whereas adjudication involves case-specific determinations. . . . [R]ulemaking governs only the future, whereas adjudications 'immediately bind parties by retroactively applying law to their past actions.'") (quoting *Safari Club Int'l v. Zinke*, 878 F.3d 316, 332–33 (D.C. Cir. 2017)). Because rulemaking impacts entire industries, it requires a greater examination of the effect on the entities involved. To that end, Congress required the Commission to conduct a cost-benefit analysis, consider reasonable alternatives, and evaluate voluntary standards to balance the burden of an industrywide rule while ensuring the safety of consumers. *See* 15 U.S.C. § 2058(c). These more stringent considerations are not applicable to an action under Section 15, where a single entity manufactures or distributes a defective product that may require expedient removal from the marketplace to ensure the safety of consumers.

By basing the Initial Decision on the "unreasonable risk of injury" standard, the Presiding Officer committed a legal error that tainted the entire Initial Decision. Section 15 adjudications simply do not require balancing tests or the more stringent requirements that are found in rulemaking proceedings. By reading such requirements into Section 15, the Presiding Officer made a crucial error, warranting that the Initial Decision be set aside.

2. *The Initial Decision Conducted an Improper Substantial Risk of Injury Analysis*

The Presiding Officer also failed to conduct the appropriate substantial risk of injury analysis required by Section 15, its regulations, and applicable case law. Specifically, the Presiding Officer failed to apply the correct legal standard for determining whether a defect creates a substantial risk of injury to the public by not following the statutorily enumerated

factors. Under Section 15, a product poses a substantial product hazard if it contains a "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). The Initial Decision completely omitted any reference to these mandatory statutory factors for determining substantial risk of injury and instead created its own *ad hoc* criteria for this determination. *See* Initial Decision at 56–64. None of the Initial Decision's novel considerations even tangentially comport with the appropriate statutory analysis for a substantial risk of injury.

For example, the Presiding Officer's "purely mathematical" assessment of the risk of injury, which in his estimation was "vanishingly small," Initial Decision at 59, is an entirely different standard than the CPSA standard, which includes an assessment of "severity of the risk." 15 U.S.C. § 2064(a)(2). The regulations provide that "[a] risk is severe 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)(iii). Importantly, this factor can be satisfied in the disjunctive by *either* a showing of a serious risk *or* a likelihood of an injury. Here, Dr. Katwa's expert testimony and the evidence of three infant deaths establish the risk of serious injury, including death by suffocation or asphyxiation.[17]

The Initial Decision also requires greater evidence of likelihood of injury than is required by law, concluding that "one would expect a profound and disturbing number of infant deaths

[17] *See* Expert Testimony of Umakanth Katwa, CCX-3, at 4 ("Infants who, due to the design of the Podster, roll or otherwise move into a position where their faces are pressed into the soft, pillow-like structure of the Podster can die from suffocation. If an infant's face rests in the soft, compressible Podster, the infant can suffer from progressively lower levels of oxygen in the blood (hypoxemia) and elevated carbon dioxide (CO2) concentrations due to reduced airflow and rebreathing of expired air. This results in brain hypoxia (reduced oxygen to the brain), reduced blood flow to the infant's body (particularly their brain), low heart rate, loss of consciousness, cardiorespiratory arrest, and eventually, death."); *see also* IDI No. 160519CCC2600: Alabama Incident, JX-6 (redacted), JX-7 (unredacted); IDI No. 200917CCC3888: Texas Incident, JX-8 (redacted), JX-9 (unredacted); IDI No. 220916HCC1454: Virginia Incident, JX-10 (redacted), JX-11 (unredacted); MECAPS Report: Virginia Incident, JX-12A (redacted), JX-12B (unredacted).

from use of the product," and speculating that "[t]he Podsters' product history is in fact analogous to a long-term observational study." Initial Decision at 59. Yet Section 15 of the CPSA only requires consideration of the number of defective products in commerce—here 180,000 products—as a measure of the exposure of the public to the hazard. Further, the law does not require proof that a hazard *has in fact* harmed consumers, only *that it could* because of the number of consumers who use the product. Indeed, CPSC regulations make clear that "[e]ven one defective product can present a substantial risk of injury and provide the basis for a substantial product hazard determination if the injury is serious and/or if the injury is likely to occur." 16 C.F.R. § 1115.12(g)(1)(ii).

C. *The Initial Decision Imposed Additional Legal Standards Not Required by Section 15 of the CPSA*

The Initial Decision also errs by imposing legal standards not required by Section 15 of the CPSA or its regulations. Specifically, the Initial Decision (1) incorrectly imposed requirements from state product liability, such as evidence of a "reasonable alternative design"; (2) required evidence of a quantified, threshold number of incidents associated with the Subject Products; and (3) improperly applied the facts in the record to the law governing misuse.

1. *The Initial Decision Improperly Relied on State Product Liability Law Standards in the Substantial Product Hazard Analysis*

The Initial Decision erred by introducing inapplicable state product liability law standards into this proceeding, even though this action is governed by Section 15 of the CPSA, 15 U.S.C. § 2064. In passing the CPSA, Congress recognized that the CPSA and state product liability law are two separate frameworks. *See* Consumer Product Safety Act, H.R.15003, 118th Cong. Rec., 31374, 31388 (September 20, 1972) ("This bill is the legislative counterpart of the growth of . . . products liability."). Therefore, product liability laws and standards are inapposite to interpretations of the CPSA, the same way regulations interpreting the CPSA are inapposite to

interpretations of product liability laws. *See* Interpretation, Policy, and Procedure for Substantial Product Hazards, 43 Fed. Reg. 34,988, 34,991 (Aug. 7, 1978) (explaining addition to 16 C.F.R. § 1115.4 of statement that Commission's definition of defect "was not intended to apply to any other areas of law" in response to comments raising concerns that the definition would be adopted by state courts); *see also In re Amazon.com, Inc.*, CPSC Dkt. No. 21-2, Dkt. 142, at 31 (July 29, 2024) (Decision and Order) (finding that where there was no gap in the statute, "Amazon cannot use common law to supplant what Congress wrote").[18]

Contrary to this clear separation of legal standards, the Initial Decision erroneously introduced standards from product liability law into the substantial product hazard analysis. Specifically, the Presiding Officer incorrectly required proof of a reasonable alternative design and that the Podsters are "unreasonably dangerous," imposing standards not found in Section 15 of the CPSA, but instead prevalent in state product liability law.

First, the Initial Decision improperly required Complaint Counsel to introduce evidence and prove the existence of a "reasonable alternative design" for the Podsters. In support of this newfound requirement, the Presiding Officer cited Black's Law Dictionary definition of design defect: "An imperfection occurring when the seller or distributor could have reduced or avoided a foreseeable risk of harm by adopting a *reasonable alternative design*, and when, as a result of not using the alternative, the product or property is not reasonably safe," and the Third Restatement of Torts' definition of the same—neither of which are binding authorities in this proceeding. Initial Decision at 40, 43 (emphasis added).

[18] Section 15 analyses may consider product liability law where "[design] aspects have been found to constitute product defects in product liability suits." Interpretation, Policy, and Procedure for Substantial Product Hazards, 43 Fed. Reg. 34,988, 34,991 (Aug. 7, 1978). However, "neither the regulation nor judicial determinations constitute the definitive statement as to which aspects of consumer products may be found to be defective. Such a determination is made *on a case-by-case basis*." *Id.* (emphasis added). Here, the Initial Decision did not focus on any instances where the Podster's design had been found in state court to "constitute product defects" (or not), but rather wrongly imposed broad legal standards derived from product liability law. *See* Initial Decision at 40, 43, 52.

However, while reasonable alternative design is a common element of product liability standards under state law,[19] such proof is not required by Section 15. *See* 15 U.S.C. § 2064. Indeed, if Congress had intended to insert a reasonable alternative design element into Section 15, it would have done so. *See BFP v. Resolution Trust Corp*., 511 U.S. 531, 537 (1994) ("'[I]t is generally presumed that Congress acts intentionally and purposely when it includes particular language in one section of a statute but omits it in another.'") (quoting *Chicago v. Environmental Defense Fund,* 511 U.S. 328, 338 (1994)); *see also United States v. Jordan*, 915 F.2d 622, 628 (11th Cir.1990) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposefully in the disparate inclusion or exclusion.") (quoting *Rodriguez v. United States*, 480 U.S. 522, 525 (1987) (per curiam)), *cert. denied*, 499 U.S. 979 (1991).

For example, when amending Section 9 of the CPSA in 1981, Congress added a requirement to consider "reasonable alternatives" in developing mandatory standards via rulemaking. Legislative history demonstrates that Congress used that phrase to require consideration of regulatory alternatives in an effort to reduce the agency's use of mandatory standards where other options, like voluntary industry standards, were available. *See* 15 U.S.C. § 2058(c); 1981 Consumer Product Safety Act Amendments, 127 Cong. Rec., S5874 & S5901 (March 31, 1981) (adding requirement of description of reasonable alternatives to advanced

[19] For states adopting the Third Restatement of Torts. *See, e.g., Wright v. Brooke Group, Ltd*., 652 N.W.2d 159, 169 (Iowa 2002) (adopting Restatement (Third) of Torts requirement that plaintiff seeking to recover damages must show harm could have been reduced by a reasonable alternative design in private personal injury action involving a smoker against several cigarette manufacturers); *Scarangella v. Thomas Built Buses, Inc.*, 717 N.E.2d 679, 681–82 (N.Y. 1999) (citing Restatement (Third) of Torts and identifying comparison to a safer alternative design as one of seven factors New York courts consider in a design defect case). Some states have not adopted the Restatement (Third) of Torts, but still require a demonstration of an alternative design. *See, e.g.*, *Evans v. Nacco Materials Handling Grp., Inc.,* 810 S.E.2d 462, 471 (Va. 2018) (finding that design was not unreasonable unless plaintiff could show safer alternative design of parking brake); Tex. Civ. Prac. & Rem. Code Ann. § 82.005(a)(1) (requiring safer alternative design as element of design defect case); Wash. Rev. Code. §7.72.030(1)(a) (requiring reasonable alternative design as an element of a design defect case).

notice of proposed rulemaking, preliminary regulatory analysis, and final rule). And despite having the chance to do so at the same time, Congress did not insert any reference to "reasonable alternatives" or "reasonable alternative design" in Section 15. Nor has the Commission considered such a requirement in any prior administrative adjudication. Thus, imposition of a reasonable alternative design requirement has no support in Section 15 and applying it in this substantial product hazard matter is error.

Second, the Initial Decision relied on principles of product liability law generally, and Oklahoma law specifically, to erroneously require proof that the Podsters are "unreasonably dangerous"—a standard which is similarly inapplicable to a Section 15 proceeding.[20] Initial Decision at 52. Specifically, the Initial Decision cited Oklahoma case law for the proposition that an "unreasonably dangerous" product is one that is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." Initial Decision at 52. However, the definition of a substantial product hazard does not reference "ordinary consumers," "ordinary knowledge," or "unreasonably dangerous," and none of those concepts is applicable in determining whether the Podsters present a substantial product hazard under Section 15. *See* 15 U.S.C. § 2064(a). It was similarly plain error for the Presiding Officer to introduce this standard.

In sum, the Initial Decision's reliance on these product liability standards is counter to Congress' intent and contrary to the plain language of Section 15. When Congress passed the CPSA, it indicated its intent for the CPSA and product liability law to remain distinct

[20] The Presiding Officer engaged in a brief, albeit confusing, discussion on how the Commission has not pre-empted product liability law, noting "the number of product liability lawsuits filed in this country likely numbers in the thousands every year." Initial Decision at 52. While it appears that the Presiding Officer did not impose any additional burden based on that statement, it is irrelevant to a Section 15 analysis generally, and to whether the Podsters in this matter present a substantial product hazard. Section 15 of the CPSA is what governs in this proceeding and makes no reference to preemption. *See* 15 U.S.C. § 2064.

mechanisms, and created a standard, separate from state product liability law, for the Commission to determine whether a product presents a substantial product hazard requiring action to protect the public.

2. *The Initial Decision Improperly Required Evidence of an Undefined Threshold of Actual Deaths to Determine That the Podster Presents a Defect*

The Initial Decision incorrectly suggests that incidents must meet some undefined threshold of injuries or deaths before a product can be found to present a substantial product hazard. Initial Decision at 47. This assertion is contrary to law. Indeed, the Commission has made clear that enforcement action to correct a substantial product hazard need not wait until actual injuries and deaths have occurred. *See Dye*, 1989 WL 435534, at *14 (finding that "the Commission is not required to have evidence of actual injuries in order to address a risk"). Where, as here, the Commission has evidence that a serious risk of injury exists, pursuing corrective action to prevent future injuries is entirely consistent with the purposes of the CPSA.

That purpose is evident in legislative history. *See* Consumer Product Safety Commission Reauthorization: Hearing Before the Subcomm. on Commerce, Consumer Protection, and Competitiveness of the H. Comm. on Energy and Commerce, H. Hearing, Serial No. 100-47, 67 (June 4, 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). Similarly, federal courts have recognized that a substantial product hazard can be established with no incidents at all—the law does not require a "body count." *See Forester v. CPSC*, 559 F.2d 774, 788–89 (D.C. Cir. 1977) (noting that in a case involving the Federal Hazardous Substances Act, an analogous statute to the CPSA also enforced by the Commission, there was no requirement "to develop a precise 'body count' of actual injuries").

Here, three infants have tragically died after being placed for sleep in the Podsters,

demonstrating the severity of the risk of injury associated with the Subject Products. The Commission need not wait until more deaths occur before deeming the Podsters a substantial product hazard and ordering corrective action. Indeed, given the hidden nature of the hazard presented by the Podsters, it would be contrary to the purposes of the CPSA to continue to allow caregivers to use the Podsters and endanger vulnerable infants while they are unaware of the concealed dangers. *See* 15 U.S.C. § 2051(a)(2) (noting Congressional findings that consumers may face "an inability . . . to anticipate risks and to safeguard themselves adequately" against harms from dangerous consumer products).[21]

3. *The Initial Decision Improperly Applied the Law Governing the Role of Consumer Misuse in Section 15 Defect Analyses*

The Initial Decision improperly applied the law governing misuse and rejected the evidence that the Podster's characteristics give rise to reasonably foreseeable misuse. In doing so, the Initial Decision imposed heightened evidentiary burdens not found in the CPSA. For instance, the Presiding Officer pointed to the impossibility of "apportioning responsibility between any alleged design defect and consumer misuse," and stated, without explanation, that "the available evidence strongly suggests that consumer misuse was the dominant factor" in the three fatal incidents. *Id.* at 48. Thereafter, despite identifying misuse as the "dominant factor," the Presiding Officer somehow still found that the evidence did not support a finding that the Podsters were defective based on consumer misuse, finding that there was no "demonstrated link

[21] The Initial Decision also reached improper and erroneous conclusions by opining that the relief sought in the complaint is "an extraordinary imposition on private citizens and is not rationally related to legitimate government interest." Initial Decision at 62 (sentence case added). Although it is unclear how protecting vulnerable infants from defective Podsters is not rationally related to a legitimate government interest, the Presiding Officer suggested that "there are limits to government action premised on models, rather than data." Initial Decision at 63 (citing *NRDC v. Herrington*, 768 F.2d 1355, 1385 (D.C. Cir. 1985)). The cited case is inapposite, however, because it involved a challenge to a rulemaking under the Energy Policy and Conservation Act and, further, the D.C. Circuit did not repudiate the economic model used in the rulemaking that was being challenged. *NRDC v. Herrington*, 768 F.2d. at 1391.

between misuse and design." *Id.* at 48–51 (requiring Complaint Counsel to show that the "Podsters have been broadly misused because the design of the product lured caregivers en masse into placing the children in their care in a dangerous setting"), 54 ("Complaint Counsel has failed to link persuasively the product characteristics to the risk or cause of serious injury.").

But neither Section 15 nor 16 C.F.R. § 1115.4 (the "Defect Regulation") requires a "demonstrated link," Initial Decision at 50, nor some other heightened evidentiary standard tying the design of a product to its operation and use or misuse. All that is required under the law is that misuse of a product be reasonably foreseeable. *See* 16 C.F.R. § 1115.4; *Zen Magnets*, 2017 WL 11672449, at *13.

Indeed, the Commission has held—contrary to the Presiding Officer's suggestion that injuries attributable primarily to misuse weigh against a finding of a design defect—that an action under Section 15 is appropriate even when based *solely* on foreseeable misuse. *See Zen Magnets*, 2017 WL 11672449, at *9, *13. Similarly, while the Presiding Officer faults the failure to consider "the role of caregivers, their responsibility, and whether they generally safeguard infants against the risks of injury from misuse of the product," Initial Decision at 47, the Defect Regulation only contemplates whether consumer misuse of a product is reasonably foreseeable, not whether the consumer could have or should have acted more responsibly. Nor is it necessary to establish that "most parents" misuse the Podster in order to demonstrate a substantial risk of injury, as the Presiding Officer appeared to require. *See id.* at 48. Complaint Counsel is only required to prove the misuse is foreseeable, which, as discussed in Section F.2. below, it did.

D. *The Initial Decision's Analysis of Products Other Than the Podster Was Both Legally Improper and Factually Erroneous*

The Initial Decision errs by giving improper consideration to products that are not the subject of this proceeding. First, it wrongly requires comparisons between the Podster and

competing products as part of the substantial product hazard determination, imposing obligations inconsistent with Section 15. Second, the Initial Decision errs in its analysis of defect and injury risk by selectively disregarding record evidence of the Podster's dangerous design features on the basis that other products may share the some of the same characteristics.

1. *The Initial Decision Erred in Requiring Proof that the Podster is "especially dangerous" Compared to Other Products in the Same Category*

The Initial Decision mischaracterizes Section 15's substantial product hazard standard as requiring a showing of "abnormalities" in product design that render the Podster "especially dangerous" in comparison to other similar products. Initial Decision at 59. First, the Presiding Officer sought evidence that there was "something 'wrong' with the product *design* that substantially contributes to the supposed danger, in a way that a different product would not." *Id.* at 51. Thereafter, in determining that the Podster had no fault, flaw, or irregularity that could be characterized as a design defect, the Presiding Officer noted that "[n]o product was introduced as an example of a lounger or pillow that did not bear the same 'weakness' or 'shortcoming' as the Podster," and that the "absence of evidence of . . . a safer product within the class of infant lounger, alone, may . . . be sufficient to refute the existence of a design defect in the Podsters." *Id.* at 40, 43. Similarly, in analyzing the risk of injury posed by the Podster, the Presiding Officer reasoned that a lack of evidence of "unique or distinctive design features rendering the Podster *especially* dangerous" was a "fatal omission" in the case. *Id.* at 59 (emphasis added).

But nothing in the CPSA or its attendant regulations supports the imposition of a requirement that the Commission engage in a "comparison to similar products which are not defective" in order to make a determination of a substantial product hazard. *See id.* at 43. Neither the definition of substantial product hazard in Section 15 of the CPSA, 15 U.S.C. § 2064(a), nor the regulations interpreting the meanings of "defect" and "substantial risk of injury," 16 C.F.R.

§§ 1115.4, 1115.12(g), contain any reference to the kind of comparative analysis the Presiding Officer improperly required here. To the contrary, the regulations specify that the Commission will determine "[o]n a *case-by-case basis* . . . whether a defect within the meaning of section 15 of the CPSA does, in fact, exist and whether that defect presents a substantial product hazard." 16 C.F.R. § 1115.4 (emphasis added); *see also In re Francis Alonso, Jr.* (Mylar Star Kites), CPSC Docket No. 75-16, at 2 (Sep. 16, 1977) (Decision and Order) (rejecting respondent's argument that its product was not defective where other products "pose[d] a similar hazard").[22]

Likewise, the Initial Decision erred in considering whether this action "singled out" the Leachco Podster "for excision from the marketplace" in comparison to other similar products. Initial Decision at 59. The Commission has repeatedly made clear that the existence of possible safety concerns with competing products offers no defense in a Section 15 mandatory corrective action. For example, in *Dye*, 1989 WL 435534, at *17, the Commission expressly rejected an argument of selective enforcement, holding that "[t]he Commission is entitled to use its prosecutorial discretion to decide which companies to proceed against first, or at all." *See also Mylar Star Kites*, CPSC Docket No. 75-16 at 2 (noting that the Commission was "not obligated to act against every product that may pose a similar hazard in order to act against one that the record establishes is a hazard").[23]

---

[22] https://www.cpsc.gov/s3fs-public/CPSC_Docket_No._75-16%3B_In_the_Matter_of_Francis_Alonso%2C_Jr.%2C_an_individual_doing_business_as_Mylar_Star_Kites_%28Decision_and_Order%29-09.16.1977.pdf?VersionId=l9afXfFti8mLyWse_6KJOPOneuTkIxP1.

[23] Even though not required, the Commission has taken substantial action to address the hazards to children posed by this category of products, including obtaining a voluntary recall of over three million Boppy Loungers in 2021. *See* CPSC, The Boppy Company Recalls Over 3 Million Original Newborn Loungers, Boppy Preferred Newborn Loungers and Pottery Barn Kids Boppy Newborn Loungers After 8 Infant Deaths; Suffocation Risk (Sep. 23, 2021), https://www.cpsc.gov/Recalls/2021/The-Boppy-Company-Recalls-Over-3-Million-Original-Newborn-Loungers-Boppy-Preferred-Newborn-Loungers-and-Pottery-Barn-Kids-Boppy-Newborn-Loungers-After-8-Infant-Deaths-Suffocation-Risk. Moreover, the record reflects that many similar products available to parents for unsupervised sleep or lounging—including regulated infant products such as play yards, bassinets, and cribs—are subject to mandatory safety standards. *See* Expert Testimony of Celestine Kish, CCX-2, at 66, ¶ 130. Accordingly, the Initial Decision is factually without basis to suggest that this Section 15 action improperly "single[d] out" Leachco or the

2. *The Initial Decision Erred in Discounting Evidence of Dangerous Characteristics of the Podster Allegedly Shared by Other Products.*

While the Initial Decision acknowledges the record evidence concerning the dangers posed by the Podster's design features—including the excessive incline, padded siding, and lack of a rigid structure—it wrongly suggests that such evidence cannot reflect a design defect here because "so many other products share the same attributes," which are "commonly found in infant sleep products, loungers, and pillows, as well as other infant products." Initial Decision at 42. However, it is error to disregard evidence of design defects in the Podster just because similar design features appear in similar products, particularly when the record reflects that those similar products are also associated with injuries and deaths.

Contrary to the analysis in the Initial Decision, in prior adjudications where the Commission has assessed products containing common design characteristics, it has consistently treated incidents and injuries linked to similarly designed products as evidence *supporting* the finding of a substantial product hazard. For example, in *Zen Magnets*, the Commission explained that the small rare-earth magnet sets ("SREMs") that were the subject of that action were "functionally identical" across multiple brands, noting that "the physical characteristics of SREMs that give rise to a risk of injury are shared by all brands: small, spherical, shiny, reflective, smooth, loose, separable, and strongly magnetic." *Zen Magnets*, 2017 WL 11672449, at *20. As a result, even though there were only two incidents specifically known to have involved ingestion of the subject magnets, the Commission explained that evidence of the incidents involving other similar SREMs from competing brands "is a sufficient basis for . . . experts to assess whether a product contains a design defect . . . and to describe the risk of injury

Podster (Initial Decision at 42), and it errs in considering the agency's treatment of competing companies as part of the substantial product hazard legal analysis.

presented by SREMs to children." *See id.* n.23. Ultimately, the Commission concluded that the Zen SREMs presented a substantial risk of injury to the public because they were "associated with at least two injuries" and "functionally identical to SREMs that have caused many serious injuries and one death." *Id.* at *34. Likewise, in *Dye*, the Commission relied on evidence of injuries and deaths involving products with the same "functional characteristics" as Subject Products in making its substantial product hazard determination—including not only evidence of competitors' products, but also incidents involving *homemade* products that had design "aspects . . . that [were] present in" the subject products in that case. *See Dye*, 1989 WL 435534, at *6–7.

The Initial Decision acknowledged that the Commission in *Zen Magnets* and other cases made its serious risk of injury determination "by reference to other cases involving [products] with similar characteristics," but wrongly found these prior cases to be "distinguishable." Initial Decision at 54. In an apparent contradiction of the earlier conclusion that the Podster's dangerous characteristics were "commonly found" in other similar products, the Initial Decision reasoned that Complaint Counsel "has failed to link persuasively the product characteristics to the risk or cause of serious injury in similar products with the same characteristics." *Id.* Specifically, the Presiding Officer erroneously claimed Dr. Mannen "did not directly compare the Po[d]ster to . . . any other product in her testimony to show that the Podster harbored a similar defect, or that the same features present in both products were responsible for any infant deaths." *Id.* at 56. Again, although such comparison is not required under Section 15, to the contrary, Dr. Mannen's testimony expressly discussed her 2022 study, *Pillows Product Characterization and Testing*, analyzing 18 different infant pillow products (including the Podster) involved in at least 47 infant deaths, from which she concluded that "the Podster could

place infants at risk of injury or death due to positional asphyxia, occlusion, or rebreathing."[24] Throughout her testimony, Dr. Mannen also repeatedly explained that there was a "substantial similarity between . . . inclined sleep products and the Leachco Podster," such that "one can conclude that the Leachco Podster is dangerous in manners similar to how those inclined sleep products were found to be dangerous."[25]

Further, Dr. Mannen's testimony highlighted several specific design characteristics of the Podster that she identified as dangerous in her in-depth testing of inclined sleep products, including "head and thigh angles" and an inclined body position that "facilitates rolling on or off of the product" and "negatively affects the ability of infant[s] to self-rescue."[26] Dr. Mannen's testimony appends her 2022 *Pillow Products Characterization and Testing* study, which examined the Podster and 17 other infant pillow products and concluded that products across the category presented "suffocation related hazards" because of "occlusion or rebreathing" and "positional asphyxia."[27] Dr. Mannen's extensive review included anti-flat head pillows, both flat and inclined infant loungers, and nursing pillows,[28] as well as an evaluation of 50 IDIs encompassing 47 deaths attributable to the same hazard patterns identified in the Podster: rolling, issues from slouched positioning, and occlusion/CO_2 rebreathing.[29]

While the Initial Decision recited much of this expert testimony on pages 12–14—and noted on pages 29–30 that Complaint Counsel's expert Dr. Katwa had also likened the dangers of the Podster to an inclined sleep product—the Presiding Officer wrongly dismissed this evidence of hazardous design characteristics as "unpersuasive." Initial Decision at 41. Without

[24] *See* Expert Testimony of Erin Mannen, CCX-1, at 10–11; *see also id.* at 174–290 (Exhibit C).
[25] *Id.* at 15–16, 33; Aug. 7, 2023 Hr'g Tr., at 80–81.
[26] *See* Expert Testimony of Erin Mannen, CCX-1,at 32–33, 41–44.
[27] *See id.* at 174–290 (Exhibit C).
[28] *Id.* at 287–90.
[29] *Id.* at 189–91. The IDIs cited in Dr. Mannen's 2022 study were also produced to Respondent in discovery by April 2023. *See* Complaint Counsel's Opp'n to Leachco's Mot. *in Limine* and *Daubert* Mot., Dkt. 122, at 12.

disputing the experts' conclusions, the Presiding Officer wrongly rejected their findings on the basis that "the Podster is not marketed for use as and has never been advertised as a sleep product." *Id.* As discussed below, however, the Podster cannot be distinguished on this basis because it is nonetheless foreseeably used for sleep.

E. *The Initial Decision Failed to Admit Relevant, Probative Evidence and Made Findings Contrary to the Evidence Improperly Excluded*

1. *The Initial Decision Improperly Excluded Testimony from Complaint Counsel's Medical Expert Dr. Katwa*

The Initial Decision and pre-hearing rulings by the Presiding Officer erred by excluding certain evidence offered by medical expert, Dr. Umakanth Katwa, which was probative of both the defect and substantial risk of injury.[30] The Initial Decision details several instances in which Dr. Katwa's expert testimony was erroneously excluded, including his opinions regarding infant movement (Initial Decision at 30 n.17), the risk of injury posed by the Podster/Section VI of the Expert Opinion (Initial Decision at 30 n.18), and utility of an inclined product such as the Podster/Section VIII of the Expert Opinion (Initial Decision at 31 n.20). Further, the Presiding Officer's August 2, 2023 pre-hearing Order excluding portions of Dr. Katwa's testimony regarding whether the Podster acts like an inclined sleeper, the facilitation of flexion by the Podsters, and the utility of the Podster was similarly erroneous.[31] Complaint Counsel properly preserved its objections to these evidentiary rulings by the submission of an Offer of Proof pursuant to 16 C.F.R. § 1025.43(f) ("When an objection to proffered testimony or documentary evidence is sustained, the sponsoring party may make a specific offer, either in writing or orally, or what the party experts to prove by the testimony or the document. . . . Written offers of proof

[30] *See* Expert Testimony of Umakanth Katwa, CCX-3; *see also* Aug. 9, 2023 Hr'g Tr., at 4–49.
[31] Order Granting in Part and Denying in Part Respondent's Mot. to Excl. The Expert Testimony Proffered by the CPSC, Dkt. 128; *see also* Aug. 9, 2023 Hr'g Tr., at 5.

or of rebuttal, adequately marked for identification shall accompany the record and be available for consideration by any reviewing authority.").[32]

Dr. Katwa's expert opinion about infant movement should have been admitted. Dr. Katwa is a medical doctor, board-certified pediatric pulmonologist, and sleep specialist who is the medical director of a renowned sleep center at Boston Children's Hospital that treats thousands of infants and children a year. Dr. Katwa has published numerous articles on pediatric pulmonology and infant sleep. Dr. Katwa's expert testimony would be helpful to the trier of fact, as it explains the risk of injury created by the Podster's design as a result of consumer behavior and infant movement based on insight gained through his clinical work. Because he is not an expert in biomedical engineering or human factors engineering, Dr. Katwa generally relied on the opinions of Dr. Mannen and Ms. Kish as a foundation for his own opinions but also drew from the expertise he has gained from treating his patients, his teaching, his leadership of the Boston Children's sleep center, and his articles.[33] *See Werth v. Makita Elec. Works, Ltd.*, 950 F.2d 643, 648 (10th Cir. 1991) (discussing Rule 703 of the Federal Rules of Evidence and noting that "the expert may rely on facts outside the record and not personally observed, but of the kind that experts in his or her field reasonably rely on in forming opinions").[34] Indeed, Respondent's

[32] Complaint Counsel's Offer of Proof Regarding the Excluded Expert Testimony of Umakanth Katwa, M.B.B.S., M.D., Dkt. 137; Aug. 9, 2023 Hr'g Tr., at 4–5. The Initial Decision also states that Dr. Katwa "was permitted to amplify the report on direct examination (although he did not do so)." Initial Decision at 26. To the extent this statement impacted the Presiding Officer's evidentiary rulings regarding Dr. Katwa's testimony, it is factually and procedurally incorrect. Complaint Counsel did not seek to amplify Dr. Katwa's expert written testimony pursuant to 16 C.F.R. § 1025.44(b). *See* Complaint Counsel's Mot. for Leave to Amplify Written Direct Expert Testimony, Dkt. 106 (seeking to amplify Dr. Mannen and Ms. Kish's written expert testimony, but not requesting amplification as to Dr. Katwa) and Order Granting Complaint Counsel's Mot. for Leave to Amplify Written Direct Expert Testimony, Dkt. 130 ("This Court therefore GRANTS Complaint Counsel's motion to amplify the direct testimony of Dr. Mannen and Ms. Kish at hearing.").

[33] *See* Expert Testimony of Umakanth Katwa, CCX-3, at 5, 36–54.

[34] *See, e.g.*, *id.* at 7 (stating expert opinion that "[h]ence any pressure on the abdomen and diaphragm by flexion of the trunk or sleeping in a slouched position will impede breathing movement, resulting in shallow breathing and low oxygen levels"); 15 (discussing arousal response and infant movement); 18–19 (discussing incline angle of Podster and medical impact on infant's movement of the diaphragm and breathing movements in general); 23 (discussing infant movements to self-rescue on Podster versus firm flat mattress).

counsel elicited testimony from Dr. Katwa about infant movement on cross-examination.[35]

The Initial Decision also wrongly excluded the section of Dr. Katwa's expert opinion entitled "Marketing Disinformation." Initial Decision at 31.[36] The substance of that section does not bear on marketing *per se*, but rather the purported medical benefits, as marketed by Leachco, of placing infants in an inclined position—the exact posture that creates a risk of suffocation. In so doing, Dr. Katwa was offering his expert medical opinion in response to Leachco's claim that the Podster "provides upper body elevation which can help aid in digestion and breathing."[37]

Properly understood in that context, the Presiding Officer should not have excluded Section VI of Dr. Katwa's testimony. As Dr. Katwa explained in his testimony, in a hospital setting, it may be medically appropriate to place infants in an inclined position to help with reflux "*under strict medical supervision and continuous monitoring*."[38] He further explained that using an inclined product at home "is very different from these controlled and study settings" and, thus, that the Podster should not be used to aid digestion and breathing, because quite the opposite, it "could inhibit an infant's breathing."[39] His testimony, based on his years of experience, would have clarified that the hazard posed by the using a Podster at home, *while not under constant medical supervision*, is due to the fact that infants are able to move within such products into positions which compromise their breathing. Thus, the Presiding Officer erred by excluding portions of Dr. Katwa's testimony.

2. *The Initial Decision Improperly Excluded Testimony from Celestine Kish Regarding the Podsters' Warnings and Instructions*

It was also plain error for the Presiding Officer to exclude certain portions of Senior

[35] *See* Aug. 9, 2023 Hr'g Tr., at 8:4-7 ("Q: Okay. And these opinions on what can happen to infants depends, does it not, on the baby's position and movement inside the Podster? A: Yes.").
[36] Expert Testimony of Umakanth Katwa, CCX-3, at 29–30.
[37] *See* Joint Stipulations, JX-51, at 2, ¶ 15; Podster Product Description from Leachco.com, JX-30.
[38] Expert Testimony of Umakanth Katwa, CCX-3, at 29 (emphasis added).
[39] *Id.*

Engineering Psychologist Celestine Kish's testimony on warnings and instructions and to prevent Complaint Counsel from proffering evidence on such testimony, when the efficacy of warnings and instructions is directly relevant to the substantial product hazard analysis in the Initial Decision. *See* 16 C.F.R. § 1115.4. Ms. Kish's full testimony and expert opinion regarding how the Podsters' warnings and instructions fail to adequately prevent misuse or mitigate against the dangers of misuse, and thus, contribute to the existence of a design defect, should have been admitted into evidence. Moreover, the defect factors, to the extent applicable, expressly take into consideration whether warnings and instructions are adequate, the role of consumer misuse, and the foreseeability of such misuse. *See id.* Thus, it was critical that the Presiding Officer admit into evidence and consider Ms. Kish's expert human factors opinion that "consumers will use the Podster for infant sleep, for co-sleeping in an adult bed, on elevated surfaces and in other infant products such as cribs" despite Leachco's warnings and instructions.[40]

As more fully discussed in Complaint Counsel's July 24, 2023 Opposition to Leachco's July 14, 2023 Motions at 13–19,[41] the Presiding Officer's exclusion of Ms. Kish's expert opinion on warnings and instructions on the purported basis that it raised a new claim or that Complaint Counsel had failed to give adequate notice of a new legal theory during discovery, is without merit. The basis for addressing the Podster's warnings and instructions was alleged in the Complaint;[42] it was addressed in one of the first documents produced to Respondent, the pre-hearing Product Safety Assessment 0598.21,[43] which included an evaluation of the warnings and instructions associated with the Podster; and Leachco took the deposition of a CPSC staff engineer who drafted that PSA. Leachco's claim of unfair surprise was entirely without merit

[40] *See* Expert Testimony of Celestine Kish, CCX-2, at 1.
[41] Dkt. 122.
[42] *See* Dkt. 1, ¶¶ 14–20.
[43] *See* JX-34. This was produced to Leachco on April 8, 2022.

and belied by pleadings that clarified the relevance of the ineffectiveness of warnings to remediate the hazard posed by the Podster.

Specifically, the Initial Decision states that "CPSC had not preserved a 'failure to warn' defect" and a prior Order "precluded the CPSC from including a failure-to-warn claim." Initial Decision at 39 n.26 & 39–40. However, even a cursory review of the Complaint in this matter shows that Complaint Counsel never alleged that the Podsters warnings were defective.[44] Rather, the Complaint alleges that the warnings were inadequate and insufficient to mitigate the risk of injury,[45] which is a relevant to the design defect determination. 16 C.F.R. § 1115.4 ("In determining whether the risk of injury associated with a product is the type of risk which will render the product defective, the Commission and staff will consider, as appropriate . . . the adequacy of warnings and instructions to mitigate such risk.").

The Presiding Officer's mischaracterization of the Complaint led to the incorrect conclusion that:

> It is undisputed that Respondent anticipated the potential non-obvious hazards arising from certain uses of its products and has provided appropriate warnings and instructions. This is clear from the CPSC's own allegations in the Complaint, which detailed the warnings Respondent provided against the very uses the CPSC has cited as creating a risk of injury.

Initial Decision at 49–50. This conclusion was erroneous because, as supported by record evidence, Complaint Counsel disputes that Leachco has provided appropriate warnings and instructions.

Put simply, the Presiding Officer's statement that the allegations on warnings and instructions were new or novel is factually incorrect. The excluded probative evidence bears

[44] Dkt. 1, ¶¶ 15–20.
[45] *Id.* at 3, ¶ 20.

directly on the issue of whether the Podster is defective, and this is an issue that Leachco has been aware of since the beginning of this matter. Accordingly, the exclusion of this evidence was legal error.

3. *The Initial Decision Erred by Excluding Unredacted Sections of the Virginia IDI*

Prior to the hearing, the Presiding Officer erroneously ordered the exclusion of certain parts of the Virginia IDI.[46] Two of those exhibits, JX-12A and JX-12B, contained information that was later admitted into the record, subject to certain redactions, because the Presiding Officer found that the exhibits contained inadmissible hearsay that goes beyond the matters that are ordinarily admissible as public records.[47] Specifically, the Presiding Officer ruled that the excluded portions "contain circumstances reported by third parties and third-party notes regarding placement on a pillow. To the extent that JX-12A and 12B are admissible as public records, such references, or the third-party notes themselves, must be redacted."[48] In his ruling, the Presiding Officer did not identify the specific third party statements that were a cause for concern.[49] The redacted IDI was eventually admitted into evidence and Complaint Counsel preserved its objection to this exclusion by filing an Offer of Proof.[50]

The Presiding Officer erred in excluding certain portions of the Virginia IDI. This IDI should have been admitted in its entirety, as the third-party statements were public records made by Virginia law enforcement, contemporaneous with their investigation of the incident. Although the Presiding Officer ruled that parts of the IDI were admissible as a public record under Federal Rule of Evidence 803(8)(A), he was concerned with the hearsay statements of law

[46] Order Deferring Decision On Complaint Counsel's Mot. In Limine And Memorandum In Support To Admit In-Depth Investigation Reports, Dkt. 127, at 2.
[47] *Id.*
[48] *Id.*
[49] *Id.*
[50] Complaint Counsel's Offer of Proof Regarding Report of Investigation, Virginia Department of Health, Office of the Chief Medical Examiner, Dkt. 135. *See also* MECAPS Report: Virginia Incident JX-12A(1), JX-12B(1).

enforcement.[51] However, the "public records" exception to the hearsay rule states that "[a] record or statement of a public office . . . [that] sets out . . . factual findings from a legally authorized investigation" is admissible as long as "the opponent does not show that the source of information or other circumstances indicate a lack of trustworthiness." Fed. R. Evid. 803(8)(A)(iii)(B). The underlying policy rationale of the "public records" exception is based on an assumption that public officials will faithfully perform their duties and will submit accurate and fair reports. Fed. R. Evid. 803 Advisory Note; *see also Bradford v. Merrill Lynch*, 805 F.2d 49, 54 (2d Cir. 1986).

The keystone principle of the public records exception is the trustworthiness of the information, and the Initial Decision did not identify any reason that the information redacted from the Virginia IDI lacked trustworthiness in any way. Moreover, Leachco did not make such a showing regarding a lack of trustworthiness. As a result, probative evidence regarding the circumstances surrounding the Virginia incident was not admitted, despite no indication that such statements, taken by public officials, lacked trustworthiness. To the contrary, the contemporaneous statements by Virginia law enforcement personnel regarding the fatal incident including the positioning of the infant are trustworthy because they were made in the ordinary course of their public responsibilities with no indication that they misstated or misrepresented any facts.

4. *The Initial Decision Erred by Excluding the Testimony of Konica McMullen, the Mother of the Deceased Infant in the Alabama Incident*

In a pre-hearing Order, the Presiding Officer erroneously ruled that "Complaint Counsel has not demonstrated the rational basis for its decision to call [Konica McMullen, the mother of

[51] Dkt. 127, at 2.

one of the infant victims of the Podster]" as a witness.[52] Ms. McMullen would have testified as to her son's physical condition at the time of the fatal incident and his ability to roll over, which were essential factors in assessing whether the Podster contributed to the infant's death. The Presiding Officer excluded the witness from testifying, finding that Ms. McMullen's testimony would "likely be irrelevant and less probative than prejudicial" and "not appear to have any logical connection to the Podster and any alleged defects."[53]

The Presiding Officer permitted Complaint Counsel to submit an Offer of Proof "prior to hearing to demonstrate why Ms. McMullen's relevant testimony may outweigh the likely prejudice to Respondent."[54] On July 31, 2023, Complaint Counsel submitted an Offer of Proof pursuant to the Presiding Officer's July 28, 2023 Order and 16 C.F.R. § 1025.43(f).[55] In that Offer of Proof, Complaint Counsel explained that Ms. McMullen was deposed by Leachco on topics that relate directly to the issues in this proceeding, including her son's condition prior to the incident, his ability to rollover, and her personal experience with her son's daycare.[56] A copy of the deposition Leachco took of Ms. McMullen was attached as an Exhibit to the Offer of Proof. Complaint Counsel also submitted a Declaration of Konica McMullen which accompanied its Offer of Proof.[57]

The measure of relevant evidence under Rule 401 of the Federal Rules of Evidence is very broad: "Evidence is relevant if (a) it has any tendency to make a fact more or less probable than it would without the evidence; and (b) the fact is of consequence in determining the action." Fed. R. Evid. 401. This standard should be interpreted liberally. *Daubert v. Merrell Dow*

[52] Order Granting Mot. to Strike Konica McMullen from the Commission's Witness List, Dkt. 125, at 3.
[53] *Id.* at 4.
[54] *Id.* at 5.
[55] Complaint Counsel's Offer of Proof Regarding the Exclusion of Konica McMullen, Dkt. 126.
[56] *Id.* at 2–4.
[57] Complaint Counsel's Offer of Proof Regarding Decl. of Konica McMullen, CCX-58.

Pharms., Inc., 509 U.S. 579, 587 (1993) ("[Rule 401's] basic standard of relevance thus is a liberal one."). A court's relevancy determination will not be overturned unless it is arbitrary or irrational. *United States v. Perez*, 387 F.3d 201, 209 (2d Cir. 2004). The Presiding Officer's decision to exclude Ms. McMullen from testifying was an abuse of discretion because it was arbitrary and irrational, and excluded relevant evidence about how an otherwise healthy infant with certain mobility capacities can suffocate within a Podster.

Part of the ruling's irrationality was that the Presiding Officer cannot, as a matter of law, "prejudice" himself, and thus justify excluding a consumer's testimony. The traditional balancing test of weighing probative value versus risk of prejudice under Rule 403 of the Federal Rules of Evidence *is not applicable* when the judge is the factfinder and there is no jury. *See United States ex. rel. Morsell v. NortonLifeLock, Inc.*, 567 F.Supp.3d 248, 258–59 (D.D.C. 2021) (first quoting *Schultz v. Butcher*, 24 F.3d 626, 632 (4th Cir. 1994) ("[I]n the context of a bench trial, evidence should not be excluded under 403 on the ground that it is unfairly prejudicial."); and then quoting *Gulf States Utils. Co. v. Ecodyne Corp.*, 635 F.2d 517, 519 (5th Cir. Unit A Jan. 1981) (holding that Rule 403 "has no logical application to bench trials" and that "excluding relevant evidence on the basis of 'unfair prejudice' [in a bench trial] is a useless procedure") (brackets in original)).

To the extent that the Presiding Officer is claiming that prejudice to Leachco is the basis for excluding Ms. McMullen, that is wholly without merit. Leachco claimed in prehearing motions that it was prejudiced by Ms. McMullen's testimony, but Complaint Counsel demonstrated that Leachco knew about her testimony since at least 2016—long before this proceeding commenced—when Leachco took her deposition in a separate lawsuit, and Respondent had the opportunity to subpoena her for a deposition in this matter but chose not to

do so. *See Sterling Nat'l Bank v. Block*, No. 16 C 9009, 2018 WL 11200447, at *3 (N.D. Ill. Apr. 18, 2018) (declining to exclude witnesses for which the party seeking exclusion had knowledge of but chose not to depose). It was error to exclude the testimony of Ms. McMullen.

F. *The Initial Decision Incorrectly Held that the Podsters Do Not Pose a Substantial Product Hazard under Section 15 of the CPSA*

Under Section 15(a)(2) of the CPSA, 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). Providing guidance on conducting the defect analysis, in *Zen Magnets*, the Commission noted:

> As explained in § 1115.4 and *In re Dye*, a defect analysis:
>
> 1. Begins with an evaluation of the product's characteristics, and whether those product characteristics give rise to a risk of injury.
>
> 2. If such characteristics do give rise to a risk of injury, we consider whether the characteristics are necessary for the product to function.
>
> a. If such characteristics are not necessary for the product to function, then we can dispense with further defect analysis and the Commission may find that the product contains a defect.
>
> b. If such characteristics are necessary for the product to function, or if the effect of the defect finding will remove the product from the market, then the Commission conducts a balancing test to determine whether the risk of injury outweighs the usefulness of the product to consumers, before the Commission may find that the product contains a defect.

Zen Magnets, 2017 WL11572449, at *8 (internal citations and footnotes omitted).

The Podsters contain a design defect because their design characteristics create a risk of injury to infants. This risk of injury occurs as a result of their operation and use, including foreseeable misuse. Further, to the extent applicable, an evaluation of the factors listed in 16

C.F.R. § 1115.4—the "balancing test" referred to in the *Zen Magnets* framework—shows that the risk of injury associated with the Podsters is the type of risk which renders them defective. Finally, the defective Podsters pose a substantial risk of injury to the public due to the pattern of defect, the number of defective products distributed in commerce, and the severity of the risk. In sum, the Presiding Officer erroneously found that the record evidence was insufficient to prove that the Podsters contain a design defect and a substantial risk of injury to the public. To the contrary, the record demonstrates by a preponderance of the evidence that the Podsters are defective and pose a substantial risk of injury to infants.

1. *The Design of the Podsters Presents a Risk of Injury to Infants*

The record demonstrates that the design of the Podster poses a risk of injury to vulnerable infants. Under the CPSA, a "defect" may include a defect in the product's design. 16 C.F.R. § 1115.4. A design defect may be present "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." *Id*. As noted, under *Zen Magnets*, the defect analysis "begins with an evaluation of the product's characteristics, and whether those product characteristics give rise to a risk of injury." *Zen Magnets*, 2017 WL11572449, at *8.

Here, Dr. Mannen testified that several characteristics of the Podster create a risk of injury, and Dr. Katwa elaborated on the medical consequences of the Podsters' dangerous features. Standing alone, any one of these characteristics renders the Podster defective. Together, these design features create a scenario that creates a grave risk of death to infants in the product. Specifically:

- **The Podsters' Incline Angles Negatively Affect Infant Breathing and Can Lead to Sliding Down Within the Product**. Dr. Mannen testified that the

inclined design of the Podster presents certain hazards related to how the infant sits and how that affects the infant's breathing.[58] Her measurements demonstrated that the body position of an infant in the Podster is analogous to the body position in a dangerous inclined sleep product.[59] Dr. Mannen therefore concluded that, like an inclined sleep product, the Podster maintains infants in a position that inhibits normal breathing and leads to a risk of suffocation or positional asphyxia.[60] Dr. Katwa elaborated that the flexion that results from this positioning poses a risk of asphyxiation to infants, even if they are placed in the intended position.[61] Furthermore, the inclined design of the Podster allows infants to slide into a slouched position where the flexion is even more pronounced and the risk of asphyxia is more severe.[62]

- **The Podsters Facilitate Rolling**. Dr. Mannen concluded that the Podster's design facilitates rolling within or off of the product, which can lead to the mouth and nose of the infant becoming obstructed.[63] Dr. Mannen compared the Podster's mechanical environment with that of a firm, flat surface and determined that the Podster's design permits infants to achieve a roll more easily and with less coordinated movements than if they were on a firm, flat surface, such as a crib mattress.[64] Dr. Katwa also testified that "the Podster, due to its unsafe design, makes it easy for an infant to roll from a supine into a prone or side position,

[58] Expert Testimony of Erin Mannen, CCX-1, at 32–34.
[59] *Id.*
[60] *Id.*
[61] Expert Testimony of Umakanth Katwa, CCX-3, at 30.
[62] Expert Testimony of Erin Mannen, CCX-1, at 18 n.10; Expert Testimony of Umakanth Katwa, CCX-3, at 21–22, 30.
[63] Expert Testimony of Erin Mannen, CCX-1, at 42.
[64] *Id.*

where the infant's face will get enveloped by or pressed against the soft surface of the U-shaped pillow portion of the Podster, resulting in nose and mouth occlusion and suffocation."[65]

- **The Podsters Increase Muscle Fatigue and Reduce an Infant's Ability to Self-Rescue**. Dr. Mannen testified that that the physical design of the Podster, such as its inclined nature, causes abdominal muscle fatigue and thus negatively affects an infant's ability to self-rescue if the infant finds itself in a position in which the infant's nose and mouth are obstructed, whether through rolling or otherwise.[66] Dr. Katwa also explained:

> During suffocation, due to the design of the Podster, it is very difficult for the infant to leverage its weight against the soft, highly flexible Podster and to lift its head and turn the head to clear the nose and mouth to breathe. Infants may need up to 70-degree rotation of the head to clear the nose to breathe from prone position, and developmentally young infants have not yet achieved muscle strength to do such maneuvers. Therefore, this makes it almost impossible for the infant to self-rescue from the prone or side position in the Podster.[67]

- **The Podsters' Lack of Firmness Creates a Risk of Suffocation**. Dr. Mannen testified that the Podsters are soft enough to conform to and envelop the face of an infant.[68] As Dr. Katwa testified: "[t]his increases the risk for suffocation and rebreathing when infants roll over to the prone or side sleeping position."[69] Indeed, "[t]he Podster's surface is very soft and highly compressible, and, without an underlying rigid back surface, the infant will be unable to leverage their weight

[65] Expert Testimony of Umakanth Katwa, CCX-3, at 30.
[66] Expert Testimony of Erin Mannen, CCX-1, at 44–46.
[67] Expert Testimony of Umakanth Katwa, CCX-3, at 30.
[68] Expert Testimony of Erin Mannen, CCX-1, at 47.
[69] Expert Testimony of Umakanth Katwa, CCX-3, at 19.

against this highly compressible surface to lift the neck and rotate their head to self-rescue and clear their nose if the infant is in a prone or side sleeping position."[70]

- **The Podsters Place Infants in Positions Where Their Breathing Can Be Compromised**. Dr. Mannen testified that, due to the physical design of the Podster, if infants rotate their heads 90 degrees during supine lying, it "results in mouth and nose contact with the soft sides of the Leachco Podster if an infant is placed in the slouched position or otherwise had slid down into the recessed portion of the pillow."[71] This positioning and head movement where the nose and mouth are in contact with the plush sides of the Podster present a "concerning suffocation scenario because of the decreased airflow and increased CO_2 inhalation."[72]
- **The Podsters' Design Allows for Insufficient Airflow and Promotes Carbon-Dioxide Rebreathing**. Dr. Mannen testified that, by virtue of their design, Podsters "exhibited *over 10 times less airflow* . . . compared to the recommended threshold."[73] Dr. Mannen also presented data and analysis regarding CO_2 rebreathing.[74] The main conclusion is that the design of the Podster causes an increase of nearly 2.5 times the amount of CO_2 rebreathing as compared to a control group. The result of this is, according to Dr. Mannen's expert testimony, that "O_2 decreases and the CO_2 substantially increases, increasing the risk for

[70] *Id.*
[71] Expert Testimony of Erin Mannen, CCX-1, at 52.
[72] *Id.* at 53.
[73] *Id.* at 48 (emphasis in original).
[74] *Id.* at 49–51.

hypoxia (not breathing enough oxygen) and breathing in too much CO_2."[75] Dr. Katwa, in turn, evaluated this restricted airflow and elevated CO_2 data and explained:

> Airflow data from Dr. Mannen's biomechanical testing revealed that there is close to a 10-fold pressure drop when testing in the prone position, resulting in substantially reduced air flow. . . . Dr. Mannen's analysis of airflow in the prone position revealed that there is reduced airflow which also increases the CO_2 by 9.4% (a three-fold increase) and drops oxygen by 1.8%. If the reduced airflow continues to occur for greater than 10 minutes, it can result in profound hypoxemia and unconsciousness resulting in irreversible brain damage and/or brain death. Even if the infant is resuscitated at this time, complete neurological recovery is very unlikely to happen, leading to irreversible neurological damage such as cerebral palsy and vegetative state requiring breathing and feeding support for life. If the hypoxemia lasts longer than 25 minutes, it can result in death and the infant may not even be able to be resuscitated.[76]

Although holding that "Complaint Counsel has failed to prove that the Podsters are defective," Initial Decision at 56, the Presiding Officer *agreed* that the design characteristics of the Podster could pose a risk of death to infants:

> As an infant product, the Podsters—if defective—would expose a highly vulnerable class of persons to a risk of injury or death. Infants are almost entirely dependent on adult caregivers for their every need. An infant has no agency in choosing where to be placed, for how long, or in what surrounding circumstances. And young infants generally lack the strength, experience, or physical capability to extricate themselves from a precarious or dangerous situation without adult assistance.
>
> The CPSC has produced sufficient evidence to support a theoretical possibility that an infant left unattended or permitted to sleep in a Podster *could* suffocate and die. Thus, there is at least the potential for a fatal injury to result from misuse of the Podster.

[75] *Id*. at 49–50.
[76] Expert Testimony of Umakanth Katwa, CCX-3, at 23–24.

Initial Decision at 46 (emphasis in original).

The expert testimony explicates how the Podsters' physical characteristics pose a risk of injury to infants. Specifically, the record reflects that the Podster is an inclined, compressible, soft, and insufficiently permeable product that poses a risk of severe injury or death if an infant is left unsupervised in the product or if it is used for sleep. In other words, the design characteristics of the Podster pose a risk of injury.

2. *The Podsters Contain Design Defects Because the Risk of Injury Occurs as a Result of Their Operation and Use*

The assessment of whether a product's characteristics create a risk of injury, the initial step of the *Zen Magnets* defect analysis, may involve consideration of the role of foreseeable misuse of the product. *See Zen Magnets*, 2017 WL 11672449, at *9. Under the Defect Regulation, a design defect may be present "if the risk of injury occurs as a result of the operation or use of the product." 16 C.F.R. § 1115.4. The Commission has made clear that "operation or use" includes foreseeable misuse. *See, e.g.*, *Zen Magnets*, 2017 WL 11672449, at *10 ("[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."); *see also In re Zen Magnets*, *LLC v. CPSC*, No. 17-CV-02645-RBJ, 2018 WL 2938326, at *6–7 (D. Colo. June 12, 2018) (Order on Cross-Motions for Summary Judgment), *aff'd in part and rev'd in part on other grounds*, 968 F.3d 1156, 1176 (10th Cir. 2020). 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 *9 (emphasis added), *13.

Here, it is foreseeable that caregivers will use the Podster for sleep (including bedsharing)

or will use the Podster without constant supervision, despite Leachco's warnings against such use, providing further evidence that the Podster's design defects give rise to a risk of injury. Indeed, the Presiding Officer recognized that misuse of the Podster contributes to the risk of infant death: "We know that consumer misuse must play a role in any product hazard determination for the Podster, because there has never been an injury reported where the product was used as intended." Initial Decision at 48. Moreover, the Presiding Officer found that such misuse of the Podster for sleep and without supervision *is* foreseeable. *See, e.g.*, Initial Decision at 46–47 (use of the Podster unattended or for sleep is "foreseeable because . . . infants sleep throughout the day, and . . . caregivers could be tempted to permit an infant to continue sleeping unsupervised or could decide to use the Podster as a sleep product, despite the product warnings"), 49 (the Podsters' warnings "appropriately advise against misuse—which is nonetheless foreseeable, to a certain extent") (modified for sentence case), 50 (the three infant deaths involving the Podster are evidence that "some consumers misuse the Podsters for infant sleep," and there is "ample evidence showing that use of the Podsters for sleep is not uncommon").

This finding is unsurprising in light of the overwhelming (and unrebutted) evidence showing that it is foreseeable that consumers will use the Podster for sleep. Leachco's own employees testified that they and their relatives had used the Podsters for infant sleep.[77] Leachco admitted that it knew consumers had placed infants in the Podster for sleep, or allowed infants to sleep in them,[78] and Jamie Leach conceded that "you can't control where babies choose to go to sleep."[79]

[77] Expert Testimony of Celestine Kish, CCX-2, at 73–74, ¶¶ 145–46; Mabry Ballard Dep., CCX-42, at 180:15–19; Tonya Barrett Dep., CCX-43, at 27:20–28:12, 29:8–30:9.
[78] Leachco's Second Supplemental Response to CPSC Request for Admission Nos. 3, 4, & 5, JX-46, at 2.
[79] Aug. 8, 2023 Hr'g Tr., at 127:2–7.

Further, Ms. Kish testified concerning the multiple scientific human factors engineering reasons that consumers would use the Podsters for sleep.[80] She also identified numerous examples of social media, forum posts, and online product reviews likely to influence consumers to believe that the Podster can be used for infant sleep. On Instagram, Ms. Kish located multiple posts showing infants sleeping in the Podster, including one with accompanying text praising the Podster as a sleep product.[81] In a product review blog hosted by *New York* magazine, the Podster was characterized as a "magical pod-napper sling contraption" that "lulls the baby to sleep."[82] And in online forums and reviews posted on Amazon, consumers discussed their experiences using the Podster for sleep, even as they acknowledged this was against Leachco's warnings and pediatricians' recommendations.[83] Leachco's own official Instagram account has "liked" photographs of infants sleeping on Podsters,[84] contributing to consumers' perception that it is safe to use the Podsters for sleep.

Relatedly, the record also reflects that the Podster is used without constant supervision.[85] Leachco's marketing of the Podsters as a "safe, secure spot to place an infant" while attending to other tasks falsely implies that it is possible to constantly supervise while multi-tasking and that it is safe to leave infants alone in the product for some period of time.[86] However, Ms. Kish presented scientific literature regarding parental supervision and multi-tasking and explained why constant supervision is not possible with a Podster. As Ms. Kish explained, "[u]nder even

[80] Expert Testimony of Celestine Kish, CCX-2, at 57–60.
[81] *Id.* at 42–44, ¶¶ 84–85.
[82] *Id.* at 45–46, ¶¶ 89–90.
[83] *See, e.g.*, *id.* at 52 ("Of course your pediatrician and the manufacture[r] will say no sleeping and no putting on anything but the floor so it's a personal decision."); 54, Figure 21 ("with the SIDS recommendations, it's so hard to feel okay doing anything other than a bassinet by the side of your bed"); 55, Figure 22 ("I know they recommend not to let them sleep in it but my baby will absolutely not sleep on her back.")
[84] Instagram Screenshot, CCX-59.
[85] Expert Testimony of Celestine Kish, CCX-2, at 66–67, ¶¶ 130–132.
[86] *Id.* at 66, ¶ 130.

the best of circumstances, perfect parental or caregiver supervision is not possible. Especially over extended periods of time, parents or caregivers cannot be perfectly attentive, regardless of their desire to do so."[87]

In sum, the Podsters are defective because a risk of injury occurs as a result of their operation and use, including foreseeable misuse. When used for sleep and without constant supervision—both foreseeable uses of the Podsters—the design characteristics of the product enable an infant to move into a compromised position, leading to a risk of suffocation or asphyxiation. Because the Podsters' dangerous characteristics are not necessary for the product to function, under the *Zen Magnets* framework, the risk of injury is sufficient to find that the Podsters are defective. *See Zen Magnets*, 2017 WL11572449, at *8. The Presiding Officer's ruling to the contrary is contradicted by his own findings and the evidence.

3. *The Risk of Injury Associated with the Podsters is the Type of Risk Which Renders the Product Defective*

As noted above, the Podsters are defective because their design characteristics, in conjunction with their operation and use, give rise to a risk of serious injury to infants. As *Zen Magnets* notes, "[i]f such characteristics are not necessary for the product to function," the Commission "can dispense with further defect analysis and . . . may find that the product contains a defect." *Zen Magnets*, 2017 WL 11672449, at *8. Although not recited expressly in those terms, the Presiding Officer found that "it cannot be said . . . that the alleged danger posed by the [Podster] is integral to its function." Initial Decision at 44. Thus, it would have been appropriate for the Presiding Officer to dispense with the remainder of the defect analysis and find the Podster defective based on the "reams of testimony, studies, and analytical data about the potential for injury" produced by Complaint Counsel, along with the overwhelming evidence

[87] *Id.*

of foreseeable misuse of the product. *See* Initial Decision at 49–51, 57.

However, the Initial Decision instead analyzed (incorrectly) the factors in the Defect Regulation—further explained in *Zen Magnets*' Step 2.b. analysis—and wrongly concluded the Podsters were not defective.

Specifically, when applicable, the Commission may consider, as appropriate:

> The utility of the product involved; the nature of the risk of injury which the product presents; the necessity for the product; the population exposed to the product and its risk of injury; the obviousness of such risk; the adequacy of warnings and instructions to mitigate such risk; the role of consumer misuse of the product and the foreseeability of such misuse; the Commission's own experience and expertise; the case law interpreting Federal and State public health and safety statutes; the case law in the area of products liability; and other factors relevant to the determination.

16 C.F.R. § 1115.4. The Commission in *Zen Magnets* incorporated these factors into Step 2.b. of its defect analysis, which considers whether the risk of injury outweighs the utility of a product. *See Zen Magnets*, 2017 WL 11672449, at *29. Again, this stage of the analysis applies, only if the product's characteristics which give rise to a risk of injury "are necessary for the product to function, or if the effect of the defect finding will remove the product from the market." *Id.* at *9. If so, "the Commission conducts a balancing test to determine whether the risk of injury outweighs the usefulness of the product to consumers, before the Commission may find that the product contains a defect." *Id.*

In *Zen Magnets*, the Commission proceeded to Step 2.b. because it found that the "feature of the Subject Products that creates the risk, that is, the attractiveness of SREMs to each other, is the 'sine qua non of their essence.' . . . . '[w]ithout the ability to attract to each other, the product is worthless.' . . . . In these circumstances, the Commission must 'examine the evidence in the record to see if it establishes that the utility to the public of ... [the product] outweighs the risk to the public that the product produces.'" *Id.* at *29 (first quoting *Zen Magnets*, CPSC Dkt. No. 12-

2, at 11 (March 24, 2016) (Decision and Order); then quoting *Dye*, 1989 WL 435534, at *9, *11).

The Initial Decision misapplied the factor analysis in two significant ways. First, the Presiding Officer misinterpreted the purpose of the factors as a framework for "determining whether a defect exists," *see* Initial Decision at 38, rather than for conducting a weighing analysis to determine "whether the risk of injury associated with a product is the type of risk which will render the product defective." *See* 16 C.F.R. § 1115.4. But, as the Commission has noted, the factor analysis does not present a separate basis for a defect finding. *See Zen Magnets*, 2017 WL 11672449, at *7 n.6. Rather, it serves as a means of determining—once a risk of injury has been established—whether the product is defective when the product's dangerous characteristics are necessary for the product to function. *See* 16 C.F.R. § 1115.4 (explaining that because a sharp blade is "necessary if [a] knife is to function adequately," the sharpness of the blade does not render the knife defective despite the risk of injury); *Dye*, 1989 WL 435534, at *9 ("[W]here a product's utility and risk are inseparable, the need of the public for the product may outweigh the risk the product presents; in such a case, the product would not be considered defective.").

Second, the Initial Decision did not properly perform Step 2 of the *Zen Magnets* analysis. After finding that the Podsters' characteristics give rise to a risk of injury, the next step is to "consider whether the characteristics are necessary for the product to function." *Zen Magnets*, 2017 WL 11672449, at *8. Then, proceeding to Step 2.a., "[i]f such characteristics are not necessary for the product to function, then [the Commission] can dispense with further defect analysis and . . . may find that the product contains a defect." *Id.* at *9; *see also id.* at *8, *29 n.35 ("[W]hen the risk of injury does not arise from a product characteristic that is necessary for

the product to function, balancing the risk of injury with the product's utility is not necessary."). The Presiding Officer correctly acknowledged that the Podsters' dangerous characteristics are not necessary to for it to function: "[n]or can it be said that the alleged danger posed by the [Podsters] is integral to its function in the same way that the sharpness of a knife—which may present a deadly hazard if used improperly—is essential to its very purpose." Initial Decision at 44. Further, the Initial Decision does not address whether a defect finding under *Zen Magnets* would remove the Podsters from the market.[88]

In any event, and as discussed below, even if the Podsters dangerous characteristics are necessary for it to function or if a defect finding would result in removal from the market, conducting a correct factor analysis under Step 2.b. of *Zen Magnets* overwhelmingly weighs in favor of finding the Podster defective.[89] The Presiding Officer weighed these factors incorrectly and a proper consideration of the factors listed in Defect Regulation—to the extent applicable—establishes that the risk of injury associated with the Podsters is the type of risk which renders the product defective.

a. Utility of the Product

The record reflects that the Podsters offer little to no utility for consumers. The Podster is

[88] The Initial Decision contains references to removal of products from the market, but only in the context of a banned hazardous product, a proceeding not applicable here. *See* Initial Decision at 38, n.25 (referring to the procedure for banning hazardous products under 15 U.S.C. § 2058); 43 ("[T]his is not a proceeding aimed at banishing all infant loungers or all products of any given type.").

[89] In *Zen Magnets* the Commission found that the "attractiveness of SREMs to each other" was the feature of the product that created the risk of injury and that this feature was essential to the character of the product. *Zen Magnets*, 2017 WL 11672449, at *29. In this case, however, the function of infant lounging does not require some of the dangerous characteristics posed by the Podster that create the risk—namely the level of incline, the high sides of the pillow, and lack of firmness. As such, the Initial Decision could have found a defect without a factor analysis under *Zen Magnets* Step 2. Further, it is not clear that a defect finding here, which will result in a mandatory recall of the Podsters as currently designed, will lead to removal from the market, like in *Dye*, where Commission staff did not "indicate[] any particular voltage that it would consider safe," and Respondent noted that a lower voltage, "which may be safe with respect to electrocution, is insufficient to maintain the utility of the device for driving worms to the surface." *Dye*, 1989 WL 435534, at *10. Thus, based on the evidence adduced, it is not clear that a *Zen Magnets* Step 2 analysis is required—even though a consideration of the factors, as detailed below, weighs overwhelmingly in favor of finding the Podster defective.

marketed as a place for infants to "lounge" while parents or caregivers can attend to other household tasks hands-free.[90] In other words, Leachco urges parents to purchase the product because it will give them an opportunity to turn their attention to other tasks while the infant is resting in the product. A resting newborn or infant who is tired or has been fed and then placed in a soft bed-like surrounding, will, in all likelihood, fall asleep unless actively engaged by a caregiver.[91] That type of parental interaction is contrary to the advertised purpose of the Podster: the product's marketing advances a use that cannot, in all practicality, be safely achieved.[92] The founder of Leachco and the designer of the Podster, Jamie Leach, admitted during cross-examination that infants falling asleep in the product or use of the product without constant supervision could not be controlled—supporting the theory that the Podster offers little to no utility but instead poses a deadly risk for infants.[93]

The Presiding Officer erroneously found that the Podsters have "some demonstrated utility," Initial Decision at 45, because:

- "It is inconceivable that scores of thousands of consumers would pay nearly $50 and as much as $90 for a product offering no utility." *Id.* at 44.
- If the Podster were not available, "consumers might choose another of the numerous substandard options available to them." *Id.*
- "Sitting at an incline permits the child to better see and interact with surroundings and other persons than a completely supine position." *Id.* at 45.
- The Podster "snuggles" a baby, according to a product review, and "the product's

[90] Expert Testimony of Celestine Kish (Exhibit 2), CCX-2, at 83.
[91] *Id.* at 61, ¶ 119.
[92] *See id.* at 66–67, ¶¶ 130–132.
[93] Aug. 8, 2023 Hr'g Tr., at 127:2–7 (Jamie Leach testified that "[y]ou can't control where babies choose to go to sleep").

padding might help keep an infant in a stable position during the brief intervals when it is intended to be used." *Id.*

- The Podster is "designed to fill a limited supportive role for caregivers who need a place to rest an infant for short intervals during the day. *Id.* at 46.

These assertions—most of which are speculative and are not supported by evidence—do not support a finding that the Podsters have utility. That 180,000 consumers were persuaded by Leachco's marketing is not evidence that the Podster is useful for its marketed purpose (and no record evidence was cited by the Presiding Officer in making this finding). There is no evidence that consumers consistently use the Podster only during "brief intervals" while the infant is awake and under constant supervision. *Id.* at 45–46. In fact, the expert testimony demonstrates that the opposite is true.[94]

Moreover, although there is some evidence that an inclined position may permit better interaction with an infant's surroundings, the Podster is not fit for this purpose. Commission staff has recognized that infants too young to sit independently can benefit from products such as rockers, bouncers, and swings that hold them in a seated position, as this can improve "cognitive outcomes such as object perception, language development, spatial memory, visual processing, and overall cognition."[95] However, because infants under four months old "may not have the muscle strength and coordination to control their body positions within seated products," it is important to use restraints.[96] The current voluntary standard for infant rockers, ASTM F3084–22, requires that infant rockers have a waist and crotch restraint.[97] CPSC staff has proposed

[94] *See, e.g.*, Expert Testimony of Celestine Kish, CCX-2, at 57–61 (caregivers are likely to use the Podsters for infant sleep, including bedsharing), at 62–64 (caregivers are likely to fail to constantly supervise infants).
[95] Staff Draft Notice of Proposed Rulemaking for Infant and Infant/Toddler Rockers, OS 63, (Sep. 13, 2023), https://www.cpsc.gov/s3fs-public/Notice-of-Proposed-Rulemaking-Safety-Standard-for-Infant-Rockers-and-Infant-and-Toddler-Rockers.pdf.
[96] *Id.* at OS 64.
[97] *Id.* OS 136.

adding firmness and concavity requirements to the standard to reduce the risk of suffocation due to occlusion of the nose or mouth on soft surfaces within the product or by contact with the sides of the product.[98] The Podster has no restraints to maintain infants in a safe position, and it is a highly compressible, concave product with soft sides that can suffocate an infant.

As "the best illustrative support for the Podster's form serving its function," the Presiding Officer quotes a product review discussed in Ms. Kish's testimony:

> Holding and feeding your baby all the time is exhausting. The little nugget spits up post-feeding and you don't want to lay them flat all the time because "flat head syndrome" is a real thing. Hence this pod. The sides are contoured so the baby is snug, secure, and also slightly elevated . . . . *No other seat out there snuggles the baby like this one.*

Initial Decision at 45 (ellipses in Initial Decision; emphasis in Kish testimony). This is a misinterpretation of the evidence. For some unknown reason, the Presiding Officer omitted the remainder of the last sentence, which ties this purported utility to the Podster's function as a sleep product:

> No other seat out there "snuggles" the baby like this one, and while others have activities and games attached to them, this lounger does you one better—*it essentially lulls the baby to sleep* without any fancy bells or whistles (or noise!).[99]

Moreover, rather than keep infants in place, unrebutted expert testimony demonstrates that the Podster's elevated sides do not maintain infants in a safe position, but rather pose a hazard to infants that may facilitate rolling or movement.[100]

Even if the Presiding Officer had been correct that the Podster is a product that has significant utility, utility is *merely one factor* that must be weighed, along with the other factors,

[98] *Id*. at OS 191–92.
[99] Expert Testimony of Celestine Kish (Exhibit 7), CCX-2, at 142 (emphasis added).
[100] *See* Expert Testimony of Erin Mannen, CCX-1, at 41–43.

against the risk of injury. *See* 16 C.F.R. § 1115.4. There is no evidence that the Presiding Officer conducted this analysis. Instead, the Presiding Officer charged that Complaint Counsel "utterly fail[ed] to address this utility of the product for its intended use," which constituted a "crippling weakness" in its case. Initial Decision at 46, 56. However, for the reasons noted, the Presiding Officer grossly overstated the product's utility and failed to properly weigh this factor against the deadly risk of the product.

b. Nature of the Risk of Injury

The record shows that the nature of the risk of injury is grave. As demonstrated by the testimony of Drs. Mannen and Katwa, infants placed on the Podster are at risk of asphyxiation, suffocation, and death. Three infants have died after they were placed on the Podster for sleep. The Presiding Officer did not directly discuss this factor in the context of balancing the risk against the utility and necessity of the product, though he did find that the Podster's design poses a risk of death. *Id.* at 46 ("As an infant product, the Podsters—if defective—would expose a highly vulnerable class of persons to a risk of injury or death. . . . The CPSC has produced sufficient evidence to support a theoretical possibility that an infant left unattended or permitted to sleep in Podster *could* suffocate and die.") (emphasis in original). Thus, this factor also weighs in favor of finding that the Podster is defective.

c. Necessity

As the evidence demonstrates, the Podster is not a necessity but rather a novel product marketed as a substitute for a safe place for infants. Unlike a knife, which requires a certain degree of sharpness to perform a necessary cutting function, *see* 16 C.F.R. § 1115.4, safer alternatives exist for an infant to be placed when not being held, including CPSC-approved

mattresses, bassinets, and play yards.[101] Further, despite certain unverified claims made by Leachco about aiding in breathing and digestion,[102] there is no need to use the Podster to assist in those functions. In fact, testimony provided by Drs. Mannen and Katwa shows that—quite to the contrary—the Podster does not aid in digestion and makes breathing more difficult and compromised.[103]

Although the Presiding Officer concurred that the Podsters are not a necessity, *see* Initial Decision at 44 ("it cannot be said that [the Podsters] are 'necessary'"), he failed to appropriately weigh this factor. This absence of necessity weighs in favor of a finding that the product is defective.

d. Population Exposed to the Product and Its Risk of Injury

The evidence demonstrates that the Podsters are marketed expressly for use with the highly vulnerable population of infant children and have caused three deaths to its intended users. Infants are unable to prevent a hazardous scenario in which their mouths or noses are obstructed by a Podster.[104] Ms. Kish testified that caregivers cannot provide constant and perfectly attentive supervision of an infant on a Podster, and as infants develop they become more able to move into a compromised position.[105] She also testified that it is likely that the Podsters will be used for sleep.[106] Dr. Mannen testified that the Podster's design facilitates movement into potentially compromised positions and negatively affects an infant's ability to self-rescue from a position in which the nose and mouth are obstructed.[107] Further, Dr. Katwa

[101] Aug. 8, 2023 Hr'g Tr., at 27:20–28:19.
[102] *Id.* ¶ 15; Podster Product Description from Leachco.com, JX-30.
[103] Expert Testimony of Erin Mannen, CCX-1, at 6; Expert Testimony of Celestine Kish, CCX-2, at 29–30.
[104] *Id.* at 6, 48–49; Demonstrative Video Created by Dr. Erin Mannen Regarding Airflow Testing on the Podster, CCX-52.
[105] Expert Testimony of Celestine Kish, CCX-2, at 66–67, ¶¶ 131–32.
[106] *Id.* at 54–55, ¶ 111.
[107] Expert Testimony of Erin Mannen, CCX-1, at 44–46.

testified about infants' immature respiratory system and how vulnerable they are during sleep, including REM sleep.[108]

Although the Presiding Officer correctly concluded that infants who use the Podster are "a highly vulnerable class of persons to a risk of injury or death," Initial Decision at 46, he failed to give any weight to this factor. The special vulnerability of the population exposed to injury or death by the Podsters weighs in favor of finding the Podsters defective.

e. Obviousness of the Risk of Injury

The seriousness of the risk posed by the Podster is heightened because the risk is hidden. The Podster is marketed by Leachco as a place for newborns and infants to "lounge," and consumers presume that using the Podster would not be dangerous. However, parents and caregivers lack an understanding that leaving an infant unattended in the Podster, even for a short period of time, could lead to deadly consequences.[109] Reasonable parents and caregivers are not likely to appreciate the risks of suffocation, asphyxiation, and death from a product marketed specifically for newborns and infants.[110] They may believe that the infant will react naturally to mouth or nose obstruction with a reflex as an adult would, without understanding that an infant's neural physiology and muscle capacities are entirely different, or without understanding, as Dr. Katwa testified, "it can take as little as 2 to 3 minutes for an infant to become non-responsive due to suffocation."[111]

---

[108] Expert Testimony of Umakanth Katwa, CCX-3, at 7, 14–16.

[109] *See, e.g.*, Expert Testimony of Celestine Kish, CCX-2, at 61 (caregivers are unlikely to understand that the Podster does not eliminate the suffocation risk when used for bedsharing), at 61–62 (Podsters' "deeply contoured sides" may create a false perception that infant will not move out of the Podster), at 62 (caregivers may believe that the design of the Podster will prevent rolling into unsafe position). *See also* IDI No. 220916HCC1454: Virginia Incident, JX-11 (unredacted), at 51 (statement by caregiver's husband that he was not aware of the hazard until after the incident and had not seen the Podster's warning labels).

[110] *See, e.g.*, Expert Testimony of Celestine Kish, CCX-2, at 34–39 (discussing consumer interaction with infant sleep products), 53–55 (discussing factors that influence caregivers to disregard warnings despite knowledge of risk).

[111] Expert Testimony of Umakanth Katwa, CCX-3, at 4.

Additionally, unsuspecting parents and caregivers may not be aware that seemingly innocuous and foreseeable use of the Podster for sleep or while multi-tasking could lead to fatal outcomes within the space of a few minutes.[112] This is further supported by Ms. Kish's testimony regarding social media and counter-examples, which may give consumers comfort in using the Podster unsupervised or for sleep, not realizing the potentially deadly consequences.[113]

On the obviousness of the risk, the Commission has spoken authoritatively: when "the hazard is not obvious to consumers . . . [this factor] weighs in favor of finding the Subject Products defective." *See Zen*, 2017 WL 11672449, at *26. The Initial Decision failed to appropriately weigh this factor against the risk of injury associated with the Podster because it incorrectly interpreted "the obviousness of such risk" to mean that a "reasonable person would have recognized the risk and alerted the public to it or taken other action required by the CPSA." Initial Decision at 49. And the Initial Decision concluded erroneously that Leachco "anticipated the potential non-obvious hazards arising from certain uses of its products and has provided appropriate warnings and instructions." *Id.* However, the fact that the hazard is not obvious weighs in favor of finding the Podster defective.

f. Adequacy of Warnings and Instructions to Mitigate Risk

The record evidence, as well as the improperly excluded testimony of Ms. Kish, shows that the undisputed serious risk associated with the Podsters cannot be adequately mitigated through warnings and instructions. Ms. Kish testified that the warnings and instructions are ineffective at preventing parents and caregivers from using the Podster for sleep.[114] This ineffectiveness stems from parents' and caregivers' desire to have their infants sleep, social

[112] *Id.* at 4.
[113] *See* Expert Testimony of Celestine Kish, CCX-2, at 39–53, ¶¶ 83–108.
[114] *See id.* at 7–34, 53–56.

media and media images of infants using the Podster for sleep, and the that fact that the Podster does not facially appear hazardous.[115] Ms. Kish also testified that the warnings and instructions are not effective in ensuring that parents and caregivers will only use a Podster with constant supervision. Perfect parental supervision is impossible—and research shows that multi-tasking necessarily takes attention away from the task of supervising an infant.[116] As a result, the deadly risk associated with the Podsters cannot be mitigated through warnings and instructions.

The Presiding Officer correctly recognized that "there is no evidence that improvements in the warnings would mitigate any potential danger." Initial Decision at 50. But rather than weighing this fact against the risk of injury, and without providing a reason that it was not an appropriate consideration, the Presiding Officer declared that "the absence of warnings is . . . a *non-factor* in the defect analysis." *Id.* (emphasis added). This is obviously incorrect: if a risk of injury is associated with a product and the risk is not obvious to the consumer, the fact that no warning or instruction would be adequate to mitigate the risk must weigh in favor of a finding the product defective. *See* 16 C.F.R. § 1115.4; *see also Zen Magnets*, 2017 WL 11672449, at *26–29, *32 (after concluding that no warnings would mitigate the risk of injury, holding that all factors weighed in favor of finding that the risk of injury outweighs utility).

g. Role of Consumer Misuse and Foreseeability of Such Misuse

The record reflects that, although the Podsters are designed for infants to be placed in the supine position on the floor while awake, consumer use behaviors that Respondent may characterize as "misuse" are highly foreseeable. As detailed above, and as thoroughly examined in Ms. Kish's testimony, it is foreseeable that parents and caregivers will use the Podster for

[115] *Id.* at 39–53.
[116] *See id.* at 64.

sleep.[117] Leachco's own employees testified during depositions that they and their relatives have used the Podster for infant sleep, and Jaime Leach conceded during the hearing that one cannot control where their infants fall asleep.[118] It is also foreseeable that the Podster will be used for sleep because many parents and caregivers are influenced by social media and other images showing infants sleeping on the Podster, including photographs posted on Leachco's own official social media pages.[119]

It is also foreseeable that a parent or caregiver will use the Podster without constant supervision, because as Ms. Kish testified, consumers are not likely to appreciate that infants placed unsupervised on a Podster can roll or move into a compromised position from which they will be unable to self-rescue, and can suffocate or asphyxiate within minutes.[120] Leachco itself markets the Podster to be used while multi-tasking and not intently supervising, leading infants to fall asleep or move in this unsafe environment. Additionally, despite Leachco's warnings, it also is foreseeable that consumers will use Podsters for bedsharing, on elevated surfaces, or within other products, such as cribs and play yards. This use is likely because, as Ms. Kish testified, the Podster may be an attractive option as it is soft, portable, and can easily be brought into the bed.[121]

This factor must be weighed in favor of finding that the risk renders the product defective. The Presiding Officer held that misuse of the Podsters is foreseeable,[122] but he

---

[117] *Id.* at 60–65, ¶¶ 117–128.
[118] *Id.* at 73–74, ¶¶ 145–46; Mabry Ballard Dep., CCX-42, at 180:15–19; Tonya Barrett Dep., CCX-43, at 27:20–28:12, 29:8–30:9; Aug. 8, 2023 Hr'g Tr., at 127:2–7.
[119] Expert Testimony of Celestine Kish, CCX-2, at 37–42, ¶¶ 72–82; Instagram Screenshot, CCX-59.
[120] Expert Testimony of Celestine Kish, CCX-2, at 65, ¶ 129.
[121] *Id*.
[122] *See*, *e.g.*, Initial Decision at 46 (use of the Podster unattended or for sleep is "foreseeable because . . . infants sleep throughout the day, and . . . caregivers could be tempted to permit an infant to continue sleeping unsupervised or could decide to use the Podster as a sleep product, despite the product warnings."), 49 (the Podsters' warnings "Appropriately Advise Against Misuse—Which is Nonetheless Foreseeable, to a Certain Extent"), 50 (the three infant deaths involving the Podster are evidence that "some consumers misuse the Podsters for infant sleep," and there is "ample evidence showing that use of the Podsters for sleep is not uncommon").

incorrectly discounted this factor in his defect analysis and instead shifted the responsibility for the infant deaths to consumers. *See, e.g.*, *id.* at 47 (discussing Complaint Counsel's failure to consider the role and responsibility of caregivers in "safeguard[ing] infants against the risks of injury from misuse of the [Podster]"), 48 ("the available evidence strongly suggests that caregiver misuse was the dominant factor" in the three fatal incidents, rather than a design defect). The Presiding Officer should have weighed this factor in favor of finding the Podsters defective.

h. Commission Experience and Expertise

The Commission has substantial experience in regulating infant products, including infant sleep products.[123] It has long advocated for safe sleep practices as recommended by the American Academy of Pediatrics.[124] Here, prior experience is buttressed by experts from crucial disciplines. Dr. Erin Mannen, a biomechanical engineering expert, conducted an extensive study of inclined sleep products in 2019 and infant pillows in 2022 for the CPSC, and her expertise has contributed to important recalls, such as more than three million Boppy infant pillows in September 2021—which share characteristics with the Podster.[125] Celestine Kish, an experienced expert on human factors, human engineering, and warnings, has years of experience assessing

[123] *See, e.g.*, Safety Standard for Infant Support Cushions, Notice of Proposed Rulemaking, 89 Fed. Reg. 2530 (Jan. 16, 2024); Ban of Inclined Sleepers for Infants, 88 Fed. Reg. 55,554 (Aug. 16, 2023); Ban of Crib Bumpers, 88 Fed. Reg. 54,878 (Aug. 14, 2023); Safety Standard for Crib Mattresses, 87 Fed. Reg. 8,640 (Feb. 15, 2022); Safety Standard for Infant Sleep Products, 86 Fed. Reg. 33,022 (June 23, 2021); Safety Standard for Bassinets and Cradles, 78 Fed. Reg. 63,019 (October 23, 2023); Safety Standard for Play Yards, 77 Fed. Reg. 52,220 (Aug. 29, 2012).
[124] *See* CPSC, A Safe Sleep For All Babies; CPSC and Child Safety Partners Launch National Education Campaign on Crib Safety for New and Expectant Parents (Oct. 22, 2010), https://www.cpsc.gov/Newsroom/News-Releases/2011/A-Safe-Sleep-For-All-BabiesCPSC-and-Child-Safety-Partners-Launch-National-Education-Campaign-on-Crib-Safety-For-New-and-Expectant-Parents; *see also* 2022 American Academy of Pediatricians Infant Sleep Recommendations, RX-37.
[125] *See* CPSC, The Boppy Company Recalls Over 3 Million Original Newborn Loungers, Boppy Preferred Newborn Loungers and Pottery Barn Kids Boppy Newborn Loungers After 8 Infant Deaths; Suffocation Risk (Sep. 23, 2021), https://www.cpsc.gov/Recalls/2021/The-Boppy-Company-Recalls-Over-3-Million-Original-Newborn-Loungers-Boppy-Preferred-Newborn-Loungers-and-Pottery-Barn-Kids-Boppy-Newborn-Loungers-After-8-Infant-Deaths-Suffocation-Risk.

how consumers interact with infant products, including loungers like the Podster. Dr. Umakanth Katwa, a board-certified medical doctor, pediatric pulmonologist, and sleep specialist, has reviewed the medical consequences to infants that can occur when their breathing is obstructed by the Podster. This expertise regarding inclined sleep and other pillow products establishes unequivocally that foreseeable use of the Podster can lead to dangerous and fatal outcomes.

The Presiding Officer discounted the Commission's experience and expertise, noting that the "The Commission's Experience in Product Safety Entitles it to *Some Deference* on Product Safety and the Need to Protect the Public." *Id.* at 55 (emphasis added). He acknowledged that Complaint Counsel's experts were qualified, noting that they were "each intelligent, accomplished, capable, and articulate," and that "[t]heir approaches and techniques were not inappropriate and were generally helpful in illustrating the issues and providing bases for understanding potential hazards." *Id.* at 57. However, he ultimately diminished their value, characterizing the whole of Complaint Counsel's case as "grounded . . . on models, hypotheticals, and unquantifiable assumptions about consumer behavior." *Id.* at 58. By doing so, the Presiding Officer failed to accord the appropriate weight to the experts.

Through the expert testimony of Dr. Mannen, Ms. Kish, and Dr. Katwa, Complaint Counsel provided substantial and persuasive evidence about the defects associated with the Podster and the dangers posed by the product. The testimony, particularly that of Dr. Mannen and Ms. Kish, drew from the Commission's extensive experience in studying and regulating similar infant products. Importantly, this testimony was unrebutted by Leachco and its witnesses. Thus, the Presiding Officer incorrectly discounted this expertise, and this factor also should weigh in favor of finding that the Podsters are defective.

i. Case Law

The relevant case law supports a finding that the Podsters are defective. As explained above, both the Commission and the federal district court in the *Zen Magnets* matter held that the foreseeable use or misuse of a consumer product is relevant to whether the product is defective. Indeed, the Commission may pursue an action under Section 15 where consumers were injured because they had "disobeyed, did not receive, or did not read [product] warnings." *Zen Magnets*, 2017 WL 11672449, at *13; *see also Zen Magnets*, *LLC v. CPSC*, No. 17-CV-02645-RBJ, 2018 WL 2938326, at *6–7 (D. Colo. June 12, 2018) (Order on Cross-Motions for Summary Judgment) (concluding that "the Commission was entitled to assess the reasonably foreseeable misuse of the magnets in determining the existence of a defect"). Here, expert testimony and common sense establish that the Podsters will be used unsupervised, for sleep, for bedsharing, and in other foreseeable manners that will put their infant occupants at risk of death. The Presiding Officer did not directly discuss this factor in considering whether the risk associated with the Podsters renders them defective; however, prior Commission decisions weigh in favor of finding the Podster defective.

Thus, to the extent a consideration of the various factors set forth in the Defect Regulation is applicable, the Podsters provide little to no utility; are not necessary; and pose a hidden, serious risk to a vulnerable population. Moreover, the risk of serious injury and death cannot be mitigated by warnings and any consumer misuse is highly foreseeable. Accordingly, when weighing the factors correctly, the risk of injury associated with the Podsters renders the products defective.

4. *The Podsters Present a Substantial Product Hazard Because They Contain Defects Which, Based on the Pattern of Defect, the Number of Defective Products, and the Severity of the Risk, Create a Substantial Risk of Injury to the Public*

The Presiding Officer held that the Podsters did not present a substantial product hazard because, even if he had found that the Podsters were defective, "the products' alleged shortcomings do not create a 'substantial risk of injury to the *public*." Initial Decision at 56 (emphasis in original). However, the Presiding Officer failed to apply the substantial risk of injury analysis required by the CPSA, which defines a 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). Notably, the factors listed in Section 15(a)(2) are disjunctive: *any one* of the factors could create a substantial product hazard. 16 C.F.R. § 1115.12(g)(1)(i). Here, all the factors are satisfied, establishing a substantial risk of injury, and thus a substantial product hazard

a. Pattern of Defect

The Presiding Officer incorrectly concluded that the evidence adduced at the hearing "did not establish a pattern of defect that creates a danger to the vulnerable population, even if product misuse is accepted as a possibility." Initial Decision at 49. It seems that this conclusion was reached without referring to the applicable law—or any record evidence, for that matter—as no explanation for this finding is given in the Initial Decision.

The "pattern of defect" analysis requires consideration of whether the defect arises from the "design, composition, contents, construction, finish, packaging, warnings, or instructions of the product, or from some other cause." 16 C.F.R. § 1115.12.(g)(1)(i). Here, all Podsters contain design defects that individually and together pose a risk of injury to an infant. Each infant placed

in a Podster is exposed to the same design defects inherent in the inclined, overly soft, overly compressible, and insufficiently permeable design of the Podsters, as well as the fact that the Podsters' design includes high sides that can occlude the nose and mouth of an infant. When these products are used unsupervised or for sleep, as the evidence showed is foreseeable, these design defects result in a risk of injury—specifically, death through suffocation/asphyxiation—to the uniquely vulnerable infant population. This pattern of defect is present in all 180,000 Podsters[126] and arises from the defects in the physical design of the product, the operation and use of the product, and the risk of injury posed by the product.

b. Number of Defective Products

The Presiding Officer also failed to consider whether the number of Podsters distributed in commerce would have supported a finding of a substantial risk of injury. Even one defective product can present a substantial risk of injury and provide a basis for a substantial product hazard determination if the injury is serious and/or if the injury is likely to occur. *See* 16 C.F.R. § 1115.12(g)(1)(ii).

Leachco admits to selling approximately 180,000 Podsters, meaning that 180,000 products have been distributed in commerce, each of which poses a hidden risk of injury or death to infants. It is beyond dispute that the injury that can result from the Podsters—death through suffocation/asphyxiation—is serious. Accordingly, the sale of 180,000 infant pillows that can lead to the death of their infant occupants creates a substantial risk of injury to the public and therefore provides a basis for establishing a substantial product hazard.

[126] Expert Testimony of Erin Mannen, CCX-1, at 13 n.5.

c. Severity of the Risk

The record reflects that the risk of injury posed by the Podsters is severe. According to the Commission's regulation, "[a] risk is severe 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)(iii) (emphasis added). This factor is disjunctive, so either seriousness or likelihood can establish severity. Here, this factor is satisfied by evidence of a risk of serious injury alone, but the Presiding Officer erred by imposing additional burdens.

In discussing whether the risk associated with the Podsters could constitute a substantial risk of injury, the Presiding Officer concluded that the Podsters pose a risk of death, acknowledging that certain design features of the Podster—"the incline, the plush, padded sides, the lack of rigid structure"—may contribute to the risk of death. Initial Decision at 60. Furthermore, Dr. Katwa's testimony establishes that the injury which might occur is death. In fact, three infants perished after being placed in Podsters for sleep and while unsupervised, just feet away from their caregivers/parents. This evidence alone is sufficient to prove that the Podsters pose a severe risk and satisfies the first prong of the regulation. *See* 16 C.F.R. § 1115.12(g)(1)(iii) ("A risk is severe if the injury which might occur is serious.").

However, in holding that the Podsters did not pose a substantial risk of injury, the Presiding Officer focused instead on his subjective opinion that the likelihood of injury is low. In determining the likelihood of injury, the Commission considers "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)." 16 C.F.R. § 1115.12(g)(1)(iii). The Presiding Officer's analysis of this factor was erroneous in that he effectively excluded the three deaths from consideration because they resulted from misuse of

the Podsters. Indeed, in each of the three fatal incidents, the infant was placed in the Podster for sleep. As the Presiding Officer correctly noted: "[t]he three incidents brought to trial here as evidence against the Podster show that in each case, the product was part of an unsafe sleep environment." Initial Decision at 60. Nothing in the CPSA or the Commission's regulations suggests that the deaths should not be considered solely because the Podsters were being used as part of an unsafe sleep environment. To the contrary, as discussed above, the Podster is defective *because* the risk of injury occurs as a result of foreseeable misuse, and the Commission's regulations expressly note that "intended or reasonably foreseeable use or misuse of the product" is a factor to be considered in determining the likelihood of the risk. 16 C.F.R. § 1115.12(g)(1)(iii).

Further, the three deaths in this matter are probative of the factors the Commission considers in evaluating likelihood of injury, specifically, reasonably foreseeable misuse and the vulnerable population subjected to this hazard (here, infants). *See id.* Specifically, each incident corroborates the experts' testimony that the Podster poses a risk of death to infants when it is foreseeably used for sleep. In the Alabama incident, the four-month-old victim was placed on a Podster within a crib and left unattended for an unknown amount of time.[127] The infant was found unresponsive and ultimately died from complications of asphyxia.[128] Despite the Podster's warning label, according to police, the daycare facility staff member who placed the victim on the Podster "stated that she did not know that putting babies on the pillow was against policy because several kids sleep on pillows."[129] In the Texas incident, the parents of the 17-day-old victim was placed in a Podster on an adult bed for overnight sleep between her parents.[130] The

[127] IDI no. 160519CCC2600: Alabama Incident, JX-7, at 47–48.
[128] *Id.* at 18.
[129] *Id.* at 50.
[130] IDI no. 200917CCC3888: Texas Incident, JX-9, at 33.

victim was found hours later unresponsive, next to her father on the bed.[131] The medical examiner classified the death as "sudden and unexpected death in infancy (SUDI)," noting that "[p]ositional asphyxia due to co-sleeping in an unsafe sleep environment cannot be excluded as contributory given the circumstances at the time of death and the finding of anterior lividity at the time of autopsy."[132] Finally, the Virginia incident involved a three-month-old infant who died from "sudden unexpected infant death with unsafe bedding and positioning"[133] at an in-home daycare after being placed within the Podster within a playpen for sleep.[134] The victim had been congested prior to the incident,[135] and the caregiver's husband stated that he and his wife had purchased the Podster for their own daughter based on their pediatrician's recommendation and online reviews because they believed that the product would aid in breathing if she was congested or had a cold.[136] Following the framework laid out in the Commission's regulation leads to the conclusion that the risk posed by the Podsters is severe. Given that the factors are disjunctive, a showing that "the injury which might occur is serious" is sufficient. And here, the evidence establishes that the injury which might, and unfortunately did occur—death—is serious. The Presiding Officer's analysis of this factor completely misses the mark.

In sum, in combination with the Podsters' defects, the evidence shows that the pattern of defect, the number of products, and the severity of the risk associated with the Podsters support a finding that the Podsters present a substantial risk of injury to the public. As such, by a preponderance of the evidence, the Podsters present a substantial product hazard within the meaning of Section 15(a)(2) of the CPSA.

---

[131] *Id.*
[132] *Id.* at 6.
[133] MECAPS Report: Virginia Incident, JX-12B(1), at 5.
[134] IDI No. 220916HCC1454: Virginia Incident, JX-11, at 11.
[135] *Id.*
[136] *Id.* at 51.

G. *The Initial Decision Erred by Not Imposing a Mandatory Recall*

The Initial Decision denied the relief sought in the complaint and did not make any rulings with regard to the specific remedies sought by Complaint Counsel. Initial Decision at 26 n.16, 65. Because the mandatory remedies requested in the Complaint are required to adequately protect the public and are in the public interest, the Commission should set aside the Initial Decision and impose a mandatory recall order as contemplated by Sections 15(c) and (d). Pursuant to Section 15(c), the Commission should require Leachco to cease distribution of the Podster and to notify all distributors and retailers to likewise cease distribution. *See* 15 U.S.C. § 2064(c)(1)(A)–(B). Additionally, the Commission should instruct Leachco to post clear and conspicuous public notice of the recall on its website and social media accounts. *See id.* § 2064(c)(1)(D). Finally, Leachco should be required to provide direct consumer notice of the recall, which the Commission has recognized "is the most effective form of a recall notice." 16 C.F.R. § 1115.26(a)(4) (part of Subpart C of 16 C.F.R. § 1115, Guidelines and Requirements for Mandatory Recall Notices). The contents of these notices, attached as Attachments A–F to the Proposed Order, reflect the content required by Section 15(i) of the CPSA, and its regulations at 16 C.F.R. §§ 1115.23–29. Finally, pursuant to Section 15(d)(1), an order requiring Leachco to provide consumers with a refund of the purchase price conditioned on return or proof of destruction is in the public interest. *See In re Amazon.com, Inc.*, CPSC Dkt. No. 21-2, Dkt. 142, at 56–58 (July 29, 2024) (Decision and Order). Providing a refund will incentivize consumers to return the product and will prevent future sales of the Podsters on second-hand markets. Considering the ongoing substantial risk of injury or death to children posed by the Podsters, action to promote the removal of these products from the marketplace is needed to remediate the hazards and to ensure the Podsters are no longer a threat to consumers. As the Commission has

previously recognized, "a substantial refund . . . is the best and most adequate incentive to encourage consumers to participate in the recall." *Zen Magnet*s, CPSC Dkt. No. 12-2, Opinion and Order Approving Public Notification Plan, 2017 WL 11672451, at *11 (December 8, 2017).

V. CONCLUSION

For the reasons detailed above, Complaint Counsel requests that the Commission set aside the Initial Decision in its entirety. 16 C.F.R. § 1025.55(b). Pursuant to 16 C.F.R. § 1025.53(b)(5), Complaint Counsel concurrently files a proposed Order (attached as Exhibit A). The proposed Order requests that the Commission find the Podsters to be a substantial product hazard under Section 15(a)(2) of the CPSA and that the Commission order a mandatory recall requiring robust public notification and the issuance of full refunds. *See* 15 U.S.C. § 2064(a)(2), (c)–(d). Pursuant to Section 15(c) of the CPSA, which requires that the Order "specify the form and content of any notice required to be given under such order," *see id.* § 2064(c), Complaint Counsel includes with the proposed Order various notice documents (Attachments A–F) for Commission approval and issuance upon acceptance of a corrective action plan. Additionally, as required by Section 15(d), the Order requires Leachco to submit a proposed corrective action plan for the Commission's consideration to effectuate refunds to consumers and other remaining corrective action logistics and allows for Complaint Counsel to provide a response to address any issues or deficiencies. *See id.* § 2064(d). Consistent with the goal of expeditiously recalling the Podsters, Complaint Counsel is proposing a streamlined process whereby Leachco submits its proposed corrective action plan within 15 days of the issuance of the Order and Complaint Counsel's response is due 15 days thereafter. *See id.* § 2064(d)(2)–(3).

Accordingly, Complaint Counsel requests that the Commission issue a Final Decision and Order requiring a mandatory recall of the Podsters. *See id.* § 1025.55(b).

Dated this 30th day of August, 2024

Respectfully submitted,

Gregory M. Reyes, Supervisory Attorney
Michael J. Rogal, Senior Trial Attorney
Caitlin O'Donnell, Trial Attorney
Thomas J. Mendel, Trial Attorney
Serena Anand, Trial Attorney

Division of Enforcement and Litigation
Office of Compliance and Field Operations
U.S. Consumer Product Safety Commission
Bethesda, MD 20814
Tel: (301) 504-7220

Complaint Counsel for
U.S. Consumer Product Safety Commission

EXHIBIT A

UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of	)	
LEACHCO, INC.	)	CPSC DOCKET NO. 22-1
Respondent.	)	

[PROPOSED] ORDER

Having considered the arguments and evidence of record in this proceeding, the U.S. Consumer Product Safety Commission ("Commission" or "CPSC") finds:

1) All Leachco Podsters ("Podsters"), manufactured and distributed by Respondent, Leachco, Inc. ("Leachco"), present a substantial product hazard under Section 15(a)(2) of the Consumer Product Safety Act ("CPSA"), 15 U.S.C. § 2064(a)(2).
2) That notification, pursuant to Section 15(c) of the CPSA, 15 U.S.C. § 2064(c), is required in order to adequately protect the public from the substantial product hazard posed by the Podsters.
3) That, pursuant to Section 15(d) of the CPSA, 15 U.S.C. § 2064(d), it is in the public interest that Leachco issue full refunds for all Podsters, conditioned upon return or proof of destruction.

It is therefore ORDERED:

1) The Presiding Officer's Memorandum Opinion and Initial Order Denying Relief Sought in the Complaint, Dkt. 148, is set aside in its entirety.
2) Pursuant to Sections 15(c)(1)(A)–(B) of the CPSA, 15 U.S.C. § 2064(c)(1)(A)–(B),

Leachco shall immediately cease distribution of the Podsters and notify all persons or entities that transport, store, distribute, or otherwise handle the Podsters, or to which the Podsters have been transported, sold, distributed, or otherwise handled, to immediately cease distribution of the Podsters using the notification included as Attachment A.

3) Pursuant to Section 15(c)(1)(C) of the CPSA, 15 U.S.C. § 2064(c)(1)(C), Leachco shall notify appropriate State and local public health officials regarding the substantial product hazard posed by the Podsters.

4) Pursuant to Sections 15(c)(1)(D)–(F) of the CPSA, 15 U.S.C. § 2064(c)(1)(D)–(F), and consistent with Section 15(i) of the CPSA, 15 U.S.C. § 2064(i), and 16 C.F.R. §§ 1115.23–.29, immediately following Commission approval of a corrective action plan:

    a) The press release, included as Attachment B, shall be issued to notify the public regarding the substantial product hazard posed by the Podsters.

    b) Leachco shall issue the notices, included as Attachments C–E.

    c) Leachco shall issue the social media postings, included as Attachment F.

5) Pursuant to Section 15(d)(1)(C) of the CPSA, 15 U.S.C. § 2064(d)(1)(C), Leachco shall provide a full refund of the purchase price for each Podster distributed in U.S. commerce.

6) Pursuant to Sections 15(d)(2)–(3) of the CPSA, 15 U.S.C. § 2064(d)(2)–(3):

    a) Leachco shall, within 15 days of the issuance of this Order, file a corrective action plan, for Commission approval.

    b) Complaint Counsel shall, within 15 days of Leachco's submission of a

corrective action plan, file a response to Leachco's proposed corrective action plan, which may include its own proposed corrective action plan.

7) Pursuant to Section 16(b) of the CPSA, 15 U.S.C. § 2065(b), Leachco shall maintain all records of actions taken to comply with the Order for a period of five (5) years after the issuance of this Order and supply such records or permit inspection to Complaint Counsel, upon request, so that Complaint Counsel can monitor compliance with this Order.

8) This Order is issued under Section 15 of the CPSA, as amended, 15 U.S.C. § 2064. Any violation of this Order is a "Prohibited Act" within the meaning of Section 19(a)(5) of the CPSA, 15 U.S.C. § 2068(a)(5), and may result in civil and/or criminal penalties under Sections 20 and 21 of the CPSA, 15 U.S.C. §§ 2069 and 2070. Further, any violation of this Order also may result in Commission enforcement of the Order, including pursuant to Sections 22 and 27(b) of the CPSA. *See* 15 U.S.C. §§ 2071, 2076(b); 16 C.F.R. § 1115.21(b).

Dated: _____

ORDER OF THE COMMISSION

_____
Alberta E. Mills
Secretary
U.S. Consumer Product Safety Commission

Attachment A – Cease Distribution Notice

IMPORTANT RECALL NOTICE – LEACHCO PODSTERS
CEASE DISTRIBUTION NOTICE

[MONTH] [DAY], [YEAR]

Dear [Retailer/Distributor Name]:

Our records indicate that you transported, stored, distributed, or otherwise handled Podsters, which may have been identified by model names Podster, Podster Plush, Bummzie, and Podster Playtime (collectively "Podsters"). These Podsters are subject to a mandatory recall by Leachco, Inc. and the U.S. Consumer Product Safety Commission. [INSERT LINK TO CPSC RELEASE]

The recalled Podsters can cause airflow obstruction if an infant rolls, moves, or is placed in a position where the infant's nose or mouth are obstructed by the Podsters and may also create a risk of positional asphyxia, posing a risk of suffocation, asphyxiation, or death.

Three deaths have been reported when infants were placed on the Podster for sleep.

The recalled Podsters measure between 71 and 75 inches in circumference and have dimensions of approximately 23.75 x 21.5 x 8 inches. They have a padded insert and a removable cover. The covers come in a variety of prints and colors and are either 100% polyester or a cotton/polyester blend. The covers also contain an elastic center made of a nylon/spandex blend.

Approximately 180,000 Podsters have been sold between 2009 and 2022 for prices ranging from $49 - $89.

Leachco Podster, Podster Plush, Bummzie, and the Podster Playtime Infant Loungers

Please immediately cease distributing the recalled Podsters. If you have recalled Podsters in your inventory, please destroy them immediately or contact us at [INSERT] for instructions on returning the products for refunds.

If you have any questions, contact Leachco via email at [INSERT EMAIL], by calling toll-free [INSERT], or by visiting our "Frequently Asked Questions" dedicated to the topic at [INSERT LINK].

Thank you for your understanding.

Attachment B – Press Release

U.S. Consumer Product Safety Commission – Recall

Release Date: MONTH, DAY, YEAR
Release Number: ###

Podster Infant Pillow Recalled by Leachco in Commission-Ordered Mandatory Recall Due to Suffocation and Asphyxiation Hazards; Three Infant Deaths Reported

Name of Product: Leachco Podster Infant Pillows

Hazard: The recalled Podster infant pillows can cause airflow obstruction if an infant rolls, moves, or is placed in a position where the infant's nose or mouth are obstructed by the Podsters and can also create a risk of positional asphyxia, posing a risk of suffocation, asphyxiation, or death.

Remedy: Refund

Consumers should immediately stop using the Podster and contact Leachco for a full refund.

Consumer Contact: Leachco toll-free at [TBD] from [X] a.m. to [X] p.m. ET Monday through Friday, email at [TBD], online at [TBD] and click on [TBD] for more information.

Washington, D.C. -- The U.S. Consumer Product Safety Commission (CPSC) is announcing a mandatory recall of about 180,000 Leachco, Inc. Podsters due to suffocation and asphyxiation hazards to infants. The recalled Podster infant pillows can cause airflow obstruction if an infant rolls, moves, or is placed in a position where the infant's nose or mouth are obstructed by the Podsters and may also create a risk of positional asphyxia, posing a risk of serious injury or death.

CPSC authorized an administrative complaint on February 9, 2022 seeking a mandatory recall of the Podsters after Leachco refused to recall the product. On [DATE], the U.S. Consumer Product Safety Commission determined that the Podsters pose a Substantial Product Hazard under Section 15 of the Consumer Product Safety Act and ordered a mandatory recall.

Three infants have tragically died while being placed on a Podster for sleep. In December 2015, a four-month-old boy died in Alabama when being placed for a nap in a Podster that was in a crib. In January 2018, a 17-day-old girl died in Texas when co-sleeping in a Podster on an adult bed. In October 2021, a three-month-old girl died in Virginia when being placed for a nap in a Podster that was in a playpen.

Consumers should immediately stop using the Podsters and contact Leachco for a full refund and instructions on how to return the product in a prepaid mailing package.

This mandatory recall involves the Leachco Podster which may have been identified by model names Podster, Podster Plush, Bummzie, and Podster Playtime. The recalled Podsters measure

between 71 and 75 inches in circumference and have dimensions of approximately 23.75 x 21.5 x 8 inches. They have a padded insert and a removable cover. The covers come in a variety of prints and colors and are either 100% polyester or a cotton/polyester blend. The covers also contain an elastic center made of a nylon/spandex blend.

The recalled Podsters were sold at Walmart and other stores nationwide and online at Leachco.com, Amazon.com and other websites from 2009 through 2022 for between $49 and $89.

The Podsters were manufactured in the United States by Leachco, Inc. of Ada, Oklahoma.

Photos

Recalled Leachco Podster, Podster Plush, Bummzie, and the Podster Playtime Infant Loungers

About the U.S. CPSC
The U.S. Consumer Product Safety Commission (CPSC) is charged with protecting the public from unreasonable risk of injury or death associated with the use of thousands of types of consumer products. Deaths, injuries, and property damage from consumer product-related incidents cost the nation more than $1 trillion annually. CPSC's work to ensure the safety of consumer products has contributed to a decline in the rate of injuries associated with consumer products over the past 50 years.

Federal law prohibits any person from selling products subject to a Commission ordered recall or a voluntary recall undertaken in consultation with the CPSC.

For lifesaving information:
- Visit CPSC.gov.
- Sign up to receive our e-mail alerts.
- Follow us on Facebook, Instagram @USCPSC and Twitter @USCPSC.
- Report a dangerous product or a product-related injury on www.SaferProducts.gov.
- Call CPSC's Hotline at 800-638-2772 (TTY 301-595-7054).
- Contact a media specialist.

Attachment C – Consumer Letter

IMPORTANT RECALL NOTICE – LEACHCO PODSTERS

[MONTH] [DAY], [YEAR]

Dear [Consumer Name]:

Our records indicate that you previously purchased a Podster, which may have been identified by model names Podster, Podster Plush, Bummzie, and Podster Playtime (collectively "Podsters"). These Podsters are subject to a mandatory recall by Leachco, Inc. and the U.S. Consumer Product Safety Commission. [INSERT LINK TO CPSC RELEASE]

The recalled Podsters can cause airflow obstruction if an infant rolls, moves, or is placed in a position where the infant's nose or mouth are obstructed by the Podsters and may also create a risk of positional asphyxia, posing a risk of suffocation, asphyxiation, or death.

Three deaths have been reported when infants were placed on the Podster for sleep.

The recalled Podsters measure between 71 and 75 inches in circumference and have dimensions of approximately 23.75 x 21.5 x 8 inches. They have a padded insert and a removable cover. The covers come in a variety of prints and colors and are either 100% polyester or a cotton/polyester blend. The covers also contain an elastic center made of a nylon/spandex blend.

Approximately 180,000 Podsters have been sold between 2009 and 2022 for prices ranging from $49 - $89.

Leachco Podster, Podster Plush, Bummzie, and the Podster Playtime Infant Loungers

Please immediately stop using the recalled Podsters. To receive a full refund for your recalled Podster, you can request a pre-paid mailing label and return the product to us, or visit [LINK] for instructions on providing proof of destruction or disposal.

If you have any questions, contact Leachco via email at [INSERT EMAIL], by calling toll-free [INSERT], or by visiting our "Frequently Asked Questions" dedicated to the topic at [INSERT LINK].

Thank you for your understanding.

Attachment D – Retailer Letter

IMPORTANT RECALL NOTICE – LEACHCO PODSTERS

[MONTH] [DAY], [YEAR]

Dear [Retailer/Distributor Name]:

Our records indicate that you sold or distributed in commerce Podsters, which may have been identified by model names Podster, Podster Plush, Bummzie, and Podster Playtime (collectively "Podsters"). These Podsters are subject to a mandatory recall by Leachco, Inc. and the U.S. Consumer Product Safety Commission. [INSERT LINK TO CPSC RELEASE]

The recalled Podsters can cause airflow obstruction if an infant rolls, moves, or is placed in a position where the infant's nose or mouth are obstructed by the Podsters and may also create a risk of positional asphyxia, posing a risk of suffocation, asphyxiation, or death.

Three deaths have been reported when infants were placed on the Podster for sleep.

The recalled Podsters measure between 71 and 75 inches in circumference and have dimensions of approximately 23.75 x 21.5 x 8 inches. They have a padded insert and a removable cover. The covers come in a variety of prints and colors and are either 100% polyester or a cotton/polyester blend. The covers also contain an elastic center made of a nylon/spandex blend.

Approximately 180,000 Podsters have been sold between 2009 and 2022 for prices ranging from $49 - $89.

Leachco Podster, Podster Plush, Bummzie, and the Podster Playtime Infant Loungers

Please immediately cease distributing the recalled Podsters. If you have recalled Podsters in your inventory, please destroy them immediately or contact us at [INSERT] for instructions on returning the products for refunds.

Additionally, we request that you send the attached CPSC press release and letter to all known consumers who have purchased the Podster [Attachments B and C]. Please send these notices to all known consumers immediately and send a second round of notices approximately two weeks after sending the first round.

If you have any questions, contact Leachco via email at [INSERT EMAIL], by calling toll-free [INSERT], or by visiting our "Frequently Asked Questions" dedicated to the topic at [INSERT LINK].

Thank you for your understanding.

Attachment E – Second-Hand Notice

IMPORTANT RECALL NOTICE – LEACHCO PODSTERS

[MONTH] [DAY], [YEAR]

Dear [Second-Hand Seller Name]:

Our records indicate that consumers may have previously sold, or you may currently have active listings for Podsters, which may have been identified by model names Podster, Podster Plush, Bummzie, and Podster Playtime (collectively "Podsters"), on your platform. These Podsters are subject to a mandatory recall by Leachco, Inc. and the U.S. Consumer Product Safety Commission. [INSERT LINK TO CPSC RELEASE]

The recalled Podsters can cause airflow obstruction if an infant rolls, moves, or is placed in a position where the infant's nose or mouth are obstructed by the Podsters and may also create a risk of positional asphyxia, posing a risk of suffocation, asphyxiation, or death.

Three deaths have been reported when infants were placed on the Podster for sleep.

The recalled Podsters measure between 71 and 75 inches in circumference and have dimensions of approximately 23.75 x 21.5 x 8 inches. They have a padded insert and a removable cover. The covers come in a variety of prints and colors and are either 100% polyester or a cotton/polyester blend. The covers also contain an elastic center made of a nylon/spandex blend.

Approximately 180,000 Podsters have been sold between 2009 and 2022 for prices ranging from $49 - $89.

Leachco Podster, Podster Plush, Bummzie, and the Podster Playtime Infant Loungers

Please immediately remove any listings for the Podsters and cease any sales. If you have recalled Podsters in your inventory, please destroy them immediately or contact us at [INSERT] for instructions on returning the products for refunds.

Additionally, we request that you send the attached CPSC press release and letter to all known consumers who have purchased the Podster [Attachments B and C]. Please send these notices to all known consumers immediately and send a second round of notices approximately two weeks after sending the first round.

If you have any questions, contact Leachco via email at [INSERT EMAIL], by calling toll-free [INSERT], or by visiting our "Frequently Asked Questions" dedicated to the topic at [INSERT LINK].

Thank you for your understanding.

Attachment F – Social Media

Facebook: Mandatory #RECALL Leachco Podsters models Podster, Podster Plush, Bummzie, and Podster Playtime due to suffocation and asphyxiation hazards. Three infants died when placed for sleep on a Podster. Stop using the recalled Podsters immediately. Get a full refund. Contact Leachco at [INSERT] or [LINK]. Full recall notice: [LINK to press release].

X (formerly Twitter): Mandatory #RECALL @Leachco models Podster, Podster Plush, Bummzie, and Podster Playtime due to suffocation and asphyxiation hazards. Three infants died when placed for sleep on a Podster. Stop using immediately. Get full refund. Contact [LINK] [LINK to press release].

Instagram: Mandatory #RECALL @Leachco models Podster, Podster Plush, Bummzie, and Podster Playtime due to suffocation and asphyxiation hazards. Three infants died when placed for sleep on a Podster. Stop using immediately. Get full refund. Contact Leachco at [LINK] [LINK to press release].

Pinterest: Mandatory #RECALL @Leachco models Podster, Podster Plush, Bummzie, and Podster Playtime due to suffocation and asphyxiation hazards. Three infants died when placed for sleep on a Podster. Stop using immediately. Get full refund. Contact Leachco at [LINK] [LINK to press release].