UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

IN THE MATTER OF **LEACHCO, INC.,** **Respondent.**	**CPSC DOCKET NO. 22-1**

LEACHCO, INC.'S BRIEF IN OPPOSITION
TO CPSC'S MOTION FOR PARTIAL SUMMARY DECISION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Regulations

Other Authorities

INTRODUCTION

The Commission's request for partial summary decision is based on an attempted rewrite of 15 U.S.C. § 2064(a)(2) and on immaterial or disputed facts. Under § 2064(a)(2), the Commission has the burden to show that the Podster is a "substantial product hazard," *i.e.*, "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." Accordingly, to establish that the Podster is a substantial product hazard, the Commission must prove (1) a defect (2) that creates (3) a substantial risk of injury.

In its Motion for Partial Summary Decision, however, the Commission asks the Court *not to decide* the first element (whether a defect exists) but it claims nonetheless that judgment is appropriate on the third element (substantial risk of injury). The Commission's argument conflicts with the plain terms of § 2064(a)(2) and is logically fallacious. Because the Commission doesn't (here) prove a defect, it cannot demand a conclusion (substantial risk of injury) that omits the necessary predicate (defect). The Commission's motion should be denied on that basis alone.

But the Commission's arguments fail on their own terms. It tries to equate severity of risk with substantial risk of injury. The plain terms of § 2064(a)(2), however, show that severity of risk is a factor used to determine whether a defect in fact creates a substantial risk of injury. The severity of risk itself is not a substantial risk of injury.

In any event, the Commission has presented zero evidence that a *substantial risk* of injury exists. The only material undisputed facts here show that Leachco sold

over 180,000 Podsters and that tragically three babies died after being placed in unsafe-sleep environments (perhaps) in or near a Podster. Assuming that each Podster was used only once—an unreasonably low estimate—the probability of injury is less than two-one-thousandths of a percent (3 / 180,000 = 0.000017 = 0.0017%). More realistically, consumers use each Podster dozens of times, which means the risk approaches zero. The Commission has no evidence to even suggest otherwise. Indeed, outside of three incidents—despite "extensive fact discovery" (CPSC Br. 2)—the Commission has no evidence of any injuries even remotely associated with a Podster. Instead, the Commission proffers "expert" speculation about what "could" or "may" happen if a Podster is used in an unsafe-sleep environment.

The Commission also tries to equate foreseeable misuse with a defect that creates a substantial risk of injury. According to the Commission, (1) it is foreseeable that caregivers will use the Podster for infant sleep and without constant supervision and, ***as a result***, (2) the Podster presents a substantial risk of injury. CPSC Br. 1, 3, 25. But under § 2064(a)(2), the Commission must prove that a substantial risk of injury was created by a defect—not by foreseeable misuse.

Finally, even if the Commission's legal analysis were correct—it is not—the Court should deny the Commission's motion since foreseeable misuse of the Podster is immaterial to the Commission's allegations. As Leachco previously explained, reasonably foreseeable misuse can be a relevant factor to claims of defective warnings or design. But the Commission has not alleged that the Podster's warnings are defective; to the contrary, the crux of the Commission's claim is that the Podster is defective

despite its warnings. And for alleged design defects, reasonably foreseeable misuse may be relevant to consider reasonable alternative designs. But, again, the Commission made no allegations—and offers no evidence whatsoever—that a reasonable alternative design exists. Thus, because misuse of the Podster is immaterial to the Commission's allegations, it cannot seek summary decision on that issue.

The Commission's Motion for Partial Summary Decision must be denied, and Leachco's Motion for Summary Decision must be granted.

STANDARD OF REVIEW

Summary decision must be denied unless "the pleadings and any depositions, answers to interrogatories, admissions, or affidavits show that there is no genuine issue as to any material fact and that the moving party is entitled to a Summary Decision and Order as a matter of law." 16 C.F.R. 1025.25(c). The Court must construe all reasonable inferences in the non-movant's—that is, Leachco's—favor. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); *see also Rinchuso v. Brookeshire Grocery Co.*, 944 F.3d 725, 729 (8th Cir. 2019) ("[A]ll evidence and reasonable inference[s]" must be made "in the light most favorable to the non-movant."). Leachco can defeat a motion for summary decision by showing that "evidence presents a sufficient disagreement to require submission to" the factfinder. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251–52 (1986).

LAW & ARGUMENT

I. Without a defect, the Commission cannot prove—and, therefore, the Court cannot conclude—that the Podster presents a substantial risk of injury

Under the Consumer Product Safety Act, the Commission must show that the Podster is a "substantial product hazard," *i.e.*, "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). The Commission accurately quotes the statute at the tail-end of its brief (p. 21) but largely ignores it.

First, and most importantly, the Commission asks the Court *not* to decide whether a defect exists. *See* CPSC Br. 2 ("Complaint Counsel has elected not to seek summary decision with respect to the entire matter, as Complaint Counsel recognizes there are certain factual matters Leachco still contests relating to whether the product is defective . . . ."). Without finding a defect, the Court cannot decide anything, because § 2064(a)(2) requires *first* proof of a defect and *then* proof that the defect creates a substantial risk of injury.

Because the Commission has not established a defect under § 2064(a)(2), it cannot seek summary decision on anything else. *Cf. Chickaway v. United States*, No. 4:11-cv-00022, 2012 WL 2222848, at *2 (S.D. Miss. June 14, 2012) ("[T]he causation element cannot be proven unless a plaintiff first proves duty and a breach thereof. And because a dispute exists" concerning the standard of care, "a genuine issue of material fact precludes the Court from reaching the causation question at this time.") (footnote omitted); *Duncan v. Black Veterans for Social Justice, Inc.*, 135 N.Y.S.3d

241, 249 (N.Y. Sup. Ct. Oct. 23, 2020) ("[T]he issue of causation is not reached unless a duty is found."); *Evans v. United States* 824 F. Supp. 93, 96 (S.D. Miss. 1993) ("This Court finds this to be a question of causation which the Court will not address unless a duty or breach of duty is established.").

The Commission's opinion, *In the Matter of Dye & Dye* (which the Commission relies on, Br. 21), supports Leachco. CPSC Dkt. No. 88-1, 1989 WL 435534 (July 17, 1991). Indeed, the Commission's discussion of § 2064(a)(2) tracks Leachco's analysis.

> The elements of a substantial product hazard, as defined in [§ 2064(a)(2)], that are relevant to this proceeding are:
>
> 1. A product defect
>
> 2. 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.

Dye & Dye, 1989 WL 435534, at *5 (emphasis in the original).

Dye & Dye next explains what must be established to prove liability under § 2064(a)(2). According to the Commission, "[e]ven though the [it] has concluded that the design or the instructions for the [product] constitutes a defect, the Commission must, in order to find that a substantial product hazard exists, *find additionally* that the product defect '. . . *creates* a substantial risk of injury to the public.'" *Dye & Dye*, 1989 WL 435534, at *13 (quoting § 2064(a)(2)) (emphasis added).

Therefore, according to the Commission itself, it must prove not only that a defect exists, but also that the defect creates a substantial risk of injury. But, obviously, before it can prove that a substantial risk of injury was created by a defect, the Commission must prove the defect itself. Here, by asking the Court to first decide

that there is a substantial risk of injury, the Commission puts the cart before the horse. This is an improper basis for summary decision.

The Court cannot assume the existence of a defect to determine whether that (hypothetical) defect creates a substantial risk of injury. The Commission's motion should be denied on this ground alone.

II. The plain terms of Section 2064(a)(2) preclude the Commission's claim of substantial risk of injury

Even if a defect were established—but the Commission has saved that issue for another day—the Commission's motion must still be denied because it tries to equate severity of risk with substantial risk of injury.

The Commission thus attempts to conflate distinct parts of § 2064(a)(2). The Commission points the Court to "severity of the risk"—one of the factors the Court may consider to determine whether a defect does in fact create a substantial risk of injury. CPSC Br. 22–23. *See* 15 U.S.C. § 2064(a)(2) (defining "substantial product hazard" as "a product *defect* which (*because of* . . . the severity of the risk . . .) *creates* a substantial risk of injury to the public") (emphasis added).

The Commission's attempted alchemy of "severity of the risk" and "substantial risk of injury" thus contradicts the plain language of § 2064(a)(2). The word "substantial" here modifies "risk"—not "of injury." As Leachco explained in its Motion for Summary Decision (Br. 37–41), "substantial risk" here means large or high likelihood of a risk (of injury).

Further, if the "severity of risk" and the "substantial risk of injury" meant the same thing, then "substantial risk of injury" would be superfluous. *See Corley v. Unit-*

ed States, 556 U.S. 303, 314 (2009) (holding statutory interpretation cannot make parts of statute "inoperative or superfluous, void or insignificant") (quotations and citation omitted). On the Commission's theory, the statute would be satisfied whenever an injury is serious. But that is not what the statute says; it requires the Commission to show that a defect creates a substantial—*i.e.*, a significant likelihood of a—risk of injury.

The Commission thus errs when it claims that the "severity of the risk [] is satisfied, *and thus* the existence of a substantial risk of injury is established." CPSC Br. 23 (emphasis added). Here, again, the Commission asks the Court to reach a conclusion without first establishing a necessary predicate. Without a defect, the Court can't consider the severity of the risk (posed by a non-existent defect), and the Court can't consider whether a defect, because of the severity of the risk, creates a substantial risk of injury.

The Commission (properly) cedes ground when it recognizes that "whether an injury is likely to occur" is relevant. CPSC Br. 22, 23. And its decision in *Dye & Dye* again supports Leachco's analysis. *See* 1989 WL 435534, at *13–*14 (considering, to determine whether defects created a substantial risk of injury, among other things, the severity of the risk and the *likelihood* of injury). This understanding matches the declared purpose of the CPSA, which is to "protect the public against *unreasonable* risks of injury associated with consumer products." 15 U.S.C. § 2052(b)(1) (emphasis added); *see also Henson v. Santander Consumer USA Inc.*, 582 U.S. 79, 89 (2017) (noting that statutes do not pursue goals "at all costs").

* * *

Even if there is no genuine issue of material fact as to the *severity* of the risk (CPSC Br. 24), that alone does not establish that a substantial risk of injury exists—much less does it establish that a defect has created a substantial risk of injury.[1] The Commission's Motion for Summary Decision should be denied.

III. Undisputed evidence shows virtually zero risk of injury

The Commission's motion should be denied not only because of its erroneous reading of § 2064(a)(2), but also because the Commission cannot prove that any defect created a substantial risk of injury. The Commission presents no evidence *at all* to quantify the injury rate or level of risk related to the Podster. Instead, it cites its own experts who make vague and indefinite statements that the Podster might create a risk of injury. Of course, *every* product on the market could—hypothetically—create a risk of injury at some point. But the Commission utterly fails to explain why or how the Podster contains a substantial risk of injury under § 2064(a)(2). Ultimately, the Commission can't make that showing because the undisputed facts prove that the risk of injury is infinitesimally small.

---

[1] The Commission's reliance on interpretive regulations (Br. 22–23) doesn't save the Commission's argument. 16 C.F.R. 1115.12(g)(1) is merely an interpretive regulation that cannot bind the public. Indeed, interpretive rules "do *not* have the force of law." *Kisor v. Wilke*, 139 S.Ct. 2400, 2420 (2019) (plurality op.) (citing *Perez v. Mortgage Bankers Ass'n*, 572 U.S. 92, 97 (2015) ("Interpretive rules do not have the force and effect of law and are not accorded that weight in the adjudicatory process.") (cleaned up)). Therefore, an "interpretive rule itself never forms the basis for an enforcement action—because such a rule does not impose any legally binding requirements on private parties." *Id*. (cleaned up). Additionally, section 1115.12(g)(1) (in fact, all subpart A of 16 C.F.R. Part 1115) by its express terms applies to a section of the CPSA—15 U.S.C. § 2064(b))—not at issue in this case. Section 1115.12(g)(1) relates to companies' *potential* reporting requirements under the CPSA. *See* 16 C.F.R. 1115.12(g) (stating information companies should report "does not automatically indicate the presence of a substantial product hazard"). Thus, section 1115.12(g) provides non-binding guidance about when "severity of the risk" *might* exist—not when (the distinct) "substantial risk of injury" does exist.

Leachco has sold over 180,000 Podsters, and tragically three babies died after being placed in unsafe-sleep environments (perhaps) in or near a Podster. *See* Leachco Br. 9–14. Assuming that each Podster was used only a single time—an unreasonably low estimate—the risk of injury is less than two-one-thousandth of a percent (3 / 180,000 = 0.000017 = 0.0017%). Under a more realistic assumption—that each Podster is used many dozens of times—the risk approaches zero. The Commission has no evidence that even suggests otherwise. Indeed, outside of three incidents—despite its "extensive fact discovery" (CPSC Br. 2)—the Commission has no evidence of any injuries even remotely associated with a Podster.

Instead, the Commission proffers expert speculation about what "could" or "may" happen if a Podster is used in unsafe-sleep environments.[2] *See* CPSC Br. 12–21. But expert speculation cannot support summary decision. As the Second Circuit held, courts must disregard "speculative or conjectural" statements by experts, and the "admission of expert testimony based on speculative assumptions is an abuse of discretion." *Major League Baseball Prop. Inc. v. Salvino Inc.*, 542 F.3d 290, 311 (2d Cir. 2008) (cleaned up). Thus, a party cannot use expert opinion to support summary decision when it is merely "conclusory assertion about ultimate legal issues." *Hayes v. Douglas Dynamics, Inc.*, 8 F.3d 88, 92 (1st Cir. 1993).[3] Therefore, the Commission's

[2] Leachco reserves the right to challenge the Commission's proffered expert testimony.

[3] *See also Bridgeway Corp. v. Citibank*, 201 F.3d 134, 142 (2d Cir. 2000) (holding expert's statement, that "'Liberia's judicial system was and is structured and administered to afford party-litigants therein impartial justice,'" was "purely conclusory"). *Auto. Ins. Co. of Hartford, Connecticut v. Abel*, No. CV 08-1004 AC, 2010 WL 11700301, at *4 (D. Or. May 24, 2010) ("Expert opinion that is conclusory is not admissible to support or defeat a summary judgment motion.") (citing *Luke v. Family Care and Urgent Medical Clinics,* 246 F. App'x 421, 424 (9th Cir. 2007) ("An expert opinion that is merely a conclusory statement without adequate supporting facts is insufficient . . . .")).

experts' speculation about what may happen in unsafe-sleep environments cannot support summary decision.[4]

Equally improper, the Commission attempts to use its proffered experts to introduce fact evidence. But "experts are not percipient witnesses to facts, and they cannot offer factual narratives in the form of expert testimony." *In re M/V MSC FLAMINIA*, No. 12-cv-8892 (KBF), 2017 WL 3208598, at *2 (S.D.N.Y July 28, 2017). Nonetheless, the Commission claims—based solely on the report of Umakanth Katwa—that "undisputed" evidence shows a likelihood of injury. CPSC Br. 23. According to the Commission, [redacted] *Id.* (emphasis added). But Dr. Katwa did not witness, and therefore could not have testified in, the Alabama incident. He merely reviewed CPSC investigation materials. He thus has no first-hand knowledge about any of the three incidents. The Commission's attempt to establish undisputed facts about the three incidents solely through Dr. Katwa is error. And courts routinely dismiss this non-evidence.[5]

[4] The Commission's rules do not allow the Commission to rely on expert testimony for purposes of summary decision motions. Under 16 C.F.R. 1025.25(c), summary decisions must be based on "the pleadings and any depositions, answers to interrogatories, admissions, or affidavits"—not on expert testimony. This makes sense because, according to the Commission's rules, expert reports are used as "direct testimony" for use during the hearing. *Id.* 1025.44(b). Nor has Leachco had the opportunity to cross-examine the Commission's proffered experts, something that, too, must wait for the hearing. *Id.* 1025.31(c)(4)(i)−(ii). In any event, as discussed below, the "expert" testimony cited by the Commission in its Motion for Partial Summary Decision is pure speculation, which is an improper basis on which to rule.

[5] *See United States v. Rankin*, No. 3:18-cr-272 (JAM), 2021 WL 5563996, at *2 (D. Conn. Nov. 27, 2021) ("[E]xpert testimony is not a substitute for proper fact testimony," so "a court should guard against the misuse of expert testimony to establish that certain facts occurred" such as when the expert "has no personal knowledge of the facts addressed."); *Johnson v. Holms*, No. 2:18-cv-00647-GMN-EJY, 2020 WL 4004208, at *2 (D. Nev. July 15, 2020) ("[E]xperts are not percipient witnesses who testify to facts."); *Highland Cap. Mgmt. L.P. v. Schneider*, 551 F. Supp. 2d 173, 187 (S.D.N.Y. 2008) (excluding

Further, the Commission's own documents show that facts about the incidents are far from undisputed. For example, [redacted]. CPSC Br. 23. But according to the Commission's own investigation, [redacted] [6] Dr. Katwa himself noted [redacted] [7]

* * *

Even if the Court were to consider Dr. Katwa's non-percipient testimony, the result would be the same: the Commission has presented no evidence that shows a likelihood of injury or even attempts to quantify the risk level. *See* Leachco Br. 38–45. To show a "substantial risk of injury" under § 2064(a)(2), the Commission must prove a significant likelihood of injury. The undisputed evidence here shows three incidents (somewhat) associated with more than 180,000 Podsters. That means—*at most*—the Podster presents a 0.00166% risk of injury. And because Podsters are used much more than once, the risk is virtually non-existent. Therefore, according to the undisputed evidence, no defect of the Podster (assuming one exists) has created a substan-

expert from offering factual narrative as inappropriate where expert "ha[d] no personal knowledge of the underlying facts"); *M/V MSC FLAMINIA*, 2017 WL 3208598, at *3 n.2 ("Acting simply as a narrator of facts does not convey opinions based on an expert's knowledge and expertise, nor is such a narrative traceable to a reliable methodology.").

[6] Ex. I, Alabama Daycare IDI, CPSC0000041, 49, 57, 58, 63, 74 [Dep. Ex. 10].

[7] Ex. V, Katwa Report, at 26.

tial risk of injury. The Commission's motion should be denied, and Leachco's motion should be granted.

IV. The Commission is not entitled to a summary decision on foreseeable misuse

The Commission's legal errors and factual deficiencies continue when it asks the Court to summarily rule on foreseeable misuse. As before, the Commission asks the Court to reach a conclusion based on assumptions. Most importantly here, the Commission seeks a summary decision based on facts that are immaterial to the Commission's claims. And it is "axiomatic that a party may not be awarded summary judgment on the basis of undisputed *immaterial* facts. As a result, a party opposing a motion for summary judgment may certainly object that particular facts (disputed or undisputed) are immaterial to the motion." *Zhao-Royo v. NY State Educ. Dep't*, No. 1:14-CV-0935(GTS/CFH), 2017 WL 149981 at *2 n.2 (N.D.N.Y. Jan. 13, 2017). Therefore, courts "cannot grant summary judgment on immaterial facts." *Tattersalls Ltd. v. Wiener*, No.: 3:17-cv-1125-BTM-KSC, 2020 WL 1062951, *1 (S.D. Cal. 2020); *see also id*. (The "Court is unable to find any indication that the purported breach is material to this case."); *cf. Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) ("[A] complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial.").

Because foreseeable misuse of the Podster is immaterial to the Commission's allegations, the Commission's motion should be denied.

A. The Commission is foreclosed from relying on foreseeable misuse as a factor to establish a defect

The Commission's complaint alleged that the Podster is defective because of foreseeable misuse.[8] But the Commission now offers a new theory. It says that reasonably foreseeable misuse is "relevant" to the question whether a product has a defect that can lead to a substantial product hazard. CSPC Br. 12. But the Commission never explains how foreseeable misuse is relevant. Its omission is telling.

As Leachco explained in its Motion (Br. 31–32), foreseeable misuse is a factor to determine whether a product has defective warnings or design. *See Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 84 (S.D.N.Y. 2001) ("A failure to warn claimant must show (1) that a manufacturer has a duty to warn; (2) against dangers resulting from foreseeable uses about which it knew or should have known; and (3) that failure to do so was the proximate cause of harm."); Restatement (Third) of Torts § 2 (Am. L. Inst. 1998) (Third Restatement), comment *p* ("Foreseeable product misuse, alteration, and modification must also be considered in deciding whether an alternative design should have been adopted.").

But the Commission does not allege that the Podster has defective warnings, and it does not allege or offer evidence concerning a reasonable alternative design. Therefore, foreseeable misuse is immaterial to the Court's analysis. It should deny the Commission's motion.

[8] *See* Ex. A, Compl., ¶¶20(a), (b), (d), 21, 38–41; *see id*. ¶50 (alleging that Podsters "contain defects because it is foreseeable that caregivers will use the product for infant sleep[,] and it is foreseeable that caregivers will leave infants unattended in the product").

1. This is not a defective-warning case

The Commission does not allege that the Podster's warnings or instructions were defective. And the Commission [redacted]. *See* Leachco Br. 26–29. Therefore, foreseeable misuse is immaterial to the Commission's allegations. And, as a result, even if the Court agrees that the uses identified by the Commission are foreseeable misuses, the Court must still deny the Commission's motion.

The Commission's reliance (Br. 13) on an unpublished district court opinion is misplaced. In *Zen Magnets v. CPSC*, the court determined (consistent with Leachco's arguments) that "foreseeable misuse" could be a factor to determine whether a product contains a defect. No. 17-cv-02645, 2018 WL 2938326, at *6–7 (D. Colo. June 12, 2018). But—unlike here—the Commission in *Zen Magnets* alleged a defect based on defective warnings.[9] Therefore—unlike here—foreseeable misuse was relevant only because the Commission alleged that the warnings were defective.[10]

The Commission's post-discovery attempt to change its theory and offer evidence of the Podster's allegedly insufficient warnings is improper.[11]

2. The Commission cannot establish a design defect

A product is defectively designed only when, "at the time it leaves the seller's hands, [it] is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous *for its intended use*; that is one whose utility does not

[9] *See* Second Am. Compl. ¶¶ 31–90, *In the Matter of Zen Magnets*, CPSC Dkt. No. 12-2, available at, https://www.cpsc.gov/s3fs-public/pdfs/lawsuit_maxzen14d.pdf, last visited June 23, 2023.

[10] *Id*. at ¶ 90.

[11] As Leachco advised the Court, the Commission's post-discovery attempt to change its theory must be rejected. *See* Leachco Br. 26–29.

outweigh the danger inherent in its introduction into the stream of commerce." *Hunter v. Shanghai Huangzhou Elec. Appliance Mfg. Co.*, 505 F. Supp. 3d 137, 152–53 (N.D.N.Y. 2020) (cleaned up) (emphasis added). *See* Leachco Br. 29–31 (discussing requirements to prove a design defect). Here, the Commission has not alleged and does not argue that the Podster, when it left Leachco's hands, was unreasonably dangerous for its *intended* use. To the contrary, the whole premise of the Commission's action is that Podster is too dangerous for its *unintended misuse*.

And the Commission has no basis to otherwise establish a design defect here. A product may have a design defect "when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design . . ., and the omission of the alternative design renders the product not reasonably safe." Third Restatement § 2(b). Here, the Commission repeatedly denied that a reasonable alternative design for the Podster had any relevance to this case.[12] *See* Leachco Br. 30.[13]

[12] Ex. H, CPSC Supp. Resp. to Leachco RFA Nos. 130–135; Ex. T, CPSC Resp. Leachco ROG, Nos. 4, 35.

[13] As Leachco showed in its Motion, the Commission cannot prove a design defect because it does not allege, and offers no proof to show, that the risk of a defect outweighs its utility. *See* Leachco Br. 29–31. Cases cited by the Commission (Br. 13) support Leachco. In *Southland Mower Co. v. CPSC*, the court—consistent with Leachco's arguments—referred to "foreseeable misuse" while assessing the risk and the utility of a product. 619 F.2d 499 (5th Cir. 1980); *see id.* at 514 ("In promulgating a safety standard, the Commission must consider the probable effect of such rule upon the utility of such products.") (cleaned up). *See also Aqua Slide 'N' Dive Corp. v. CPSC*, 569 F.2d 831, 839 (5th Cir. 1978) (noting that the Commission is required to engage in a "balancing test like that familiar in tort law: The regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation itself imposes upon manufacturers and consumers") (quoting *Forester v. CPSC*, 559 F.2d 774, 789 (D.C. Cir. 1977); *id.* at 844 ("[T]he Commission has a duty to take a hard look, not only at the nature and severity of the risk, but also at the potential the standard has for reducing the severity or frequency of the injury, and the effect the standard would have on the utility, cost or availability of the product.").

Finally, for the reasons set forth above (*see* fn. 1), the Commission's reliance on non-binding interpretive regulations that apply to an irrelevant section of the CPSA is misplaced. *See* CPSC Br. 12–13 (discussing 16 C.F.R. 1115.4 and 1115.12). These interpretive guidance documents cannot trump the text of § 2064(a)(2), which requires the Commission to prove that the Podster contains a product defect that creates a substantial risk of injury. The Commission cannot meet the elements of § 2064(a)(2); its extra-textual arguments should be ignored.

* * *

Foreseeable misuse is relevant—if at all—to determine whether (adequate) warnings are required or to show that foreseeable risks of harm could have been reduced or avoided by through a reasonable alternative design. Here, the Commission does not allege a warning defect, and it does not make any contention about reasonable alternative designs. Accordingly, foreseeable misuse is immaterial to this case, and the Commission's request for partial summary decision on "foreseeable misuse" should fail as a matter of law.

B. Alternatively, the Commission's speculative assertions do not establish undisputed material facts to support a summary decision on foreseeable misuse

In the alternative, the Commission's Motion for Partial Summary Decision should be denied because the Commission's evidence of "foreseeable misuse" is based almost entirely on "expert" speculation—here, the conjecture of its long-time

employee Celestine Kish.[14] *See* CPSC Br. at 14–18. But as noted, expert speculations cannot form the basis for a ruling on summary decision. *See* above, pp. 9–10

Ms. Kish [redacted]. *See* CPSC Br. 17. And she speculates [redacted] *Id*. (emphasis added). Ms. Kish, thus, offers speculation-upon-conjecture about [redacted]. Her speculation and conjecture abound,[15] and she nowhere identifies a scientific standard to justify her opinions.

Further, Ms. Kish—without any support—creates an unknown standard for infant products: [redacted]. *See* CPSC Br. 16–18 (discussing Ms. Kish's speculations). Ms. Kish thus asserts: [redacted] *Id*. (emphasis removed). The Commission also claims, based on Ms. Kish's report, [redacted]

[14] The Commission itself, without citation, speculates that the Podster's "deep, padded sides *may* lead caregivers to falsely believe that an infant can be left alone in the product, making it foreseeable that the caregivers *may* leave an infant unattended in a Podster." CPSC Br. 17.

[15] [redacted]

[redacted] (CPSC Br. 7)—but this non-sequitur is not based on a standard found in the CPSA.

Because they are pure speculation, the Commission's "expert" opinions cannot be used to establish, as a matter of material fact, that it is reasonably foreseeable that a reasonable caregivers would misuse the Podster.

Other than its experts' speculation, the Commission is left with [redacted]. CPSC Br. 15–16. This limited evidence cannot establish, as a matter of undisputed material fact, that it is "reasonably foreseeable" that reasonable caregivers will misuse the Podster.[16]

At bottom, neither conjectural and conclusory statements made by the Commission's experts nor isolated incidents of Podster misuse (and an isolated opinion of an insurance broker) can serve to establish that there is no dispute as to the material facts over "foreseeable misuse" and thus the Commission's Motion should be denied.

CONCLUSION

The Commission's Motion for Partial Summary Decision should be denied. The Commission cannot show liability under 15 U.S.C. § 2064(a)(2) without proving that the Podster has a defect. In its Motion, however, the Commission asks the Court not to reach that issue. Accordingly, the Commission has no basis at all to seek a summary decision.

[16] [redacted]

But the Commission's requests for summary decision on foreseeable misuse and the substantial risk of injury should be denied regardless. The foreseeable-misuse issue relates only to alleged warnings or design defects. The Commission has not alleged a warnings defect. The foreseeable misuse is immaterial to the Commission's design-defect claim because the Commission does not propose a reasonable alternative design.

Finally, the Commission presents no evidence—there is no evidence—that any defect creates a substantial risk of injury. Even if the Commission had not waived (for purposes of its Motion) the defect issue, it still cannot prove that a substantial likelihood of injury exists. The undisputed facts show that the risk is virtually zero. The Commission does not and cannot claim otherwise.

Therefore, the Court should deny the Commission's Motion for Partial Summary Decision and grant Leachco's Motion for Summary Decision.

* * *

DATED: June 23, 2023.

Respectfully submitted,

JOHN F. KERKHOFF
Ohio Bar No. 0097134
FRANK D. GARRISON
Indiana Bar No. 34024-49
JESSICA THOMPSON
North Carolina Bar No. 48112
Pacific Legal Foundation
3100 Clarendon Boulevard, Suite 1000
Arlington, VA 22201
Telephone: 202.888.6881
Fax: 916.419.7747
JKerkhoff@pacificlegal.org
FGarrison@pacificlegal.org
JLThompson@pacificlegal.org

s/ *Oliver J. Dunford*
OLIVER J. DUNFORD
Florida Bar No. 1017791
Pacific Legal Foundation
4440 PGA Blvd., Suite 307
Palm Beach Gardens, FL 33410
Telephone: 916.503.9060
Fax: 916.419.7747
ODunford@pacificlegal.org

Counsel for Respondent Leachco, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on June 23, 2023, the foregoing was served upon all parties and participants of record as follows:

Honorable Michael G. Young
Federal Mine Safety and Health Review Commission
Office of the Chief Administrative Law Judge
1331 Pennsylvania Ave., N.W., Suite 520N
Washington, D.C. 20004-1710
myoung@fmshrc.gov
cjannace@fmshrc.gov
whodnett@fmshrc.gov

Alberta Mills
Secretary of the U.S. Consumer Product Safety Commission
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814
amills@cpsc.gov

Mary B. Murphy
Director, Div. of Enforcement & Litigation
U.S. Consumer Product Safety Comm'n
4330 East West Highway
Bethesda, MD 20814
mmurphy@cpsc.gov

Robert Kaye
Assistant Executive Director
Office of Compliance and Field Operations
U.S. Consumer Product Safety Comm'n
4330 East West Highway
Bethesda, MD 20814
rkaye@cpsc.gov

Leah Ippolito, Supervisory Attorney
Brett Ruff, Trial Attorney
Rosalee Thomas, Trial Attorney
Caitlin O'Donnell, Trial Attorney
Michael Rogal, Trial Attorney
Frederick C. Millett, Trial Attorney
Gregory M. Reyes, Supervisory Attorney
Complaint Counsel
Office of Compliance and Field Operations
U.S. Consumer Product Safety Comm'n
Bethesda, MD 20814
lippolito@cpsc.gov
bruff@cpsc.gov
rbthomas@cpsc.gov
codonnell@cpsc.gov
mrogal@cpsc.gov
fmillett@cpsc.gov
greyes@cpsc.gov

s/ *Oliver J. Dunford*
Oliver J. Dunford
Counsel for Respondent Leachco, Inc.