UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

IN THE MATTER OF	CPSC Docket No. 22-1
LEACHCO, INC.	HON. MICHAEL G. YOUNG PRESIDING OFFICER

LEACHCO, INC.'S PREHEARING BRIEF

Leachco, Inc. submits this Prehearing Brief under 16 C.F.R. 1025.22. The briefs filed by Leachco in its Summary Decision, *Daubert*, and *in limine* motions provide a detailed view of the relevant facts and the relevant law this Court must consider in this proceeding. Here, Leachco provides an issue statement, a summary of the facts, a statement of the burden of proof, and an overview of the legal arguments supporting Leachco.

INTRODUCTION

Leachco is a small, family-owned business that designs and manufactures safe and helpful products for families. One product is an infant lounger called the "Podster." Since 2009, Leachco has sold over 180,000 Podsters, providing thousands of parents and other caregivers with a safe and useful place to lay infants while doing everyday activities. Now, after the Podster has been on the market for over 15 years, the Consumer Product Safety Commission claims the lounger presents "a substantial product hazard" under the Consumer Product Safety Act and asks the Court to order Leachco to recall the product, refund consumers, and pay damages to third parties who incur recall-associated costs.

Before this Court may find the Podster presents a substantial product hazard, however, the Commission must prove by a preponderance of the evidence that the Podster (1) has "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 (3) "substantial risk of injury to the public." 15 U.S.C. § 2064(a)(2).

The Commission cannot meet its burden. *First*, the Podster is not a defective product. The Commission alleges that the product's design becomes dangerous and therefore defective because some consumers will foreseeably misuse the Podster—despite the specific warnings and instructions against that misuse. But the Commission [redacted]

Second, the Commission has put forth no credible evidence to date and cannot produce any credible evidence at trial that the Podster's design "creates" a substantial risk of injury to the public. Rather, any risk of injury arguably associated with the Podster results from unsafe sleep environments—not the Podster's design. Tragically, while three infants allegedly died in the same location as a Podster, the evidence won't support a conclusion that the Podster's design caused any deaths. Evidence will show that unsafe-sleep environments—multiple soft items in cribs and co-sleeping circumstances—unfortunately arise with all manner of nursery-related

products. But the Commission does not seek a ban of infant products, nor has it sought to recall cribs, highchairs, playpens, or other products associated with many more infant deaths than is (allegedly) the Podster. And the Commission [redacted]

Finally, even if the Podster has a defect that creates a risk of injury to the public, that risk is far from "substantial." The Commission alleges only three injuries associated with the Podster out of over 180,000 Podsters sold. Even assuming those alleged injuries resulted from the Commission's hybrid misuse/defective-design allegation, each of the other thousands of Podsters have been used by consumers thousands upon thousands of times with no resulting injuries. Thus, the likelihood of injury from the Podster's design is infinitesimally tiny and far from "substantial."

* * *

The Commission cannot prove by a preponderance of the evidence that the Podster is defectively designed or that the Podster creates a substantial risk of injury to the public. Its claim that the Podster presents a "substantial product hazard" fails as a matter of law and fact.

ISSUE STATEMENT

Under the CPSA, the Commission may order a manufacturer to take remedial action only if it proves by a preponderance of the evidence that a consumer product "presents a substantial product hazard." 15 U.S.C. § 2064(c)–(d). The Act 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." *Id.* § 2064(a)(2).

Thus, the issues the Court must address are:

1. Can the Commission prove by a preponderance of the evidence that the Podster has a "product defect"?

2. If the Commission can prove that the Podster has a "product defect," can the Commission prove by a preponderance of the evidence that the alleged defect creates a risk of injury to the public?

3. If the Commission can prove that the Podster has a product defect and that the defect creates a risk of injury to the public, can the Commission prove by a preponderance of the evidence that the risk is "substantial"?

SUMMARY OF FACTS

LEACHCO

Thirty-five years ago, Jamie Leach and her husband Clyde started Leachco Inc. out of their home in Ada, Oklahoma. Leachco designs and manufactures products to help families care for their children, including products designed to help with infant care. Through the years, Leachco has grown but is still a small family-owned and family-run business.

Jamie Leach—a registered nurse, mother, and grandmother—designs Leachco's products and has secured over 40 patents and dozens of trademarks. Jamie and Clyde's children Alex, Andrew, and Mabry have worked at the company in just about every capacity—from sweeping floors to removing trash to packaging products to running the company. Alex has worked in all of Leachco's nine buildings and serves as Leachco's COO. Andrew, too, worked in different jobs over the years and is now Leachco's Controller. Mabry started working on the production floor and has worked

as a full-time as a receptionist. She currently heads up Leachco's customer service department, and her husband Steve serves as Leachco's CFO. Now, the third generation is getting its start, as Jamie and Clyde's granddaughter has worked in the office and modeled for Leachco's marketing department.

Jamie and Clyde see Leachco as their American Dream: through hard work, innovation, sacrifice, and perseverance, they built a successful small business in their hometown. They've always modeled these virtues for their children and hope to pass on a thriving business. They also feel obligated to sustain the company and find enough work for Leachco's approximately 30 full-time employees.

THE PODSTER

The Podster—developed and patented over 15 years ago in 2008—is just one of the many products that Leachco has designed and manufactured for families and caregivers. The Podster is a lounger that lets a caregiver place an infant in a reclined position during supervised, awake time. The patented design features a sling seat with adjustment tabs that allow for a custom fit. Jamie designed the Podster to help with daytime care of awake infants for the countless times each day when parents and caregivers need to free up their hands for daily life activities. Since 2009, Leachco has sold over 180,000 Podsters.

The Podster. *See* https://leachco.com/products/podster (last visited May 31, 2023).

THE COMMISSION'S ALLEGATIONS

The Commission asserts one count in its Complaint—that the Podster is a "substantial product hazard" under the CPSA. The Commission acknowledged in its Complaint, however, that the Podster is not and has never been advertised as a sleep product; that the Podster contains warnings that the product should not be used for sleep and that adult supervision is always required; that the Podster contains warnings that the product should only be used on the floor, and not in another product, such as a crib, on a bed, table, playpen, counter, or any elevated surface; that the Podster contains warnings that infants should not be placed prone or on their side in the product; that the Podster contains instructions that it should be used for infants not to exceed 16 pounds, and should not be used if an infant can roll over; and that the Podster contains warnings and instructions that use of the product in contravention to these warnings could result in serious injury or death.

Now, after the Podster has been on the market for well over a decade, the Commission alleges that the Podster is defectively designed because it is foreseeable—despite the warnings and instructions—that consumers will misuse the Podster by allowing infants to sleep in the Podster, will not supervise infants while they are in

the Podster, and will use the Podster for bedsharing. The Commission then alleges that—because this misuse is foreseeable—the Podster's design creates a "substantial risk of injury." As a remedy, the Commission asks this Court to order Leachco to issue a notice to the public that the Podster creates a substantial product hazard, order Leachco to conduct a recall, refund purchasers, and pay damages to third parties who incur recall-related costs.

THE COMMISSION'S BURDEN OF PROOF

The Court's "initial decision shall be based upon a consideration of the entire record and shall be supported by reliable, probative, and substantial evidence." 16 C.F.R. 1025.51(b). The CPSA adopts the Administrative Procedure Act's hearing standards, which apply to adjudicatory proceedings. 5 U.S.C. §§ 554, 556. And when a statute requires an agency to prove "substantial evidence," "adjudicatory proceedings subject to the APA" require an agency to prove each element of its case by a "preponderance of the evidence." *Steadman v. SEC*, 450 U.S. 91, 101–02, 104 (1981); *see also Zen Magnets*, CPSC Dkt. 12-2, No. 163, 2017 WL 11672449, *7–8 (CPSC Oct. 26, 2017); *In the Matter of Dye and Dye*, CPSC Dkt. 88-1, 1989 WL 435534, *4 (CPSC July 17, 1991) (The preponderance of the evidence "means that each requisite contested fact must be established by relevant evidence that a reasonable person, considering the record as a whole, would accept as sufficient to find that the fact is more likely to be true than untrue.") (cleaned up).

The preponderance of the evidence standard "is not a mere weighing of the amount of testimony, number of witnesses, and the like" but requires "the consideration of the credibility and qualifications of witnesses and the significance of particular

testimony in making the overall determination of whether the total evidence for a fact being true is more convincing than the evidence for the fact being not true." *In the Matter of Dye and Dye,* 1989 WL 435534, at *4 (citation omitted).

Thus, to establish the Podster presents a "substantial product hazard," the Commission bears the burden to prove each element of its claim by a preponderance of the evidence.

ARGUMENT

Before this Court may find that the Podster creates a substantial product hazard, the Commission must prove by a preponderance of the evidence that it has met each statutory element. *See Zen Magnets*, CPSC Dkt. 12-2, No. 163, 2017 WL 11672449, at *8 (CPSC Oct. 26, 2017) ("To find a substantial product hazard under Section 15(a)(2) of the CPSA, the Commission must conclude that: the Subject Products contain a defect; and such defect, 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."). The Commission cannot meet this burden, and this Court should thus rule for Leachco.

I. THE COMMISSION CANNOT ESTABLISH BY A PREPONDERANCE OF THE EVIDENCE THAT THE PODSTER IS DEFECTIVELY DESIGNED.

As Leachco argued in its Motion for Summary Decision, the term "product defect" is undefined in the CPSA. It must thus take on its traditional ordinary or common law meaning—a manufacturing, design, or warning/marketing defect. Foreseeable misuse is merely a factor used to determine whether a design-defect exists. Specifically, foreseeable misuse may be used as part of a risk-utility analysis when there

is an allegation that no alternative design that could render a product safe.[1] And because the Commission has not alleged that the Podster is defective under this traditional understanding, its claim should fail as a matter of law.

But this Court ruled in its Summary Decision Order that foreseeable misuse is a factor in determining whether the Podster is defective under 16 C.F.R. 1115.4 and that regulation controls here.[2] Yet, even under the regulation, the Commission has not produced, and cannot produce at trial, evidence that a reasonable consumer would foreseeably misuse the Podster.

As Leachco explains in its Motion *in limine*, because the Commission is not bringing a defective-warning claim, the Commission cannot attempt to establish the inadequacy of Leachco's warnings and instructions. And even if the Court considers expert testimony on warnings, it does not establish, as Leachco argued in its Motion for Summary Decision, that it is reasonably foreseeable that an objective consumer would disregard the Podster's warnings and instructions and misuse the Podster.

The Commission's only evidence, then, will be [redacted]

[1] Foreseeable misuse may also a relevant factor in a defective-warning case. But the Commission does not allege a defective-warning case.

[2] Indeed, as this Court acknowledged in its order denying both parties' motions for summary disposition, foreseeable misuse alone cannot establish a defect. *See* Order (Dkt. No. 99) at 4. It can be considered only as a factor to determine whether a product has a design flaw. Moreover, the regulations simply do not contemplate a finding of a defect based entirely on the misuse of a consumer product, *i.e.*, a defect existing solely because of misuse or the unreasonable misuse of a product.

[redacted]

The Commission's allegation that the Podster itself—its design—is defective also lacks merit on its own terms. The Podster operates as an infant lounger, providing infants with a safe and comfortable place to lay while parents are awake and supervising the infant. The Commission puts forth no evidence and cannot produce evidence that any infant has been injured by the Podster when consumers use the product for its intended purpose and when its warnings and instructions are heeded. Nor will the evidence show, as explained below, that any injury has resulted from the Podster's design, even when misused.[3]

Leachco will offer the expert testimony of Peggy Shibata, P.E., to support its defense.

II. THE COMMISSION CANNOT PROVE BY A PREPONDERANCE OF THE EVIDENCE THAT THE PODSTER'S ALLEGED DEFECT "CREATES" A SUBSTANTIAL RISK OF INJURY.

The Commission must prove that "*because of*" the "pattern of defect, the number of defective products distributed in commerce, the severity of risk, or otherwise," the Podster "*creates* a substantial risk of injury to the public." 15 U.S.C. § 2064(a)(2) (emphasis added). As explained in Leachco's Motion for Summary Decision, the terms "because of" and "creates" require the Commission to prove a connection between the

[3] The Commission [redacted]

Podster's alleged defect and the factors that "create" a substantial risk of injury. When statutory terms are undefined, courts apply their ordinary meanings. Here, "the ordinary meaning of 'because of'" incorporates the standard of but-for causation, *Bostock v. Clayton County*, 140 S.Ct. 1731, 1739 (2020), and the ordinary meaning of "create" is "to bring into existence" or "to cause to be or to produce by fiat or by mental, moral, or legal action" or "to bring about by a course of action or behavior," WEBSTER'S THIRD NEW INT'L DICTIONARY 532 (1993).

But the Commission cannot establish this connection by a preponderance of the evidence. [redacted]. The Commission's evidence does not and cannot show that a Podster was the cause of any infant injury. As explained in Leachco's Motion for Summary Disposition, the Commission cannot prove at all, much less by a preponderance of the evidence, that the Podster's design was the but-for or proximate cause of the alleged deaths. At best, [redacted] Thus, the Commission cannot establish that because of a pattern of defect, number of products in commerce, severity of the risk, or otherwise create a substantial product hazard.

[redacted]

The expert reports [redacted]

[redacted]

In sum, aside from allegations of tragic deaths of three infants who happened to be near Podsters—in unsafe-sleeping environments—the Commission has no evidence of any injuries even remotely associated with a Podster. The most that the Commission might be able to show is that some injuries "could" occur—which does not establish by a preponderance of the evidence that the Podster's alleged defect does in fact create a substantial risk of injury to the public. Even if the Podster has a "product defect"—which Leachco contests—the Commission's claim under § 2064(a)(2) still fails because the Commission cannot show that any defect *caused* a substantial risk of injury to the public.

III. THE COMMISSION CANNOT PROVE BY A PREPONDERANCE OF THE EVIDENCE THAT THE PODSTER PRESENTS A "SUBSTANTIAL RISK OF INJURY TO THE PUBLIC"

Even if the Commission could show that the Podster's design has a "defect" that "creates" a risk of injury—which Leachco contests—the Commission's claim again fails because the "defect" does not create a "*substantial* risk of injury to the public." 15 U.S.C. § 2064(a)(2) (emphasis added). As Leachco explained in its Motion for Summary Decision, "*substantial* risk of injury" means a significant likelihood that a product defect will cause an injury.

The Podster—assuming it has a defect that causes any risk—presents an infinitesimally small risk of injury. The Commission thus cannot prove by a preponderance of the evidence—it indeed has no proof—that there is a substantial likelihood that Podster will cause injuries to the public. The Commission has not even tried to

measure the injury rate, nor do any of its proffered experts opine on that metric. And all data point in the same direction: the probability approaches zero. Leachco has sold over 180,000 Podsters—which are used many dozens of times—and only three injuries have occurred (because of unsafe-sleep environments).

The Commission also admits [redacted]

And the Commission concedes [redacted]

Even if the Podster is a defective product that causes a risk of injury, the undisputed evidence shows unmistakably that the likelihood of harm is infinitesimally small. The Commission's own allegations show that the Podster's injury rate is *at most* 0.0017%. Consider: If each consumer used each of the 180,000 Podsters only a single time (an unreasonably low estimate), the injury rate that the Commission links to the Podster is 0.0017 percent (3 / 180,000). In other words, for every 100,000 Podsters sold, the Commission can point to 1.7 injuries. If each Podster was used only ten times—still a vast underestimate—the injury rate (3 / 1,800,000) would be 0.0000017, or 0.00017 percent. A realistic estimate of hundreds of uses per Podster would make the injury rate virtually zero. If that vanishingly small injury rate amounts to a "*substantial* risk of injury," then § 2064(a)'s language has no teeth—*any* product can meet that meager standard.

The Commission's expert testimony [redacted]

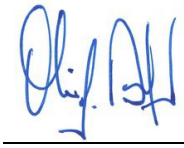
The plain statutory language of § 2064(a)(2) requires more. It calls for a "substantial" possibility. Because the evidence cannot possibly establish, by a preponderance of the evidence, that the Podster creates a *substantial* risk of injury, the Commission cannot carry its burden under § 2064(a)(2).

CONCLUSION

The Commission is alleging that (unproven) isolated incidents of consumer misuse can somehow transform a product's safe design for its intended use into a mechanical design defect. This despite specific and adequate warnings and instructions not to misuse the product in a way that is allegedly causing the defect. If that claim is sustained, then there is no product on the market that is not susceptible to being recalled by the Commission. But even on its own terms, the Commission has not proven what it is alleging. The Commission thus cannot establish that the Podster presents a "substantial product hazard" and the Court should find for Leachco.

DATED: July 14, 2023.

Respectfully submitted,



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CERTIFICATE OF SERVICE

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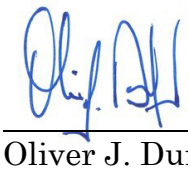

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TABLE OF AUTHORITIES

Cases

Commission Decisions

Statutes

Regulations

Other Authorities