UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

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

**COMPLAINT COUNSEL'S REPLY BRIEF**

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Pursuant to 16 C.F.R. § 1025.53(f) and the Commission's July 26, 2024 Order Granting Joint Motion to Set Briefing Schedule, Dkt. 152, Complaint Counsel hereby submits its Reply Brief in support of its appeal of 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"), on July 3, 2024, as well as its response to Leachco's Answering Brief ("Answering Brief") and Opening Brief in Support of Cross-Appeal ("Cross-Appeal") (collectively, "Brief"), Dkt. 159. 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

Leachco's voluminous "kitchen-sink" Brief fails to rebut the ample evidence establishing that the Podsters present a substantial product hazard under Section 15(a)(2) of the Consumer Product Safety Act ("CPSA") and the urgent need for Leachco to conduct a mandatory recall to protect infants. Specifically, Leachco's Brief contains numerous inaccuracies and incorrect statements, including: mischaracterizing the *de novo* standard applicable in this proceeding, misconstruing the statutory requirements for Section 15 adjudications, erroneously interpreting the standards for admissibility of expert testimony and hearsay evidence, and asserting constitutional arguments which are wrong or have already been addressed and rejected in federal court.

## II. LEACHCO MISCHARACTERIZES THE STANDARD OF REVIEW ON APPEAL

Leachco's Answering Brief wrongly suggests a standard of review that would give heightened deference to the Initial Decision. Leachco advances that position by omitting key portions of the cases it cited.

The Commission has previously explained that the Rules of Practice for Adjudicative Proceedings ("Rules of Practice") provide for *de novo* review of the record. *See In re Amazon.com, Inc.*, CPSC Dkt. No. 21-2, Dkt. 142, at 24 (July 29, 2024) (Decision and Order); *see also Landry v. FDIC*, 204 F.3d 1125, 1132 (D.C. Cir. 2000), *cert. denied*, 531 U.S. 924 (2000). Further, as required by 16 C.F.R. § 1025.55, and as explained in Complaint Counsel's Appeal Brief, Dkt. 153 at 5 ("Complaint Counsel's Appeal Brief"), when analyzing the Initial Decision and accompanying record, the Commission evaluates 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. Complaint Counsel's Appeal Brief at 5 (citing 16 C.F.R. § 1025.55).

Leachco relies on *La. Pub. Serv. Comm'n v. FERC*, 522 F.3d 378 (D.C. Cir. 2008), to incorrectly suggest a heightened burden when departing from a Presiding Officer's findings. Although Leachco correctly states that the Commission must provide "attentive consideration" to the Presiding Officer's findings if departing from them, Answering Brief at 17 (quoting *La. Pub. Serv. Comm'n*, 522 F.3d at 395), it omits the rest of the quote, which explains that the Presiding Officer's findings "are not entitled to any special deference," and instead must simply be treated as "part of the record." *La. Pub. Serv. Comm'n*, 522 F.3d at 395. The court in *Louisiana Public Service Commission* explained that a Commission decision departing from a Presiding Officer's findings only need be supported by the evidence in the record; conversely, a Commission decision cannot differ from a Presiding Officer's findings if that difference is unsupported by the record. *Id.* However, the court explained that if both the Commission and a Presiding Officer's findings are supported by the record, a reviewing court will uphold the Commission decision if it is supported by substantial evidence, as it is the "agency's choice" that governs. *Id. See also*

*Simon v. Simmons Foods, Inc*., 49 F.3d 386, 391 (8th Cir. 1995) (finding that "the record substantially supports the findings of the Secretary and the ALJ" and affirming, even though the administrative law judge and Secretary of Labor made differing findings regarding employee's discharge). Leachco also fails to note that the Commission itself has previously held that in Section 15 adjudications "[d]e novo review means 'an independent determination of the issues,' and deference to the Initial Decision is not required." *In re Zen Magnets, LLC* (Zen Magnets), CPSC Dkt. No. 12-2, 2017 WL 11672449, at *6 (CPSC Oct. 26, 2017) (citation omitted) (quoting *United States v. First City Nat'l Bank of Houston*, 386 U.S. 361, 368 (1967)) (citing *La. Pub. Serv. Comm'n v. FERC*, 522 F.3d 378, 395 (D.C. Cir. 2008)).

In sum, in rendering its decision, the Commission must include a statement of the reasons for its action as required by the Rules of Practice, 16 C.F.R. § 1025.55(b), must demonstrate that it is aware of the Initial Decision, and must consider the Initial Decision as part of the entire record in this case. But the Commission need not, as suggested by Leachco, afford *any* deference to the Presiding Officer's findings from the Initial Decision or meet any other heightened burden in order to set aside the Initial Decision.

## III. LEACHCO'S ANSWERING BRIEF CONTINUES TO ERRONEOUSLY INTERPRET THE CPSA

The core arguments in Leachco's Answering Brief depend heavily on misunderstandings of the applicable law and mischaracterizations of the Initial Decision. First, Leachco's attempts to excuse and defend the faulty legal analysis in the Initial Decision are unavailing. Second, Leachco's proposed defect analysis disregards the CPSA and the Defect Regulation and instead relies on inapplicable standards borrowed from products liability law. Finally, Leachco's argument that the Podster does not pose a serious risk of injury incorrectly suggests that the CPSA contains a "but-for" or "proximate" causation element. Because these arguments are

inconsistent with the CPSA, its regulations, and all applicable case law, they should be rejected.

A. Leachco's Arguments in Support of the Erroneous Substantial Product Hazard Analysis in the Initial Decision Are Meritless

Leachco offers a perfunctory defense of the Presiding Officer's faulty substantial product hazard analysis that fails to address the numerous legal errors highlighted in Complaint Counsel's Appeal Brief. As a result, Leachco's attempt to prop up the Initial Decision's erroneous Section 15 analysis fails.

First, Leachco attempts to excuse the Presiding Officer's improper reliance on the rulemaking standard of "unreasonable risk" in this Section 15 adjudication by contending that it was harmless error. Answering Brief at 49. However, Leachco cites no case law regarding harmless error and how it would apply in this proceeding. And, to the contrary, as detailed in Complaint Counsel's Appeal Brief, the rulemaking standard contains more burdensome requirements than the substantial risk of injury standard articulated in Section 15, and for good reason; a Section 15 adjudication retroactively affects one product, whereas rulemaking impacts the future conduct of an entire industry. Complaint Counsel's Appeal Brief at 6–9. The Commission has soundly rejected the application of the unreasonable risk standard in a Section 15 substantial product hazard adjudication. *See id.* at 8.

Moreover, the Supreme Court and federal law have defined "harmless error" as error that does not affect "the parties' 'substantial rights.'" *Shinseki v. Sanders*, 556 U.S. 396, 407–08 (2009) (quoting 28 U.S.C. § 2111, federal harmless error statute). The record is clear: the Presiding Officer expressly defined "substantial risk of injury" and "unreasonable risk of injury" as interchangeable terms, noting "Complaint Counsel must . . . establish a 'substantial risk of injury to the public,' or an unreasonable risk of injury, created by the design" of the Podster. Initial Decision at 50. This error of law affected the substantial rights of the parties because it

was the basis upon which the Presiding Officer decided the case. Notwithstanding Leachco's attempt to recharacterize the Presiding Officer's application of an "unreasonable risk" standard only as an alternative and harmless mode of analysis, the entire Initial Decision is tainted by the Presiding Officer's improper reliance on "unreasonable risk of injury" in conducting an incorrect analysis of the substantial product hazard posed by the Podster. *Id.*

Second, Leachco offers a similarly unavailing defense of the Presiding Officer's baseless requirement that Complaint Counsel demonstrate the Podster to be "especially dangerous" compared to other similar products or to contain dangerous design features not present in other infant products. Contrary to Leachco's assertions, the fact that Complaint Counsel's expert Dr. Erin Mannen examined other infant products when assessing whether the Podster was hazardous did not invite the Presiding Officer's imposition of a burden not present in the statute. As explained in Complaint Counsel's Appeal Brief at 18–23, these requirements have no basis in the CPSA or its regulations and are inconsistent with prior Commission decisions that have properly treated common design characteristics linked to injuries or incidents as evidence *supporting* the finding of a substantial product hazard. *See, e.g.*, *Zen Magnets*, 2017 WL 11672449, at *20 (explaining that evidence of incidents involving products with similar characteristics "is a sufficient basis . . . for experts to assess whether a product contains a design defect . . . and to describe the risk of injury presented").

Finally, Leachco misleadingly relies on a single sentence in the Initial Decision to minimize the Presiding Officer's erroneous requirement that a certain quantity of injuries is required to establish a substantial product hazard. Specifically, Leachco highlights that the Presiding Officer made a cursory reference to the fact that the "Commission does not need to prove that the Podster actually caused any of the three deaths." Answering Brief at 51. However,

despite this statement, the Initial Decision expressly and erroneously concludes that, absent a showing of additional infant deaths, the Podster does not pose a substantial product hazard because the number of known deaths that occurred with infants left unsupervised in the product is insufficient. *See* Initial Decision at 59 ("In the entire history of the Podster product line, there have been three incidents . . . where an infant died. . . . From a purely mathematical standpoint, the risk of injury from use of the Podsters appears to be vanishingly small."); 59 (reasoning that, if Complaint Counsel's theories of injury risk were true, "one would expect a profound and disturbing number of infant deaths from use of the product"); 64 (concluding that the number of reported incidents "invalidat[es] . . . the existence of a defect or a substantial product hazard"). The Presiding Officer's requirement of some undefined quantity of deaths to establish a substantial risk of injury, however, is contrary to long-standing Commission precedent. *See In re Dye and Dye* (Dye), CPSC Dkt. No. 88-1, 1989 WL 435534, at *14 (July 27, 1991) (Opinion and Order) (finding that "the Commission is not required to have evidence of actual injuries in order to address a risk"); *see also* Complaint Counsel's Appeal Brief, at 15–16.

B. Contrary to Leachco's Assertions, Common Law Product Liability Standards Do Not Control a CPSA Defect Analysis

Leachco continues to wrongly assert that the definition of "product defect" in the Restatement (Third) of Torts: Products Liability, including the requirement for a reasonable alternative design, controls in these proceedings rather than the Commission's regulation at 16 C.F.R. § 1115.4 ("Defect Regulation"). Answering Brief at 36. Ignoring the Defect Regulation and the purposes behind the CPSA, Leachco asserts that "the ordinary and common-law meaning of [Section 15]" requires proof that there is a "safer infant lounger design" available. Answering Brief at 2. Such a requirement is belied by the language of the statute, the Defect Regulation, legislative history, and case law. As explained in Complaint Counsel's Appeal Brief at 11–15,

"the case law in the area of products liability" is only one of the factors to consider under Section 15 and the Defect Regulation—it does not comprise the entire defect analysis.

To the contrary, at the time of the CPSA's passage, Congress made clear that the CPSA was specifically intended to provide a separate "legislative counterpart" to products liability law that would offer consumers "a means of protection from defective goods before they reach the marketplace" rather than "only aid[ing] people after they have suffered injury." *See* Consumer Product Safety Act, H.R.15003, 118th Cong. Rec., 31374, 31388 (September 20, 1972).[1] The "Findings and Purposes" section of the CPSA even notes that, at the time of the passage of the CPSA, state and local government regimes, as well as existing Federal authority, were inadequate to protect consumers. *See* 15 U.S.C. § 2051(a)(4)–(5).

Indeed, given the longstanding role of "reasonable alternative design" in products liability law, Congress was undoubtedly aware of this concept when enacting the CPSA and subsequent amendments thereafter. However, Congress chose not to require reasonable alternative design in Section 15. *See Animal Legal Def. Fund v. U.S. Dep't of Agric.*, 789 F.3d 1206, 1217 (11th Cir. 2015) ("Where Congress knows how to say something but chooses not to, its silence is controlling.") (citation omitted); *see also* Complaint Counsel's Appeal Brief at 13–14 (noting that "when amending Section 9 of the CPSA in 1981, Congress added a requirement to consider 'reasonable alternatives' in developing mandatory standards via rulemaking," but did not make the same addition to Section 15). And this makes sense, because Congress did not intend the CPSA to be a federal case-by-case products liability regime, but instead a broad safety

[1] For the same reasons, the Initial Decision also correctly concluded that product liability law and the CPSA are separate regimes with divergent purposes: "Product liability suits at common law are intended to provide compensation for injuries caused by defective products. The CPSA, on the other hand, is intended to prevent defective products from harming consumers, by requiring warnings, instituting recalls, or by banning a product or class of products." Initial Decision at 52.

statute designed to protect the public as a whole from hazardous products.

Consistent with this mandate, in prior Section 15 proceedings the Commission has relied on the Defect Regulation as the applicable analytical framework for design defects—not state product liability law. *See Dye*, 1989 WL 435534, at *5 n.7, *9–10 (applying the defect analysis prescribed by 16 C.F.R. 1115.4 and noting that the regulation "embod[ies] a longstanding Commission interpretation"); *Zen Magnets*, 2017 WL 11672449, at *8 n.7 (grounding its defect analysis in Section 1115.4, which "provides guidance on how the Commission interprets and enforces the concept of a product defect under Section 15(a) of the CPSA"). Neither Leachco nor the Presiding Officer have identified any prior Commission decisions requiring a showing of a "reasonable alternative design" and, in fact, the Commission in *Dye* specifically found that a design defect existed *even where there was no available safer design*: "In this case, there has been no suggestion of a way to repair or replace the worm probes manufactured by respondents that would eliminate the substantial product hazard." *Dye*, 1989 WL 435534 at *22.

As such, Leachco's proposed defect analysis entirely disregards longstanding precedent applying the Defect Regulation in Section 15 cases, including federal court precedent. *See Zen Magnets, LLC* v. *CPSC*, No. 17-CV-02645-RBJ, 2018 WL 2938326, at *4–7 (D. Colo. June 12, 2018) (Order on Cross-Motions for Summary Judgment) (rejecting an argument that the Commission was bound to the dictionary definition of "defect" and applying the Defect Regulation in substantial product hazard assessment), *aff'd in part and rev'd in part on other grounds*, 968 F.3d 1156 (10th Cir. 2020). Moreover, as detailed in the record, the Podster as currently manufactured cannot be designed safely, so imposing a requirement that Complaint Counsel identify a safe design is not only contrary to law—but impossible. *See* Complaint Counsel's Appeal Brief at 32–61.

C. Leachco Incorrectly Imposes Causation Elements Not Contained in the CPSA

In an attempt to muddy a straight-forward interpretation of Section 15, Leachco disputes the meaning of two words found in Section 15—"because of." 15 U.S.C. § 2064(a)(2) ("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."). Leachco incorrectly argues that Section 15 requires a showing that the Podster "was the but-for or proximate cause" of consumer injury in order to establish a substantial risk of injury. Answering Brief at 46. Nothing in the CPSA or the Defect Regulation imposes a "but-for" or "proximate" causation requirement before the Commission can take remedial action. Indeed, even the Presiding Officer correctly rejected Leachco's arguments in the Initial Decision, reasoning, "This is not a product liability case, and the Commission . . . need not prove that the Podster was the proximate cause of any death to act against a product." Initial Decision at 64.

Undeterred, Leachco cites case law in support of imposing a "causation" requirement that is simply inapposite. For example, Leachco's reliance on the meaning of "because of" under *Bostock v. Clayton County*, 590 U.S. 644 (2020) is irrelevant, as *Bostock* is an employment discrimination case interpreting Title VII of the Civil Rights Act, and in no way discusses, let alone controls, the definition of "because of" as it appears in Section 15 of the CPSA. Leachco's citation to the Seventh Circuit decision in *Zepik v. Tidewater Midwest, Inc.*, 856 F.2d 936 (7th Cir. 1988), is similarly off the mark as *Zepik* analyzed Section 23 of the CPSA, which provides a private right of action for consumers "injured 'by reason of any knowing . . . violation of a consumer product safety rule,'" 856 F.2d at 938 (quoting 15 U.S.C. § 2072(a)). *Zepik* held that Section 23's private right of action does not extend to reporting violations, *see* 856 F.2d at 944,

and does not even address Section 15 actions seeking to protect consumers from substantial product hazards. Indeed, the phrase called out by Leachco from *Zepik* and Section 23 of the CPSA is not "because of," but rather "by reason of"—a term that does not appear in Section 15 at all. These cases, as well as the state product liability cases Leachco cites, have no applicability to the statutory construction of the requirements for proving a substantial product hazard under Section 15.

## IV. LEACHCO WRONGLY ARGUES COMPETENT, RELIABLE, AND HELPFUL EXPERT TESTIMONY AND OTHER TYPES OF PROBATIVE EVIDENCE SHOULD NOT BE CONSIDERED

Leachco argues that Complaint Counsel's expert testimony does not support a finding that the Podsters are defective, and, in its Cross-Appeal, that all expert testimony admitted and considered by the Presiding Officer should have been stricken. In both instances, Leachco's arguments are founded upon a misapplication of Federal Rule of Evidence ("FRE") 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Leachco had a full and fair opportunity to cross-examine Complaint Counsel's experts and present its own expert evidence, and Complaint Counsel's competent, reliable, and helpful expert testimony was properly admitted.

### A. The Rules of Practice and Case Law Support Admissibility of Complaint Counsel's Expert Testimony

Pursuant to the Commission's Rules of Practice, "all relevant and reliable evidence is admissible" unless the Presiding Officer determines that "its probative value is substantially outweighed by unfair prejudice or confusion of the issues," or certain other factors apply. 16 C.F.R. § 1025.43(c). The Rules also note that "the Federal Rules of Evidence shall apply to all proceedings held pursuant to these Rules," but "may be relaxed by the Presiding Officer if the ends of justice will be better served by so doing." 16 C.F.R. § 1025.43(a).

The Rules of Practice also define an expert witness as:

> [O]ne who, by reason of education, training, experience, or profession, has peculiar knowledge concerning the subject matter to which his/her testimony relates and from which he/she may draw inferences based upon hypothetically stated facts or offer opinions from facts involving scientific or technical knowledge.

16 C.F.R. § 1025.44. This standard is consistent with FRE 702.

Expert testimony is admissible under FRE 702 if it concerns scientific, technical, or other specialized knowledge that will aid the jury or other trier of fact to understand or resolve a fact in issue. *Daubert*, 509 U.S. at 592. In making this determination, a court has the task of "ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Id.* at 597.

In reviewing the admissibility of the testimony of potential experts, courts have a "gatekeeper" role to exclude unreliable and irrelevant expert testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 145, 152–53 (1999). However, in bench trials or adjudicative proceedings like this one, it is well-settled that the standards for admissibility are much more relaxed because there is no concern with confusing or misleading a jury. "There is less need for the gatekeeper to keep the gate when the gatekeeper is keeping the gate only for himself." *United States. v. Brown*, 415 F.3d 1257, 1269 (11th Cir. 2005). *See also Consolidation Coal Co. v. Dir., Off. Of Workers' Comp. Programs*, 294 F.3d 885, 893 (7th Cir. 2002) (noting that administrative litigations "are not bound by the specific evidentiary strictures of *Daubert*"); *Gibbs v. Gibbs*, 210 F.3d 491, 500 (5th Cir. 2000) ("Most of the safeguards provided for in *Daubert* are not as essential in a case such as this where a district judge sits as the trier of fact in place of a jury."); *Braggs v. Dunn*, No. 2:14cv601-MHT, 2017 WL 2984312, at *3 (M.D. Ala. July 13, 2017) ("[T]he *Daubert* barriers to admissibility are more relaxed in a bench trial, 'where the judge is

serving as factfinder,' and the court need not be 'concerned about dumping a barrage of questionable scientific evidence on a jury.'") (quoting *Brown*, 415 F.3d at 1268).

Further, exclusion of expert testimony should never be the first step or preference for a court—instead, vigorous cross-examination of expert witnesses and presentation of contrary evidence should take the place of exclusion. *See Fish Farms P'ship v. Winston-Weaver Co.*, No. 2:09-CV-163, 2012 WL 12965440, at *1 (E.D. Tenn. Oct. 23, 2012) ("As *Daubert* itself recognizes, vigorous cross examination is to be preferred to pretrial exclusion of expert testimony. . . . [I]f there is any serious doubt regarding the facts or data relied upon by an expert, then the resolution of that doubt should be left to the [trier of fact]."), *aff'd*, 531 F.App'x 711 (6th Cir. 2013); *Hearts with Haiti, Inc. v. Kendrick*, No. 2:13-CV-00039-JAW, 2014 WL 4773479, at *5 n.5 (D. Me. Sep. 24, 2014) ("[T]he Supreme Court in *Daubert* preferred cross-examination, presentation of contrary evidence, and instructions on burden of proof over exclusion."); *see also Garcia v. Sec'y of Health & Hum. Servs.*, No. 05-0720V, 2010 WL 2507793, at *9 (Fed. Cl. May 19, 2010) ("Extremely rare will be the case where a party's expert witness is truly so patently unqualified to opine, or his opinion so unreliable in methodology, that exclusion from admission into evidence is warranted."). Consistent with this preference, deficiencies in an expert's qualifications or knowledge "generally go to the weight of the witness's testimony, not its admissibility." *Robinson v. GEICO General Ins. Co.*, 447 F.3d 1096, 1100 (8th Cir. 2006) (quoting 29 Charles A. Wright & Victor J. Gold, *Federal Practice and Procedure: Evidence* § 6265 (1997)).

Against this backdrop, and as noted below, the expert testimony proffered by Complaint Counsel's experts was based on validated and competent science and was properly admitted. In

fact, the Presiding Officer correctly found that all three experts were qualified to testify.[2] Leachco had ample opportunity to cross-examine the expert witnesses and present its own expert testimony at the hearing. Accordingly, Leachco's renewed attempt to strike the expert testimony from the record is not supported by law.

B. Dr. Mannen's Expert Testimony Contains Appropriate Benchmarks and Was Properly Admitted

Leachco's Answering Brief argues that Dr. Mannen's testimony should be stricken because "she failed to identify . . . any objective benchmarks or thresholds by which to identify at what point the Podster's design becomes dangerous or defective such that it creates a substantial risk of injury." Answering Brief at 23.

But neither FRE 702 nor *Daubert* contains a requirement that expert testimony be based on measuring data against a specific numerical benchmark. And, even assuming some type of benchmark criteria were required for Dr. Mannen's expert testimony to meet the standards of FRE 702 and *Daubert*, Leachco is simply wrong in its assertion that Dr. Mannen did not use benchmarks or thresholds in her analysis. In fact, Dr. Mannen did employ objective benchmarks. Her head/neck flexion and head rotation measurements were compared to a firm, flat surface, which is known to be safe for infants.[3] In her firmness testing, "[a] threshold of <1" displacement at a 10 N load was . . . used as a control because that would approximate the safe degree of displacement present in a typical crib mattress."[4] The airflow testing used 0.31 inches

[2] "While Respondent challenged CPSC experts' experience, equipment, means, and methodologies, the witnesses were each intelligent, accomplished, capable, and articulate. Their approaches and techniques were not inappropriate and were generally helpful in illustrating the issues and providing bases for understanding potential hazards." Initial Decision at 57. *See also id.* ("[Dr. Mannen] thus possesses the qualifications to discuss infant physiology and biomechanics in this context. . . . [Dr.] Katwa is clearly qualified to testify about the medical and physical effects of positioning based on Mannen's conclusions."; *id.* at 58 ("[Ms. Kish's] thoughtful and informed testimony about the propensity for even informed consumers to ignore warnings and downplay risks provided a helpful perspective on the *potential* for danger." (emphasis in original)).

[3] *See* Expert Testimony of Erin Mannen, CCX-1, at 20 (head/neck flexion), 28 (head rotation).

[4] *Id.* at 23.

of water (a unit of pressure), the airflow associated with mesh-like material, as the threshold of safety.[5] Also, Dr. Mannen compared the head incline and thigh angle measurements to her findings in her 2019 Biomechanical Analysis of Inclined Sleep Products, concluding that infants' head and thigh angles in the Podster are similar to dangerous inclined sleep products.[6] Similarly, Dr. Mannen's $CO_2$ rebreathing testing was compared to a crib mattress with a cotton sheet, again, because the crib mattress is known to be a safe surface for infants, even in a prone position.[7] And, although Leachco takes issue with Dr. Mannen's $CO_2$ rebreathing measurements and that "she admitted that she has no idea how much [$CO_2$] is too much," it was Dr. Umakanth Katwa who explained that, according to Dr. Mannen's findings, an infant in a prone position on a Podster is exposed to a nearly three-fold increase in $CO_2$ retention compared to an infant on a flat crib mattress, and that such exposure can result in hypoxemia, posing a risk of irreversible neurological damage and death.[8]

In seeking to exclude Dr. Mannen, Leachco also misapplies *Rovid v. Graco Children's Products, Inc.*, 2018 WL 5906075 (N.D. Cal. Nov. 9, 2018), where the plaintiffs alleged an infant death was caused by a defective play yard. In *Rovid*, the expert was excluded for not explaining how the results of his $CO_2$ rebreathing testing of a Graco play yard mattress correlated "to what a live infant would experience. Nor [did] he explain what objective standard these values should be compared against." *Id.* at *4. Notably, the expert's testimony in *Rovid* was also found to be unreliable for multiple other reasons: each of his results was a product of a single test rather than multiple trials, the analysis was insufficiently rigorous, he failed to explain

[5] *Id.* at 25.
[6] *Id.* at 32–33.
[7] *Id.* at 27.
[8] *See* Expert Testimony of Umakanth Katwa, CCX-2 at 24. It is entirely permissible for experts to base their opinion on the work of other testifying experts. *See* Fed. R. Evid. 703; *see also Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 612–13 (7th Cir. 2002) ("Now it is common in technical fields for an expert to base an opinion in part on what a different expert believes on the basis of expert knowledge not possessed by the first expert.").

whether he controlled for the position of the doll he used to test each mattress, and there was no showing that the results had "any correlation to a mattress producing a hazardous level of $CO_2$ rebreathing." *Id.* at *5–7. *Rovid* does not stand for the proposition that objective benchmarks are required under FRE 702 or *Daubert*. However, even if it did, as noted above, Dr. Mannen—unlike the expert in *Rovid*—employed objective benchmarks where appropriate.

Further, the expert's testimony in *Rovid* was excluded not only because it was unreliable, but also because it did not satisfy *Daubert*'s requirement "that the expert's testimony 'fit' the facts of the case." *Id.* at *8 (quoting *Daubert*, 509 U.S. at 591). In *Rovid*, the court found that the expert's testimony was not relevant to whether the Graco mattress played a role in the infant death: not only did his testing fail to explain his conclusions, he also "testified that the testing did not even attempt to simulate the position in which [the infant] was found." *Id.* Here, Dr. Mannen demonstrated the specific and multiple ways that the Podster's design poses a risk of suffocation to infants. *See* Complaint Counsel's Appeal Brief at 33–37. Unlike in *Rovid*, Dr. Mannen, in combination with Dr. Katwa, detailed how various scenarios—including the increased neck flexion, roll-over, occlusion of breathing, and increased $CO_2$ consumption—pose a risk of suffocation.

C. Leachco Mischaracterizes Settled Case Law by Stating that Peer Review of Expert Testimony is Always Required

Leachco also wrongly argues that Dr. Mannen's testimony is unreliable and should not have been admitted because "none of the methods employed have been peer-reviewed or validated." Leachco Cross-Appeal at 35. However, peer review is *not* a requirement for admissibility, and does not guarantee reliability, as the Supreme Court recognized in *Daubert*:

> Another pertinent consideration is whether the theory or technique has been subjected to peer review and publication. Publication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability, and in some instances well-grounded

> but innovative theories will not have been published. Some propositions, moreover, are too particular, too new, or of too little interest to be published. But submission to the scrutiny of the scientific community is a component of "good science," in part because it increases the likelihood that substantive flaws in methodology will be detected. The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

509 U.S. at 593–94 (citations omitted). Thus, contrary to Leachco's assertion, absent a demonstrated connection between the lack of publication and the reliability of the methodologies employed by the expert, the lack of peer review does not render an expert's opinion unreliable. *See Smith v. Ford Motor Co.*, 215 F.3d 713, 720 (7th Cir. 2000) (exclusion of expert witness based solely on lack of peer review was an abuse of discretion when trial court failed to consider other factors, such as whether expert had applied "well-established engineering techniques to the particular materials at issue").

Here, Leachco has not explained how the lack of peer review renders Dr. Mannen's well-supported conclusions unreliable, and as Leachco learned during cross examination, her techniques were derived from peer-reviewed studies she co-authored.[9] Accordingly, the Presiding Officer properly found that Dr. Mannen's testimony met the *Daubert* criteria for admissibility.[10] Striking or excluding her testimony is simply not the appropriate remedy: "As long as an expert's scientific testimony rests upon 'good grounds, based on what is known,' it should be tested by the adversary process—competing expert testimony and active cross-examination," rather than being excluded. *Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998) (quoting *Daubert*, 509 U.S. at 590) (emphasis added).

Leachco's argument that Dr. Mannen's methods were not validated is not supported by

[9] Aug. 7, 2023 Hr'g Tr. at 85:5–86:5.
[10] *See* Dkt. 128 at 5–6; Initial Decision at 57–58.

the record. In fact, Leachco's cross-examination of Dr. Mannen revealed that she used validated measurements. For example:

> Q: Right, but you still haven't validated that the measurements you took for purposes of your expert report actually correlate to how an infant would sit or move in the Podster, correct?
>
> A: So, it might not be in the report, but internally in the laboratory we have done those tests.
>
> Q: Okay, but it's not in your report, Dr. Mannen, is it?
>
> A: It's not in this report.
>
> Q: And there are—in fact there is no device that validly measures head and neck flexion of infants, isn't that correct?
>
> A: No, that's not correct.[11]

Leachco had a chance to explore this issue further on cross-examination, but chose not to, and cannot now seek exclusion to remedy that failure. *See, e.g.*, *Farra v. Stanley-Bostich, Inc.*, 838 F.Supp. 1021, 1032–33 (E.D. Pa. 1993) (party's failure to explore factual basis for expert's opinion during cross-examination did not render expert testimony inadmissible); *United States v. Santarpio*, 560 F.2d 448, 454–55 (1st Cir. 1977) (court was entitled to credit expert's conclusion when defense counsel chose not to cross-examine, despite expert's lack of explanation of facts underlying opinion on direct), *cited in Farra*, 838 F.Supp. at 1033; *see also* Fed. R. Evid. 705 ("Unless the court orders otherwise, an expert may state an opinion—and give the reasons for it—without first testifying to the underlying facts or data. But the expert may be required to disclose those facts on cross-examination.").

D. Celestine Kish's Expert Testimony was Properly Admitted

Leachco argues that the testimony of Engineering Psychologist and human factors expert,

[11] Aug. 7, 2023 Hr'g Tr. 82:22–83:12. *See also*, *e.g.*, *id.* at 113:18–114:2 (Q: And you didn't validate that the measurements you took of the CAMI dolls can be correlated with actual infant neck angles, did you? A: We have done that research in the lab, and that internal . . . validation in preparing for publication.").

Ms. Celestine Kish, was inadmissible because it is unreliable, "not based on any methodology, much less any proven methodology," relies on anecdotal evidence, and lacks any standards or thresholds. Answering Brief at 51–61. To the contrary, Ms. Kish's opinion was founded upon her decades of experience as an Engineering Psychologist, her extensive knowledge of consumer behavior, and was supported by peer-reviewed scientific literature. "[A]n expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation," provided "the expert's opinion will have a reliable basis in the knowledge and experience of his discipline." *Daubert*, 509 U.S. at 592. It is therefore permissible to use anecdotal examples to illustrate and support the expert's opinion. *See Butler v. Home Depot, Inc.*, 984 F.Supp. 1257, 1262–64 (N.D. Cal. 1997) (testimony of social psychologist who used anecdotal evidence to illustrate conclusions was admissible under *Daubert*). As such, Ms. Kish's testimony, some of which was anecdotal and based on studies of consumer behavior in contravention of warnings, met the requirements for admissibility under the Commission's Rules of Practice, FRE 702, and *Daubert*.

Leachco's objections to Ms. Kish's testimony stem from its failure to read the sources cited in Ms. Kish's expert report and to ask the right questions during cross-examination. Specifically, Ms. Kish testified that if a parent or caregiver sees another parent advance a product as safe for sleep, even if they know there are risks associated with such use, that parent or caregiver may disregard the risk and engage in that risky behavior. Ms. Kish illustrated that point in her written testimony by analogizing unsafe sleep practices to other common risky behaviors, noting that "people are more likely to speed, jaywalk, and engage in other unsafe behaviors such as not wearing seat belts when they see other drivers or pedestrians defying those laws without

consequence."[12] Leachco criticizes this testimony for failing to indicate "how much 'more likely' this phenomenon is," and for failing to discuss "other factors that could persuade people *not* to speed, jaywalk, etc." Leachco Cross-Appeal at 52. However, Leachco ignores that that these opinions are grounded in a peer-reviewed study regarding jaywalking behavior that explains precisely how much more likely the study's subjects were to jaywalk when they saw others do so, and discusses the influence of "obedient models" (*i.e.*, positive influences) on behavior compared to "non-obedient models."[13] This jaywalking study was just one of several peer-reviewed articles cited in support of Ms. Kish's opinion on the effect of counter-examples on warning compliance.[14] Moreover, Leachco had a full and fair opportunity to cross-examine Ms. Kish on this topic and others, but did not elicit any testimony undercutting the reliability of the scientific studies she cited.[15]

Significantly, Leachco's own expert did not contest the quality of the scientific literature cited by Ms. Kish or dispute the scientific evidence that parents or caregivers may be encouraged to use the product for sleep notwithstanding the warnings. Although Leachco's expert, Ms. Peggy Shibata, P.E., states that "CPSC has provided no foundation or supporting basis for the allegation that the Podster *uniquely* will lead to caregivers ignoring the provided warnings and instructions," and that "caregiver misuse exists across all categories of infant products, and the Podster is *not unique* in this regard,"[16] she *does not dispute* that the Podster—like other products—may be used contrary to warnings. In fact, Ms. Shibata agrees with Ms. Kish that consumers might use the Podster for sleep and bedsharing, contrary to Leachco's warnings.[17]

[12] Expert Testimony of Celestine Kish, CCX-2 at 32, ¶ 67.
[13] Mullen et al., *Jaywalking as a Function of Model Behavior*, 16 Personality and Soc. Psych. Bull. 2, 320 (June 1990), *cited in* Expert Testimony of Celestine Kish, CCX-2 at 32, n.61.
[14] *See* Expert Testimony of Celestine Kish, CCX-2 at 31–33, nn.55–65.
[15] *See, e.g.*, August 8, 2023 Hr'g. Tr. at 42:11–43:5 (Leachco's cross-examination on the jaywalking study).
[16] Expert Testimony of Peggy Shibata, P.E., RX 01, at 14 (emphasis added).
[17] *Id.* at 10.

E. Dr. Umakanth Katwa's Testimony was Properly Admitted

Leachco argues that Dr. Katwa's expert testimony "was contingent on" the expert testimony of Dr. Mannen and Ms. Kish, and thus must be excluded as a follow-on consequence of excluding the predicate expert testimony, since this evidence would not be "relevant" to the case. Answering Brief at 61–63. This baseless argument fails because, as detailed above, the testimonies of Dr. Mannen and Ms. Kish are admissible. Further, as noted in Complaint Counsel's Appeal Brief at 23–25, 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. Dr. Katwa is a widely published expert of pediatric pulmonology and infant sleep. In this case, he appropriately relied on the biomechanical engineering expertise presented by Dr. Mannen and the human factors engineering expertise presented by Ms. Kish as a foundation for his medical opinion on what types of injuries or death could result from use of the Podster. *See Werth v. Makita Elec. Works, Ltd.*, 950 F.2d 643, 648 (10th Cir. 1991) ("[T]he 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."). In short, Leachco has set forth no valid reason to independently exclude Dr. Katwa's expert opinions or disturb the Initial Decision's assessment that Dr. Katwa "explained the potential effects within his area of (considerable) expertise." Initial Decision at 58 n.32.[18]

F. The In-Depth Investigation Reports Are Admissible

In its Appeal Brief, Complaint Counsel explained why the Initial Decision erred by excluding certain parts of the Virginia In-Depth Investigation Report. Complaint Counsel's Appeal Brief at 28–29. Leachco now claims that the Presiding Officer erred by admitting "other

[18] Complaint Counsel requests that the Commission also admit the portion of Dr. Katwa's expert opinion excluded by the Presiding Officer. *See* Complaint Counsel's Appeal Brief at 23–25.

hearsay documents" from the Alabama, Texas, and Virginia IDIs. Leachco Cross-Appeal at 63–64. However, the rules governing this proceeding and applicable case law support admitting the IDIs into evidence in their entirety. All three IDIs, including the erroneously excluded portions of the Virginia IDI in JX-12A and JX-12B, are admissible under the public records hearsay exception under FRE 803(8). It was error for the Presiding Officer to exclude part of the Virginia IDI and it would be error to exclude any of the three IDIs currently in evidence.

Although the "Federal Rules of Evidence shall apply to all proceedings held pursuant to" the Rules of Practice, they "may be relaxed by the Presiding Officer if the ends of justice will be better served by so doing." 16 C.F.R. § 1025.43(a). Also, "[a]ll relevant and reliable evidence is admissible, but may be excluded by the Presiding Officer if is probative value is substantially outweighed by unfair prejudice or confusion of the issues, or by considerations of undue delay, waste of time, immateriality, or needless presentation of cumulative evidence." 16 C.F.R. 1025.43(c).

Under FRE 803(8), a public record is admissible if:

> (A) it sets out: (i) the office's activities; (ii) a matter observed while under a legal duty to report, but not including, in a criminal case, a matter observed by law-enforcement personnel; or (iii) in a civil case or against the government in a criminal case, factual findings from a legally authorized investigation; and (B) *the opponent does not show that the source of information or other circumstances indicate a lack of trustworthiness*.

Fed. R. Evid. 803(8) (emphasis added).

As was detailed in Complaint Counsel's Appeal Brief, at 28–29, and Complaint Counsel's Motion in Limine and Memorandum in Support to Admit In-Depth Investigation Reports, Dkt. 107, the IDIs meet the requirements to be admitted as public records. Further, Complaint Counsel put forth testimony during the hearing which led to the admission of the Virginia IDI by the Presiding Officer and Leachco's agreement to allow the admission of the

Alabama and Texas IDIs.[19]

Leachco does not contest that the IDIs are public records. Instead, it argues that they are inadmissible hearsay. But this argument misses the mark completely—FRE 803(8) is an exception allowing the admissibility of trustworthy hearsay. As FRE 803(8) notes, the *opponent* of a public record must show that such record lacks trustworthiness and Leachco has not met that burden, having never contested the trustworthiness of these documents. Trustworthiness is the touchstone concept of whether a public record is admissible as an exception to the hearsay rule. "Factual findings from a legally authorized investigation" are 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) and (B). *See also Bradford Trust Co. v. Merrill Lynch, Pierce, Fenner and Smith, Inc.*, 805 F.2d 49, 54 (2d Cir. 1986) ("To exclude evidence . . . there must be 'an affirmative showing of untrustworthiness, beyond the obvious fact that the declarant is not in court to testify.'") (quoting *Kehm v. Proctor & Gamble Mfg. Co.*, 724 F.2d 613, 618 (8th Cir. 1983)).

Leachco has not carried its burden of affirmatively showing untrustworthiness of these IDIs—indeed, Leachco's Answering Brief does not even mention the word "trustworthiness." Nor has Leachco claimed that the IDIs contain any information not provided by the applicable personnel faithfully executing their duty to "submit accurate and fair reports." Fed. R. Evid. 803 Advisory Note. Because the hearsay statements within the Alabama, Texas, and Virginia IDIs were made by officials in the ordinary course of their public responsibilities with no indicia that they misstated or misrepresented any facts, the IDIs were properly admitted into evidence, and, contrary to Leachco's request, should be admitted in full. *See Beech Aircraft Corp. v. Rainey*,

[19] Aug. 7, 2024 Hr'g. Tr. at 186:7–187:6; 203:15–206:14; Aug. 8, 2024 Hr'g Tr. at 7:3–9:17 (stipulation on Alabama and Texas IDIs).

488 U.S. 153, 170 (1988) (holding public record investigatory reports admissible under Rule 803(8)).

G. Contrary to Leachco's Assertions, the Initial Decision Properly Admitted Certain Excerpted Deposition Testimony

Leachco argues it was improper for the Presiding Officer to admit minor portions of deposition transcripts of Leachco employees Mabry Ballard (CCX-42) and Tonya Barrett (CCX-43). Leachco Cross-Appeal at 65–67. In the depositions, Ms. Ballard testified that she had allowed her infant to sleep in a Podster and Ms. Barrett testified that she is aware of family members who had used the Podster for infant sleep.[20] These deposition excerpts were cited in Ms. Kish's written testimony as examples of consumers using the Podster for sleep despite being well-aware of warnings not to do so.[21]

These exhibits were properly admitted as facts supporting Ms. Kish's opinion. FRE 703 states:

> An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.

The Presiding Officer reviewed the exhibits, properly admitted them, and correctly ruled that there was no prejudicial effect.[22] Leachco has not articulated how it would be prejudiced by this limited introduction of the deposition transcript. Indeed, there is no prejudice to Leachco, which has been aware that Ms. Kish referred to the witnesses' testimony since written testimony

[20] CCX-42 at 180:15–181:16; CCX-43 at 27:20–31:11.
[21] Expert Testimony of Celestine Kish, CCX-2 at 73–74, ⁋⁋ 145–46.
[22] Aug. 8, 2023 Hr'g Tr. 21:3–22.

was served on April 29, 2023. Further, the deposition excerpts were on Complaint Counsel's Exhibit List.[23] Finally, Leachco does not assert that the testimony is untrue or unreliable. Accordingly, the deposition evidence showing Leachco employee and Leachco family use of the Podster, contrary to the warnings and instructions, was properly admitted.

## V. LEACHCO'S CONSTITUTIONAL ARGUMENTS ARE UNAVAILING

Leachco's raises a series of constitutional arguments that are without merit.[24] First, Leachco says that Complaint Counsel's arguments in this matter, if adopted by the Commission, would violate the major questions doctrine. Answering Brief at 47. Second, Leachco argues that Complaint Counsel's arguments would violate the nondelegation doctrine. *Id.* at 54. Third, Leachco submits that Complaint Counsel's interpretations of the Defect Regulation and Section 15 would make the CPSA unconstitutionally vague. *Id.* at 56. Finally, in a section of its Cross-Appeal entitled "Constitutional Issue Preservation" Leachco claims the Commission is unconstitutionally structured and this action violates Leachco's due process rights. Leachco Cross-Appeal at 69. Each of these arguments fails.

### A. This Section 15 Adjudication Does Not Violate the Major Questions Doctrine

Leachco says that Complaint Counsel's arguments assert a "novel and radical" view of the CPSA that, if accepted by the Commission, would cause this adjudication to violate the major questions doctrine. Answering Brief at 51–52. This argument has no merit.

The major questions doctrine states that in certain cases of economic and political significance, agencies must point to "clear congressional authorization" for the authority to

[23] *See* Dkt. 104. Complaint Counsel notes that Leachco included both Ms. Ballard and Ms. Barrett on its July 14, 2023 Witness List. *See* Dkt. 112.

[24] Leachco asserts that its structural constitutional challenges "cannot be addressed by the Commission." Leachco Cross-Appeal at 69. However, the Commission has previously ruled that it was able to address similar challenges to the constitutionality of the Commission and its Section 15 adjudications. *See In the Matter of Amazon.com, Inc.*, Dkt. 142, at 62–69. In any event, as discussed below, Leachco's arguments are precluded by prior federal court rulings.

regulate, and such authority will not be read into "ambiguous statutory text." *See West Virginia v. EPA*, 597 U.S. 697, 724 (2022). Instead, courts require "more than a plausible textual basis" for the agency action. *Id*. Here, congressional intent and the clear, unambiguous language of the CPSA indicate that the Commission has the authority to recall products that present a substantial product hazard. *See* 15 U.S.C. § 2064(c)–(d) (providing authority to recall product found to present a substantial product hazard); Second Session on National Commission on Product Safety, Serial 91-82, Hearing Before the Committee on Commerce, 91. Cong. 7 (1970) (finding one of the "primary powers" proposed for the Commission to "[r]equire notice to consumers and recall or replacement of substantially defective products").

Leachco does not argue to the contrary, and instead misconstrues Complaint Counsel's argument as advancing a novel interpretation of defect and substantial risk of injury. In doing so, Leachco incorrectly invokes the major questions doctrine arguing that this action would be a "transformative expansion [of] regulatory authority." Answering Brief at 52 (citing *West Virginia v. EPA*, 597 U.S. 697, 724 (2022)). Contrary to Leachco's arguments, however, Complaint Counsel is not relying on a novel or transformative interpretation of the terms "product defect" or "substantial risk of injury." Indeed, the factors that go into a defect analysis, as applied to the Podster here, have existed since the Defect Regulation was promulgated in 1978—10 years before Leachco's founding and decades before the Podster was distributed in commerce—and "substantial risk of injury" is defined by the statute and addressed in detail by Complaint Counsel in its Appeal Brief. Complaint Counsel's Appeal Brief at 57–61. Further, the Commission has applied this framework in adjudications for decades. *See, e.g.*, *Dye*, 1989 WL 435534, at *5 (describing the elements of a substantial product hazard). Moreover, "foreseeable misuse" as a consideration of product safety "has been an integral part of consumer product

safety analysis for more than 40 years, including before the creation of [the] agency." *Zen Magnets*, 2017 WL 11672449, at *10. Indeed, the Commission has expressly found that it has the authority to pursue an action under Section 15 even under a defect theory "based *solely* on reasonably foreseeable misuse," including where consumers were injured because they had "disobeyed, did not receive, or did not read [product] warnings." *Id*. at *11 (emphasis added), *15. *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) (affirming Commission's Final Decision and Order), *aff'd in part and rev'd in part on other grounds*, 968 F.3d 1156 (10th Cir. 2020).

Leachco's reference to the fact that the Podster does not violate a consumer product safety rule and is therefore, by Leachco's characterization, "legal," Answering Brief at 53, is unavailing and ignores that the Podster is defective and presents a substantial risk of injury under Section 15. Leachco claims that some "exceedingly clear language" authorizing a recall for non-regulated products is missing from the CPSA. *Id.* However, Congress specifically gave the Commission the power to promulgate product safety rules and bans through Sections 7, 8, and 9 of the CPSA, 15 U.S.C. §§ 2056–2058. And the Commission can either recall products that violate such a rule or ban under Section 15(a)(1), 15 U.S.C. § 2064(a)(1), *or* recall products that pose a substantial product hazard as set out in Section 15(a)(2)—products that are defective and present a substantial risk of injury. 15 U.S.C. § 2064(a)(2). These are two separate enforcement regimes, and it is appropriate to recall the Podsters because they pose a substantial product hazard. Therefore, Leachco's invocation of the major questions doctrine is a makeweight that the

Commission need not rule upon, and if addressed, should be rejected entirely.[25]

B. This Section 15 Action Does Not Violate the Non-Delegation Doctrine

Leachco also argues that finding a substantial product hazard here would violate the non-delegation doctrine. Answering Brief at 54–56. Pursuant to the non-delegation doctrine, "a delegation is permissible if Congress has made clear to the delegee 'the general policy' he must pursue and the 'boundaries of [his] authority.'" *Gundy v. United States*, 588 U.S. 128, 146 (2019) (quoting *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946)). Accordingly, only statutes lacking "'any policy or standard' to confine discretion" present a nondelegation problem. *Gundy*, 588 U.S. at 146 (quoting *Mistretta v. United States*, 488 U.S. 361, 373 n.7 (1989)). The CPSA contains numerous boundaries to the agency's authority. First, as essentially recognized by Leachco, Section 15(a)(2) provides a definition for the phrase "substantial product hazard," detailing the requirements that must be met for the Commission to make such a finding. 15 U.S.C. § 2064(a)(2). Second, Section 15(c) authorizes the agency to order a manufacturer to cease distribution and notify the public of the defect *only* if "notification is required *in order to adequately protect the public*," and Section 15(d) authorizes the agency to order a remedy *only* if it finds that such action "is *in the public interest*." 15 U.S.C. § 2064(c)–(d) (emphasis added).

As applied to this matter, Leachco outlandishly suggests that this Section 15 safety adjudication creates "new definitions of 'product defect' and thereby [can] ban any product that presents 'any risk of injury.'" Answering Brief at 54. This assertion is clearly belied by the

[25] The cases cited by Leachco invoking the major questions doctrine are inapposite. Those cases dealt with "fundamental revision[s]" to regulations that would affect entire industries in a new, prospective manner, which is not comparable to the retrospective recall of a hazardous product, based on an established defect analysis. *See West Virginia v. EPA*, 597 U.S. 697, 700–02 (2022) (striking EPA's attempts to regulate "overall power system" by implementing cap-and-trade program for carbon emissions and shift "overall power system" from using coal- and natural-gas fired power plants to renewable sources, after Congress had already declined to do so); *Nat'l Fed'n of Indep. Bus. v. OSHA*, 595 U.S. 109, 112 (2022) (striking OSHA vaccination mandate that affected "much of the Nation's work force" and raised "a question of vast national significance"). Neither case is applicable to the present action, which represents a routine application of well-established precedents to a single product and a single firm.

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

C. Section 15 of the CPSA is Not Unconstitutionally Vague

Leachco's final non-structural constitutional claim argues that the CPSA and Defect Regulation, as applied here, are unconstitutionally vague. Answering Brief at 56–59. Leachco claims that the law fails to provide Leachco with constitutionally sufficient notice of what is defective or not. Again, Leachco's claim is wholly without merit.

Leachco's vagueness argument focuses on the phrase "other factors relevant to the determination" in 16 C.F.R. § 1115.4(e). Courts, however, have rejected prior vagueness challenges to regulations containing undefined references to "other relevant factors," like in the Defect Regulation, reasoning that such provisions can be interpreted in the context of the broader regulatory scheme.[26] *See United States v. Taylor*, 232 F.Supp.3d 741, 756 (W.D. Pa. 2017) (rejecting challenge to Department of Transportation regulations referencing phrases "other relevant factors"). Here, "other factors relevant to the determination" in 16 C.F.R. § 1115.4(e) can be read in the context of the other factors referenced in the regulation, as well as the

[26] The term "otherwise" in Section 15(a)(2) can also be interpreted by the enumerated factors listed before it and similarly does not present a vagueness concern. 15 U.S.C. § 2064(a)(2).

examples provided in the definition, which the Commission specifically included to help regulated parties understand the meaning of a defect. *See* Interpretation, Policy, and Procedure for Substantial Product Hazards, 43 Fed. Reg. 34,988, 34,991 (Aug. 7, 1978).

Alongside its vagueness complaints, Leachco argues that its constitutional rights to fair notice would be violated if the Commission were to treat reasonably foreseeable misuse of the Podster as an appropriate consideration in the defect analysis. Leachco's assertions are largely based on a flawed understanding of the Defect Regulation, which clearly specifies foreseeable misuse as a factor that should be considered in a defect analysis. While not a substantive rule, the Defect Regulation was promulgated through notice-and-comment rulemaking pursuant to the procedures listed in 5 U.S.C. § 553 and 5 U.S.C. § 556, was issued not long after the CPSA was passed, represents a longstanding position of the agency, and was promulgated with thorough consideration of the comments and viewpoints received by the agency.[27] For all those reasons, federal courts reviewing agency action based on the Defect Regulation would likely afford it considerable deference. Leachco, however, ignores the Defect Regulation, promulgated in 1978—ten years before Leachco's founding and almost thirty years before Leachco began selling the Podster—as well as Commission precedent that has considered the use and misuse of a Subject Product going back as far as the mid-1970s.[28] *See In re Francis Alonso, Jr.* (Mylar Star

[27] Interpretive rules will be afforded deference based on the thoroughness evident in [the rule's] consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *Skidmore v. Swift & Co*., 323 U.S. 134, 140 (1944). An interpretive rule is "entitled to deference unless it can be said not to be a reasoned and supportable interpretation of the Act." *Whirlpool Corp. v. Marshall*, 445 U.S. 1, 11 (1980). Interpretive rules will also be accorded more deference by courts if they have been promulgated according to notice and comment procedures. *Prod. Tool Corp. v. Emp. & Training Admin., U.S. Dep't of Lab*., 688 F.2d 1167 (7th Cir. 1982). In addition, interpretive rules that represent the "longstanding position of the agency" and were "promulgated near the time the agency's enabling act was passed" are considered by courts to have more authoritative effect and be given more weight. *General Electric Co. v. Gilbert*, 429 U.S. 125, 140–46 (1976).

[28] Leachco also ignores the Commission's explanation in issuing the Defect Regulation, that its aim was to "put members of the public, especially subject firms, fairly on notice that a product may contain a defect even if it is

Kites), CPSC Docket No. 75-16, at 4–5 (Initial Decision and Order) (June 18, 1976), *findings of fact aff'd*, *Initial Decision and Order set aside on jurisdictional grounds*, Final Decision and Order (Sept. 16, 1977); *see also Dye*, 1989 WL 435534 at *2, *5–7; *Zen Magnets*, 2017 WL 11672449, at *9, *13.

D. Leachco's Structural Constitutional Arguments are Precluded by Prior Federal Court Litigation

Leachco asserts additional "structural" constitutional claims related to how the Commission is comprised, as well as claims regarding a lack of due process, an Article III tribunal, and a jury trial. Leachco Cross Appeal at 67–69. These arguments are incorrect,[29] and perhaps more fundamentally, Leachco is here attempting to obtain a second bite at the apple for arguments that have already been considered and rejected in federal court. Undeterred despite continuous losses at the federal judiciary level, over the last two years, Leachco has attempted to enjoin this administrative proceeding ten times, through filings in the Eastern District of Oklahoma, the United States Court of Appeals for the Tenth Circuit, and the Supreme Court. Those filings have all elaborated on, and recycled, Leachco's constitutional arguments, and none to date have been successful.[30] In particular, Leachco did not prevail in the Tenth Circuit with its

designed, manufactured, and marketed exactly as intended," signaling that a defect could exist based solely on consumer misuse. Interpretation, Policy, and Procedure for Substantial Product Hazards, 43 Fed. Reg. 34,988, 34,990 (Aug. 7, 1978).

[29] *See* Dkt. 95 at 37-44; *see also In re Amazon.com, Inc.*, Dkt. 142, at 62–69 (rejecting similar structural constitutional claims).

[30] *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.); *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).

structural argument that the Commission was unconstitutional.[31] *See Leachco v. CPSC*, 103 F.4th 748, 760 (10th Cir. 2024) (finding the removal protections of CPSC Commissioners and the Presiding Officer overseeing the Section 15 adjudication against Leachco constitutional);[32] *see also In re Amazon.com, Inc.*, Dkt. 142, at 62–69 (rejecting similar structural constitutional claims).

The law of preclusion "ordinarily bars relitigation of an issue of fact or law raised and necessarily resolved by a prior judgment." *Bravo-Fernandez v. United States*, 580 U.S. 5, 10 (2016) (first citing Restatement (Second) of Judgments § 17 at 148, § 27 at 250 (1980)); and then citing 18 C. Wright, A. Miller & E. Cooper, *Federal Practice and Procedure* § 4416, at 386 (2d ed. 2002)). The Supreme Court explained that "the doctrine serves to 'avoid multiple suits on identical entitlements or obligations between the same parties.'" *Bravo-Fernandez*, 580 U.S. at 9 (quoting 18 Wright & Miller, *Federal Practice And Procedure* § 4402, at 9). The same parties and same constitutional structural issue regarding the Commission was raised in Leachco's federal court litigation and the law of issue preclusion means it does not get to relitigate those issues, *ad infinitum*, before the Commission or in a future appeal of any Commission decision in federal court.

## VI. CONCLUSION

For the reasons detailed above, Complaint Counsel requests the Commission set aside the Initial Decision in its entirety and dismiss Leachco's Cross-Appeal. Complaint Counsel requests that the Commission issue a Final Decision and Order finding that the Podsters pose a substantial

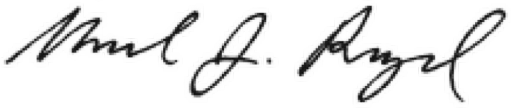
[31] The Fifth Circuit has also recently rejected a challenge to the CPSC structure. *Consumers' Research v. CPSC*, 91 F.4th 342 (5th Cir. 2024) (following *Humphrey's Executor* and rejecting constitutional challenge to CPSC structure), *cert. denied*, __ S.Ct. __, 2024 WL 4529808 (Oct. 21, 2024) (mem.).

[32] Leachco's petition for certiorari before the Supreme Court was filed on August 9, 2024, and is currently pending briefing. The Government has until November 14, 2024, to file a response.

product hazard and requiring a mandatory recall of the Podsters.

Dated this 7th day of November, 2024

Respectfully submitted,



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## CERTIFICATE OF SERVICE

I hereby certify that on November 7, 2024, I served Complaint Counsel's Reply Brief as follows:

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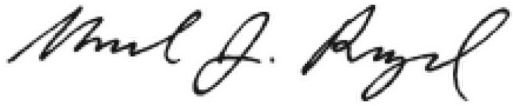

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