

Consumer Product Safety Commission

**IN THE MATTER OF LEACHCO,
RESPONDENT.**

On Appeal from the Initial Decision
of Hon. Michael G. Young, Administrative Law Judge

**RESPONDENT LEACHCO'S
REPLY BRIEF IN SUPPORT OF CROSS-APPEAL**

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TABLE OF CONTENTS

| | |
|--|----|
| Table of Authorities | ii |
| Glossary..... | iv |
| I. The Presiding Officer Erred by Not Excluding CPSC’s Expert Testimony in its Entirety | 2 |
| A. Dr. Mannen did not use any peer-reviewed or otherwise validated methodologies and (with one exception that supports Leachco) did not identify any objective benchmarks against which to identify or measure a defect or a risk | 3 |
| 1. Dr. Mannen did not use reliable methods | 3 |
| 2. Dr. Mannen did not identify objective benchmarks..... | 8 |
| B. Ms. Kish did not use any peer-reviewed or otherwise validated methodologies and did not identify any objective benchmarks against which to identify or measure a defect or a risk | 12 |
| C. Dr. Katwa’s testimony is not relevant to this case..... | 15 |
| II. The Presiding Officer Erred by Admitting Hearsay..... | 15 |
| A. The Presiding Officer erred by admitting hearsay documents from the Commission’s In-Depth Investigation Reports | 15 |
| B. The Presiding Officer erred by admitting deposition testimony of witnesses who attended or who could have attended the hearing | 16 |
| III. Leachco Preserves Its Constitutional Objections | 16 |
| Conclusion..... | 16 |
| Certificate of Compliance | 18 |
| Certificate of Service..... | 19 |

TABLE OF AUTHORITIES

| Cases | Page(s) |
|---|---------|
| <i>Adkins v. Marathon Petroleum Co., LP</i> , 105 F.4th 841 (6th Cir. 2024) | 7 |
| <i>Chapman v. Proctor & Gamble Distributing, LLC</i> , 766 F.3d 1296 (11th Cir. 2014) | 11 |
| <i>Daubert v. Merrell Dow Pharms., Inc.</i> , 509 U.S. 579 (1993) | 2, 7 |
| <i>In re Deepwater Horizon BELO Cases</i> , 119 F.4th 937 (11th Cir. 2024) | 8 |
| <i>Gen. Elec. Co. v. Joiner</i> , 522 U.S. 136 (1997) | 7 |
| <i>Grodzitsky v. Am. Honda Motor Co., Inc.</i> , 957 F.3d 979 (9th Cir. 2020) | 11 |
| <i>Rosen v. Ciba-Geigy Corp.</i> , 78 F.3d 316 (7th Cir. 1996) | 3 |
| <i>In re Roundup Liab. Litig.</i> , – F.Supp.3d –, Nos. 16-md-02741-VC, 20-cv-03719-VC, 2024 WL 3074376 (N.D. Cal. June 20, 2024) | 6 |
| <i>Rovid v. Graco Children’s Products, Inc.</i> , No. 17-cv-01506-PJH, 2018 WL 5906075 (N.D. Cal. Nov. 9, 2018) | 11–12 |
| <i>Salomon Constr. & Roofing Corp. v. James McHugh Constr. Corp.</i> , No. 18-cv-21733, 2019 WL 5256980 (S.D. Fl. Mar. 22, 2019)..... | 2 |
| <i>UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres</i> , 949 F.3d 825 (3rd Cir. 2020) | 2 |
| <i>United States v. Brien</i> , 59 F.3d 274 (1st Cir. 1995) | 14 |
| <i>Young v. Cree Inc.</i> , No. 4:17-cv-06252-YGR, 2021 WL 292549 (N.D. Cal. Jan. 28, 2021)..... | 11 |
| <i>Zenith Elec. Corp. v. WH-TV Broadcasting Corp.</i> , 395 F.3d 416 (7th Cir. 2005) | 7 |

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|---|------|
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| Wright, Charles A., and Miller, Arthur R., 29 Fed. Prac. & Proc. Evid. § 6293 (2d ed.) (June 2024) | 14 |
| Fed. R. Civ. P. 26(a)(2)(B)(i) | 7 |
| Fed. R. Civ. P. 26(a)(2)(B)(ii) | 7 |
| Fed. R. Evid. 702 | 2, 7 |
| Fed. R. Evid. 702(c) | 7 |
| Fed. R. Evid. 705 | 14 |

GLOSSARY

Alabama IDI: [JX-06 (redacted), JX-07 (unredacted)] CPSC In-Depth Investigation Report of Alabama Incident

Carleton 1998: [RX-28] Carleton JN, Donoghue AM, Porter WK. Mechanical model testing of rebreathing potential in infant bedding materials. *Arch Dis Child.* 1998 Apr;78(4):323-8. doi: 10.1136/adc.78.4.323. PMID: 9623394; PMCID: PMC1717516

CCX-___: Complaint Counsel Exhibit

Chandler 1974: Chandler, R.F. (1974, March). Construction of an Infant Dummy (Mark II) for Dynamic Tests of Crash Restraint Systems (Includes Revision 1 & 2). Report number AAC-119-74-14

Compl.: Complaint, In the Matter of Leachco, Inc., No. 22-1, Dkt. 1 (Feb. 9, 2022)

CPSC Br.: Complaint Counsel’s Appeal Brief, Dkt. No. 153 (Aug. 30, 2024)

CPSC Reply: Complaint Counsel’s Reply Brief, Dkt. No. 160, (Nov. 7, 2024)

Daubert Order: Aug. 2, 2023 ALJ Order Granting in Part and Denying in Part Respondent’s Motion to Exclude the Expert Testimony Proffered by the Consumer Product Safety Commission, Dkt. No. 128

Drago 2021: Drago, et al., “Infant fatality patterns in shared sleep: keys to intervention strategies?” Proceedings of the 2021 HFES 65th International Annual Meeting, 1322–26 (2021)

IDI: In-Depth Investigation Report

Initial Decision: Memorandum Opinion and Initial Order Denying Relief Sought in the Complaint (July 3, 2024), In the Matter of Leachco, CPSC No. 22-1

JX-___: Joint Exhibit

Katwa Report: [CCX-3] Expert Testimony of Umakanth Katwa, M.B.B.S., M.D.

Kish Report: [CCX-2] Expert Testimony of Celestine Kish, M.A.

Kobayashi 2016: [RX-29] Kobayashi, Yoshia, et al., 2016. Movement patterns of limb coordination in infant rolling. *Exp. Brain Res.* 234 (12), 3433–3445. <https://doi.org/10.1007/s00221-016-4741-2>

Leachco MSD: Leachco, Inc.’s Motion for Summary Decision and Memorandum in Support, Dkt. No. 91, (June 9, 2023)

Leachco Post-Hearing Br.: Leachco, Inc.’s Post-Hearing Brief, Dkt. No. 144 (Sept. 29, 2023)

Leachco X-App. Br.: Leachco, Inc.’s Opening Brief in Support of Cross-Appeal, submitted as part of Respondent Leachco’s Combined Answering Brief and Opening Brief in Support of Cross-Appeal, Dkt. No. 159 (Oct. 17, 2024)

Lee 2010: [RX-30] Lee, L.-J., et al., 2010. Changes in sitting posture induce multiplanar changes in chest wall shape and motion with breathing. *Respir. Physiol. Neurobiol.* 170 (3), 236–245. <https://doi.org/10.1016/j.resp.2010.01.001>

Limine Order: Aug. 2, 2023 ALJ Order Granting in Part and Denying in Part Leachco, Inc.’s Motion in Limine to Exclude (1) All Post-Fact-Discovery Evidence & (2) Testimony & Documents Regarding Alleged Defects in the Podster’s Warnings, Dkt. No. 129

Lin 2006: [RX-31] Lin, F., et al., 2006. Effect of different sitting postures on lung capacity, expiratory flow, and lumbar lordosis. *Arch. Phys. Med. Rehabil.* 87 (4), 504–509. <https://doi.org/10.1016/j.apmr.2005.11.031>

Maltese & Leshner 2019: [RX-32] Maltese MR, Leshner M. Carbon dioxide rebreathing induced by crib bumpers and mesh liners using an infant manikin. *BMJ Paediatr Open.* 2019 Apr 26;3(1):e000374. doi: 10.1136/bmjpo-2018-000374. PMID: 31206068; PMCID: PMC6542454

Mannen 2019: [CCX-1, Ex. B] Mannen, Biomechanical Analysis of Inclined Sleep Products – Final Report (Sept. 19, 2019)

Mannen 2022: [CCX-1, Ex. C] Mannen, Pillows Product Characterization and Testing (June 30, 2022)

Mannen 2023: [RX-36] Manen, Seated Products Characterization and Testing

McMullen Order: July 28, 2023 ALJ Order Granting Leachco, Inc.’s Motion to Strike Konica McMullen From the Commission’s Witness List, Dkt. 125

Reiterer 1994: [RX-34] Reiterer F, Abbasi S, Bhutani VK. Influence of head-neck posture on airflow and pulmonary mechanics in preterm neonates. *Pediatr Pulmonol.* 1994 Mar; 17(3):149-54. doi: 10.1002/ppul.1950170303. PMID: 8196994

RX-___: Respondent Leachco Exhibit

Texas IDI: [JX-08 (redacted) & JX-09 (unredacted)] CPSC In-Depth Investigation Report of Texas Incident

Tr. 1: Aug. 7, 2023 Hearing Transcript, In the Matter of Leachco, Inc.

Tr. 2: Aug. 8, 2023 Hearing Transcript, In the Matter of Leachco, Inc.

Tr. 3: Aug. 9, 2023 Hearing Transcript, In the Matter of Leachco, Inc.

Tr. 4: Aug. 10, 2023 Hearing Transcript, In the Matter of Leachco, Inc.

Virginia IDI: [JX-10 (redacted), JX-11 (unredacted), JX-12A(1) (redacted MECAPS report), & JX-12B(1) (unredacted ME-CAPS report)] CPSC In-Depth Incident Report of Virginia Incident

Wang 2020: [RX-34] Wang, J., et al. “Do inclined sleep surfaces impact infants’ muscle activity and movement? A safe sleep product design perspective,” *Journal of Biomechanics*. Oct 9; 111:109999. Epub 2020 Aug 17. doi: 10.1016/j.jbiomech.2020.109999. PMID: 32862027

Wang 2021: [RX-35] Wang J., et al. “Infant inclined sleep product safety: A model for using biomechanics to explore safe infant product design.” *J Biomech*. 2021 Nov 9; 128:110706. doi: 10.1016/j.jbiomech.2021.110706. Epub 2021 Aug 28. PMID: 34624615

**REPLY IN SUPPORT OF
LEACHCO'S CROSS-APPEAL**

The Presiding Officer correctly concluded: (1) Complaint Counsel failed to prove that the Podster has a defect and, “even if a defect might be found to exist in some technical sense,” (2) Complaint Counsel failed prove that any defect created a substantial risk of injury to the public. Initial Decision 65. Complaint Counsel does not dispute that its case “relied almost exclusively on expert testimony,” *id.* 6, and the Presiding Officer found Complaint Counsel’s expert testimony unpersuasive. Properly so. As Leachco has exhaustively documented, Dr. Mannen and Ms. Kish failed to employ peer-reviewed or validated methodologies. And, with one exception that supports Leachco’s case, they provided zero objective benchmarks against which to identify or measure the supposed dangers posed by the Podster. Complaint Counsel’s remaining evidence consisted of contradictory hearsay.

Leachco submits that the Presiding Officer’s conclusion should be affirmed because Complaint Counsel came woefully short of its burden to establish a substantial product hazard. But the overwhelming majority of the evidence presented by Complaint Counsel should never have been admitted in the first place. *See* Leachco X-App. Br. 3–67.

Finally, the Commission’s proceedings—which include a hearing before an Executive Branch official, procedural and evidentiary deficiencies, the attempted exercise of judicial power by Executive Branch officials, and a prosecution and decision-maker housed in the same agency—violate Leachco’s rights under Article III and the Due Process of Law Clause.

ARGUMENT

I. THE PRESIDING OFFICER ERRED BY NOT EXCLUDING CPSC'S EXPERT TESTIMONY IN ITS ENTIRETY

The reports of Complaint Counsel's proffered experts, Dr. Mannen and Ms. Kish, were hopelessly unreliable because they used methods that were neither peer reviewed nor otherwise validated, and because they established no objective benchmarks. *See* Leachco X-App. Br. 3–67. And since their testimony should have been excluded, Dr. Katwa's generalized opinions about infant breathing are not relevant and should also have been excluded.

Complaint Counsel's primary response is a request for a lower standard of admissibility. CPSC Reply 11–12. To be sure, judges in (appropriately) jury-less proceedings may be willing to review expert testimony that just barely meets the 702/*Daubert* standard.¹ And cross-examination can be helpful. CSPC Reply 12, 17. But when cross-examination confirms that expert testimony fails to meet that standard—because it is unreliable and unhelpful to the trier of fact—it should be excluded. Leachco X-App. Br. 5–7; *see, e.g., UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 831–36 (3rd Cir. 2020) (finding district court abused its discretion by not excluding expert testimony in a bench trial); *Salomon Constr. & Roofing Corp. v. James McHugh Const. Corp.*, No. 18-cv-21733, 2019 WL 5256980, *4–5 (S.D. Fl. Mar. 22, 2019) (recognizing that the standard may be lower in bench trials but still excluding expert evidence). And on the merits, Complaint Counsel offers little more than the *ipse dixit* of the witnesses themselves. Here, the evidence is overwhelming that the testimony of Dr. Mannen and Ms. Kish cannot meet the 702/*Daubert* standard.

¹ The lack of a jury here, however, is one of the constitutional defects of this process. Toleration of lower evidentiary standards only adds to the problem.

A. Dr. Mannen did not use any peer-reviewed or otherwise validated methodologies and (with one exception that supports Leachco) did not identify any objective benchmarks against which to identify or measure a defect or a risk

1. Dr. Mannen did not use reliable methods

There is little dispute that Dr. Mannen did not apply methods that have been subject to peer review. Nor did she establish that her methods were otherwise validated as accurately corresponding to live infants in Podsters. At best, Dr. Mannen can claim that her techniques are “progressing toward becoming” “valid measurement tool[s]” RX-36 (Mannen 2023), p. 200. But the “courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it.” *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996). As the following table shows, Dr. Mannen’s techniques are not valid tools for use in court.

| Method/Technique | Lack of Peer Review or Other Validation |
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| <p>Dr. Mannen borrowed heavily from three studies she conducted for the CPSC: Mannen 2019, Mannen 2022, and Mannen 2023.²</p> | <p>Mannen 2019 was not peer reviewed; Mannen 2022 was not peer reviewed; Mannen 2023 was not peer reviewed.³ None of the techniques employed in those studies and used for Dr. Mannen’s testimony here have been validated. Indeed, Dr. Mannen admitted that her use of crash-test dummies (CAMI dolls) to measure neck flexion (in Mannen 2019 and Mannen 2022) did <i>not</i> provide accurate results.⁴</p> |

² See Leachco X-App. Br. 9 (citing CCX-1 (Mannen Report), pp. 8–12 (discussion); 13–14, 16, 21, 23, 25, 29, 32–33, 34, 38, 44, 46, 48–49 (citations)).

³ See Leachco X-App. Br. 9 (citing Tr. 1, 83:22–85:4 (Mannen’s admitting that Mannen 2019, Mannen 2022, and Mannen 2023 were not peer reviewed)).

⁴ See Leachco X-App. Br. 14; Tr. 112:5–11.

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| <p>To measure “trunk” and “thigh” “flexion,” Dr. Mannen used a four-plane sagittal device that her team created.⁵</p> | <p>Dr. Mannen pointed to no peer-reviewed study that used this device; she presented no evidence in her testimony that measurements using this device have been validated.⁶</p> |
| <p>To measure “neck” “flexion,” Dr. Mannen used a CAMI doll.⁷</p> | <p>Dr. Mannen cited Chandler 1974 but does not know whether that report even discussed measuring neck angles with CAMI dolls. She is unaware of any peer-reviewed study confirming the use of CAMI dolls to accurately measure neck angles, and she conducted no studies to validate the use of CAMI dolls for this purpose.⁸</p> <p>Dr. Mannen is unaware of any device that can accurately measure a threshold for safety with respect to neck flexion.⁹</p> |
| <p>To opine about the effects of “trunk” and “head/neck” flexion, Dr. Mannen relied on Lin 2006 and Lee 2010.¹⁰</p> | <p>Lin 2006 and Lee 2010 did not use a sagittal-plane device or a CAMI doll to measure “flexion.”¹¹</p> |
| <p>To measure “facilitation of rolling” in a Podster, Dr. Mannen pointed to her trunk- and thigh-flexion measurements made with the four-plane sagittal device, and cited Kobayashi 2016.¹²</p> | <p>Kobayashi 2016 did not use a four-plane sagittal device; Kobayashi 2016 involved live infants on flat, non-inclined mattresses.¹³</p> <p>Dr. Mannen’s team has since developed a supposedly improved five-plane sagittal device that itself is merely “progressing toward becoming a valid measurement tool.”¹⁴</p> |

⁵ See Leachco X-App. Br. 10–12.

⁶ See Leachco X-App. Br. 12.

⁷ See Leachco X-App. Br. 12–16.

⁸ See Leachco X-App. Br. 14–15.

⁹ See Leachco X-App. Br. 15.

¹⁰ See Leachco X-App. Br. 15–17.

¹¹ See Leachco X-App. Br. 15–17.

¹² See Leachco X-App. Br. 17–21.

¹³ See Leachco X-App. Br. 19.

¹⁴ See Leachco X-App. Br. 45 (quoting RX-36 (Mannen 2023), p. 200).

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| <p>To measure (alleged) muscle fatigue and inability to self-rescue in a Podster, Dr. Mannen relied on Mannen 2019, Wang 2020, and Wang 2021.¹⁵</p> | <p>Mannen 2019 was not peer reviewed.¹⁶ And for her testimony here, Dr. Mannen did not employ the techniques used in Wang 2020 or Wang 2021.¹⁷</p> |
| <p>To measure firmness, Dr. Mannen used (a) a “firmometer” and (b) a “vertical lifter device” used in Mannen 2022.¹⁸</p> | <p>Dr. Mannen acknowledged the firmometer’s limitation, which prompted the development (for Mannen 2022) of the “vertical lifter device.”¹⁹ But Mannen 2022 was not peer reviewed, and Dr. Mannen never validated these techniques.²⁰</p> |
| <p>To measure the Podster’s “airflow,” Dr. Mannen used a device created for Mannen 2022.²¹</p> | <p>Mannen 2022 was not peer reviewed, and Dr. Mannen presented no evidence that her device has been validated.²²</p> |

¹⁵ See Leachco X-App. Br. 21–23,

¹⁶ See Leachco X-App. Br. 9 (citing Tr. 1, 83:22–85:4 (admitting that Mannen 2019 was not peer reviewed)).

¹⁷ See Leachco X-App. Br. 21, 44–45; *see also below* at 7–8 (discussing Dr. Mannen’s and Complaint Counsel’s misplaced reliance on Wang 2020 and Wang 2021).

¹⁸ See Leachco X-App. Br. 23–24; CCX-1 (Mannen Report) 21–24.

¹⁹ See CCX-1 (Mannen Report) 23.

²⁰ See Leachco X-App. Br. 9 (citing Tr. 1, 83:22–85:4 (admitting that Mannen 2022 was not peer reviewed)).

²¹ See Leachco X-App. Br. 24–27.

²² See Leachco X-App. Br. 9 (citing Tr. 1, 83:22–85:4 (admitting that Mannen 2022 was not peer reviewed)).

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| <p>To measure the supposed “re-breathing” risk,” Dr. Mannen used methods from Carleton 1998, as modified in Maltese & Leshner 2019.²³</p> | <p>Dr. Mannen did not validate these tests for live infants.²⁴ And the cited studies do not help her.</p> <p>Carleton 1998: “Because the model cannot physically respond to increased CO₂ like an infant ..., CO₂ rapidly equilibrates in the trachea in concentrations that <i>probably exaggerate the effect an infant would experience.</i>” And “it would <i>not</i> be appropriate to <i>speculate</i> on the role that rebreathing might have played in any specific case, based solely upon these results.”²⁵</p> <p>Maltese & Leshner 2019: “[T]he mechanical compliance (stiffness) of the ARS face <i>has not been shown to have fidelity to the human infant ...</i>” “[W]ithout additional research, <i>none</i> of the [CO₂ re-breathing] values reported herein should be interpreted as that which would be expected in a human infant.”²⁶</p> |
| <p>To measure “head rotation,” Dr. Mannen placed CAMI dolls in Podsters, rotated the “heads” herself, and measured the distance between a Podster’s side and a doll’s nose/mouth “region.”²⁷</p> | <p>Again, the only authority cited by Dr. Mannen to support her use of CAMI dolls was Chandler 1974, which said nothing about measuring head rotation in inclined loungers. And Dr. Mannen offered no evidence to validate these measurements.</p> |

Complaint Counsel raises a straw man in response. It says that peer review is not *always*, or not always *the only*, requirement for the admission of expert testimony. CPSC Reply 15–16. Leachco never claimed otherwise. See Leachco X-App. Br. 6.²⁸ But the methods Dr. Mannen employed here didn’t

²³ See Leachco X-App. Br. 27–29.

²⁴ See Leachco X-App. Br. 28.

²⁵ See Leachco X-App. Br. 28–29 (quoting RX-28 (Carleton 1998) RX-28, p. 004 (emphasis added); *id.*, p. 005 (emphasis added)).

²⁶ See Leachco X-App. Br. 29 (quoting RX-32 (Maltese & Leshner 2019), pp. 006–007) (emphasis added).

²⁷ See Leachco X-App. Br. 30–35.

²⁸ Indeed, peer review itself may be insufficient. See *In re Roundup Liab. Litig.*, – F.Supp.3d –, Nos. 16-md-02741-VC, 20-cv-03719-VC, 2024 WL 3074376, at *7 (N.D. Cal. June 20, 2024).

satisfy any of the factors judges must consider: (1) her methodologies here have not been tested, (2) her techniques here have not been subjected to peer review, (3) she identifies no known or potential rate of error of the methodologies employed, and (4) she presented no evidence that her methodologies are generally accepted. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593–94 (1993); *see also* Fed. R. Evid. 702(c) (A proffered witness’s testimony must be “the product of reliable principles and methods.”).

Complaint Counsel cites Dr. Mannen’s hearing testimony in which she claims to have validated her CAMI-doll methods “in the lab.” *See* CPSC Reply 17 n.11 (citation omitted). But Dr. Mannen’s mere *ipse dixit* is insufficient. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *see, e.g., Zenith Elec. Corp. v. WH-TV Broadcasting Corp.*, 395 F.3d 416, 419 (7th Cir. 2005) (“A witness who invokes ‘my expertise’ rather than analytic strategies widely used by specialists is not an expert as Rule 702 defines that term.”); *Adkins v. Marathon Petroleum Co., LP*, 105 F.4th 841, 850 (6th Cir. 2024) (An expert’s report “must contain ‘a complete statement of all opinions the [expert] witness will express and the basis and reasons for them’ and ‘the facts or data considered by the witness in forming them.’”) (quoting Fed. R. Civ. P. 26(a)(2)(B)(i)–(ii)).²⁹

Finally, Complaint Counsel erroneously claims that Dr. Mannen used “techniques derived from peer-reviewed studies she co-authored.” Reply 16 (referencing Wang 2020 and Wang 2021). But as Leachco noted, the techniques in Wang 2020 and Wang 2021 (live infants, placed on either a custom-made crib or sleeping products, measured with motion-analysis and electromyography tools)

²⁹ Similarly, Complaint Counsel cites testimony from the hearing, in which Dr. Mannen disagreed that no device can accurately measure head/neck flexion. CPSC Reply 17 (quoting Tr. 1, 82:22–83:12). But Dr. Mannen later admitted—Tr. 1, 114:5–9—that her expert report fails to validate the device she used for head/neck flexion. Regardless, her mere say-so is insufficient.

were *not* used for Dr. Mannen’s report here. Leachco X-App. Br. 21, 44–45; see RX-34, p. 002; RX-35, p. 004. Dr. Mannen nonetheless claims that she may rely on the “results” from those studies to compare with the Podster.³⁰ But she was forced to admit, *inter alia*, that (1) in Wang 2021 she and her co-authors could *not* compare results even among the three different products they studied because they had not created a statistical design to do so; and that (2) she had not created a statistical design to compare results here. See Leachco X-App. Br. 45. Those studies do not help Complaint Counsel’s argument.

2. Dr. Mannen did not identify objective benchmarks

Dr. Mannen was retained by Complaint Counsel to “assess whether [the Podster’s] design creates a risk of injury for infants.”³¹ Yet Dr. Mannen did not identify objective benchmarks against which to determine whether a risk existed.³² Instead, she compared (a) various measurements of or on a Podster with (b) measurements of or on (mainly) a firm, flat mattress. But the Podster measurements relative to a different product’s measurements establish only relative measurements; they do *not* establish danger or risk. See, e.g., *In re Deepwater Horizon BELO Cases*, 119 F.4th 937, 945 (11th Cir. 2024) (affirming exclusion of testimony by expert who “did not provide any opinions about the level of exposure at which the alleged toxin causes harm” and, therefore, “did not follow the basic methodology that scientists use to determine causation”) (cleaned up).

³⁰ CCX-1 (Mannen Report), p. 44.

³¹ CCX-1 (Mannen Report), p. 5.

³² The lone exception: Dr. Mannen’s identified a 45-degree neck flexion as dangerous. But she admitted that she is not aware of any device that can accurately measure neck flexion. Further, her speculative test results either show neck flexion below 45 degrees or relate to a contingency that has never occurred. See Leachco X-App. Br. 36–37.

Yet Dr. Mannen relied solely on comparisons:

| Supposed Risk/Defect | Unscientific Benchmark |
|--|---|
| Head/neck and trunk flexion may affect breathing. ³³ | <p>Trunk Flexion: based on comparing the angles of the four-segment device against a baseline of 0° of a firm, flat mattress,³⁴ or compared to a normal standing posture.³⁵</p> <p>Dr. Mannen “calculated the increase in head flexion ... compared to the normalized firm flat surface measurements.”³⁶</p> <p>Dr. Mannen admitted that no “hard and fast” safety/danger threshold has been defined for head/neck flexion.³⁷</p> |
| Podster may facilitate rolling. ³⁸ | Dr. Mannen claims it is “easier”—she does not know how much—for an infant to roll on or off a Podster than it is to roll on a firm, flat mattress. ³⁹ |
| Podster may cause muscle fatigue and inhibit ability to self-rescue. ⁴⁰ | Dr. Mannen claims an increase in muscle activity on a Podster, versus that on a firm, flat mattress. ⁴¹ |
| The Podster is supposedly insufficiently firm. ⁴² | Dr. Mannen opines that a product cannot be “too soft” or else it will deform “too much” and envelop an infant’s face <i>if</i> the infant is prone or her face is pressed against the side of a product. ⁴³ |

³³ See Leachco X-App. Br. 10–15.

³⁴ See Leachco X-App. Br. 10–15, 39–43.

³⁵ See Leachco X-App. Br. 15–16, 39–43; CCX-1 (Mannen Report) p. 39.

³⁶ See Leachco X-App. Br. 10–15, 39–43.

³⁷ See Tr. 1, 83:13–21.

³⁸ See Leachco X-App. Br. 17–21.

³⁹ See Leachco X-App. Br. 10–15, 39–43.

⁴⁰ See Leachco X-App. Br. 21–23.

⁴¹ See Leachco X-App. Br. 21–23, 39–43.

⁴² See Leachco X-App. Br. 23–24; CCX-1 (Mannen Report) 21–24.

⁴³ See Leachco X-App. Br. 23–24, 39–43.

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| The Podster’s airflow ⁴⁴ | Dr. Mannen compared the airflow of a Podster and the airflow of crib bumpers and mesh liners. ⁴⁵ Mannen 2022, on which Dr. Mannen relied here, notes that her “ <i>testing and the available literature do not adequately define what upper limit [of airflow] is safe.</i> ” ⁴⁶ |
| Rebreathing ⁴⁷ | Dr. Mannen claims the Podster may “pool” CO ₂ and an infant may rebreathe “too much” CO ₂ —but she does not know how much is too much. ⁴⁸ Therefore, Dr. Mannen’s opinion was based merely on the comparison between the Podster and a firm, flat mattress. ⁴⁹ |
| Head rotation ⁵⁰ | Dr. Mannen measured the distance between the “nose/face” “region” of a CAMI doll and the sides of a Podster, but she admitted that she does not know how close to a product a baby’s face needs to be before a danger arises. ⁵¹ |

In response, Complaint Counsel says that Dr. Mannen did use benchmarks. CPSC Reply 13. But Complaint Counsel just points to the comparisons discussed above. *See id.* 13–14 (noting head/neck flexion and head-rotation measurements *compared to* measurements in a Podster; the approximately safe displacement of a mattress *compared to* displacement of a Podster; etc.). These comparisons do not establish a defect or a danger. A firm, flat mattress *may* be

⁴⁴ See Leachco X-App. Br. 24–27.

⁴⁵ See Leachco X-App. Br. 26, 39–43.

⁴⁶ See Leachco X-App. Br. 26, 39–43.

⁴⁷ See Leachco X-App. Br. 27–29.

⁴⁸ See Leachco X-App. Br. 27–29, 39–43 (citing CCX-1, pp. 27, 49–50; Tr. 1, 131:5–13, 139:15–19).

⁴⁹ See Leachco X-App. Br. 27–29, 39–43 (citing Tr. 1, 139:2–3)

⁵⁰ See Leachco X-App. Br. 30–35.

⁵¹ Tr. 1, 123:9–124:2; *see also* Leachco X-App. Br. 30–35, 40, 42–43.

safer than a Podster or *may* pose less risk than a Podster, but that *doesn't make the Podster dangerous*.

Complaint Counsel also claims—without citation—that experts need not measure against benchmarks. CPSC Reply 13. But Complaint Counsel fails to explain how Dr. Mannen can demonstrate any risk without identifying at what point trunk flexion or airflow or rolling or head rotation *actually poses a risk*. Again, merely comparing products does not demonstrate that either of them is dangerous.

Finally, Dr. Mannen did not identify any defect or risk—she assumed them. *See* Leachco X-App. Br. 46–47. Courts routinely exclude testimony with these defects, and exclusion is appropriate here. *See, e.g., Young v. Cree Inc.*, No. 4:17-cv-06252-YGR, 2021 WL 292549, at *11 n.20 (N.D. Cal. Jan. 28, 2021) (excluding an expert in part because he assumed a defect and “then employ[ed] a methodology that assume[d] this premise”); *Grodzitsky v. Am. Honda Motor Co., Inc.*, 957 F.3d 979, 986 (9th Cir. 2020) (affirming exclusion of an expert who merely identified “potential problems” without testing “designed to identify any defects”); *Chapman v. Proctor & Gamble Distributing, LLC*, 766 F.3d 1296, 1306–07 (11th Cir. 2014) (noting all substances potentially can be toxic, experts were properly excluded because they failed to show “how much [the product] must be used for how long to increase the risk”); *Rovid v. Graco Children’s Products, Inc.*, No. 17-cv-01506-PJH, 2018 WL 5906075, at *8 (N.D. Cal. Nov. 9, 2018) (“Many, if not most, substances do not become hazardous until a certain threshold level is reached. Without supporting evidence or qualifying expertise, [the expert] cannot merely assert that any amount of CO₂ rebreathing is hazardous.”).

Thus, Complaint Counsel’s attempt to distinguish *Rovid* fails. CPSC Reply 14–15. Indeed, as Complaint Counsel itself acknowledges, the expert there—Michael Leshner (upon whom Dr. Mannen relies)—failed to show how his CO₂ rebreathing test correlated “to what a live infant would experience,” and failed to “explain what objective standard these values should be compared against.” CPSC Reply 14 (quoting *Rovid*, 2018 WL 5906075, at *4). As demonstrated above, those are precisely the same errors Dr. Mannen made here.⁵²

B. Ms. Kish did not use any peer-reviewed or otherwise validated methodologies and did not identify any objective benchmarks against which to identify or measure a defect or a risk

Complaint Counsel proffered long-time CPSC employee Celestine Kish, who provided only speculative opinions about the supposed influence of observed behavior (or “pacifiers” or “counter-examples”), which was based on her arbitrary internet searches.⁵³ Thus, for example, Ms. Kish opined about online “consumer interaction” with the Podster,⁵⁴ but she didn’t *study* consumer interaction with the Podster. Instead, she made up internet searches—*e.g.*, she searched Instagram with the tag “#leachcopodster” and cherry-picked a *New York Magazine* article to discuss, etc.⁵⁵—all without first developing or using a validated method of searches that could reliably demonstrate whether and to what extent consumers actually “interacted” with the Podster.

⁵² Complaint Counsel notes that *Rovid* “also found [Leshner’s testimony] to be unreliable for multiple other reasons.” CPSC Reply 14–15. And those reasons, again, also apply Dr. Mannen’s report: product of a single test rather than multiple trials (like Dr. Mannen’s rebreathing test (*see* Leachco X-App. Br. 30–31)); insufficiently rigorous (like Dr. Mannen’s mere-comparison methodology); failure to explain whether he controlled for doll position (like Dr. Mannen’s flexion and head-rotation techniques).

⁵³ *See* Leachco X-App. Br. 51–59.

⁵⁴ CCX-2 (Kish Report) 39–53.

⁵⁵ *See* Leachco X-App. Br. 51–59.

Ms. Kish's testimony on this point is unequivocal:

Q [B]ut you don't have any data about how many consumers actually review the internet for product reviews of the Podster, do you?

A No, I do not.

Q And you don't have any data for how many consumers review product reviews for any product, do you?

A No, I do not.

Q *You didn't study the issue at all.*

A *No, I did not.*

Q ... [F]or all of the examples that you give [in your report], you didn't conduct any surveys or studies to determine whether consumers actually saw any of the images or product reviews or any other examples in your report, do you?

A *No, I do not.*⁵⁶

Therefore, Ms. Kish neither used reliable methods nor reached—or could reach—conclusions on the actual consumer interactions with the Podster.⁵⁷

Ms. Kish's testimony concerning foreseeable misuse was equally speculative.⁵⁸ One example suffices: Ms. Kish claims that Leachco's statements will "contribute" to consumers' belief that bedsharing with the Podster is safe, but she admitted that she had no evidence about consumers' bedsharing beliefs to begin with.⁵⁹

Complaint Counsel responds that Ms. Kish's report is based on her experience and knowledge of consumer behavior. CPSC Reply 18. But that experience and knowledge cannot fix the unreliable nature of her opinions that are

⁵⁶ Tr. 2, 50:19–51:13 (emphasis added).

⁵⁷ See Leachco X-App. Br. 52–56.

⁵⁸ See Leachco X-App. Br. 56–59.

⁵⁹ See Leachco X-App. Br. 57.

premised upon that which *she did not study or consider at all*—*e.g.*, how consumers search for or come upon Podster information, how long consumers viewed the information, whether the Podster “may be” an attractive option for consumers who want to bedshare.^{60, 61}

Complaint Counsel claims that Ms. Kish’s opinions are supported by the sources cited in her report. CPSC Reply 18–19. Not so. First, Ms. Kish’s testimony is replete with statements unsupported by any citation.⁶² Further, Ms. Kish’s sources confirm only that, *e.g.*, media “*can* influence” individuals; people are “more likely to” jaywalk when they observe others jaywalking; or advertisements are “sources of societal pressure.”⁶³ And, regardless, Ms. Kish’s testimony goes beyond these qualified statements when she claims, *e.g.*, that “real-world experience shows that consumers are inundated” with pacifiers *without defining “inundated”*; or that internet and social media are “rife” with counter-examples *without defining “rife”*; or that certain counter-examples are “prevalent throughout the internet” *without quantifying “prevalent”*.⁶⁴ These statements are unsupported by the sources cited in Ms. Kish’s report and are pure speculation.

⁶⁰ See Leachco X-App. Br. 56; see *id.* 56–59 (examples of statements made without research).

⁶¹ Complaint Counsel again notes that cross-examination may be used. CPSC Reply 17. But, as noted above, Ms. Kish’s testimony is so unreliable that it shouldn’t have been admitted in the first place. Further, Complaint Counsel’s reliance on Fed. R. Evid. 705 (CPSC Reply 17) is misplaced. As Wright & Miller explain, “Rule 705 addresses only the order of an expert’s testimony, not its admissibility, the weight the trier of fact should give it, or the sufficiency of expert testimony to meet the burden of proof or other requirements established by the substantive law.” 29 Charles A. Wright & Arthur R. Miller, Fed. Prac. & Proc. Evid. § 6293 (2d ed.) (June 2024) (footnotes omitted); see also *United States v. Brien*, 59 F.3d 274, 278 (1st Cir. 1995) (“Rule 705 relates to the presentation of testimony at trial ... The rule does not impair—indeed, has nothing to do with—the trial judge’s right to insist that he or she be given the underlying information by proffer as an aid to the preliminary ruling on admissibility.”).

⁶² See Leachco MSD 36 n.151 (quoting litany of speculative statements by Ms. Kish (and Dr. Mannen) with zero citations).

⁶³ CCX-2 (Kish Report) 32, 34 (emphasis added) (citations omitted).

⁶⁴ See Leachco X-App. Br. 53–54.

Finally, Ms. Kish admitted that for others' behavior to have any influence, people must observe that behavior⁶⁵—but nowhere in her report does she say whether or how many people observed the supposedly negative behavior.

C. Dr. Katwa's testimony is not relevant to this case

Complaint Counsel does not dispute that if the testimonies of Dr. Mannen and Ms. Kish are excluded, Dr. Katwa's testimony is irrelevant. Indeed, Complaint Counsel concedes that Dr. Katwa relied on their testimony "as a foundation for his medical opinion" CPSC Reply 20. Therefore, because Dr. Mannen and Ms. Kish's testimony was deficient, Dr. Katwa's general opinions on infant breathing are unhelpful to the trier of fact and should have been excluded. *See* Leachco X-App. Br. 61–63.

II. THE PRESIDING OFFICER ERRED BY ADMITTING HEARSAY

A. The Presiding Officer erred by admitting hearsay documents from the Commission's In-Depth Investigation Reports

Complaint Counsel asserts that Leachco "does not contest that the IDIs are public records" and, therefore, it was Leachco's burden to show that certain documents within the IDIs were untrustworthy. CPSC Reply 21–22. That's incorrect. In its Cross-Appeal Brief, Leachco explained that the documents at issue are *not* public records and that Complaint Counsel failed to identify any (other) hearsay exception. Leachco X-App. Br. 63–64. Complaint Counsel did not respond to these arguments at all. The documents Leachco identified on page 64 of Leachco's Cross-Appeal Brief should have been excluded.

⁶⁵ Tr. 2, 42:7–10.

B. The Presiding Officer erred by admitting deposition testimony of witnesses who attended or who could have attended the hearing

Leachco explained that deposition testimony may be admitted only if the requirements of Rule 32 are met. *See* Leachco X-App. Br. 65 (quoting Fed. R. Civ. P. 32(a)(1) & 8A Fed. Prac. & Proc. Civ. § 2142 (3d ed.) [Wright & Miller]); *see id.* 65–67. Complaint Counsel again fails to respond. Instead, Complaint Counsel notes that its expert Ms. Kish cited the testimony. CPSC Reply 23–24. But hearsay testimony does not become non-hearsay simply because an expert witness cites it. And Complaint Counsel cites no authority for such a proposition. The hearsay deposition testimony should have been excluded.

III. LEACHCO PRESERVES ITS CONSTITUTIONAL OBJECTIONS

Leachco submits that its Cross-Appeal Brief addressed the arguments presented by Complaint Counsel concerning Leachco’s constitutional objections. Therefore, Leachco incorporates by reference those arguments here. *See* Leachco X-App. Br. 67–69.

CONCLUSION

Leachco does not challenge the Presiding Officer’s ultimate conclusion:

As set forth in this decision, the Commission has not demonstrated by a preponderance of the evidence that the Podsters have a substantial design or other defect and, even if a defect might be found to exist in some technical sense, the Commission has also failed to demonstrate that such defect creates or has created a substantial risk of injury to the public. The relief sought in the Complaint is therefore DENIED, and the Complaint is DISMISSED.

Initial Decision 65.

But Leachco submits that, notwithstanding the Presiding Officer’s conclusion in his Initial Decision and to preserve issues, the Presiding Officer erred

in admitting certain evidence and that the Commission's administrative hearing violated Leachco's constitutional rights. A ruling in Leachco's favor here would only confirm that Complaint Counsel failed to prove its claim that the Podster is a substantial product hazard under the CPSA.

DATED: November 21, 2024.

Respectfully submitted,

s/ Oliver J. Dunford

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CERTIFICATE OF COMPLIANCE

Pursuant to the Commission's October 2, 2024 Order (Dkt. 158), Leachco's reply brief was limited to 15 pages or 6,500 words. Accordingly, I certify that this Reply Brief—not including the Cover Page, Table of Contents, Table of Authorities, Glossary, Signature Block, and Certificates—contains 4,691 words and therefore complies with the October 2, 2024 Order.

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CERTIFICATE OF SERVICE

I hereby certify that on November 21, 2024, the foregoing was served via email on the following:

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